



Australian Government

Department of Health



Schedule of Pharmaceutical Benefits

Efficient Funding of Chemotherapy

Effective 1 December 2016



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Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 December 2016. The Schedule is updated on the first day of each month and is available on the internet at www.pbs.gov.au.

Efficient Funding of Chemotherapy (Private Hospital)

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

2638W **IPILIMUMAB**,
ipilimumab 50 mg/10 mL injection, 10 mL vial (Yervoy);
ipilimumab 200 mg/40 mL injection, 40 mL vial (Yervoy)

Efficient Funding of Chemotherapy (Public Hospital)

Alterations

Alteration – Restriction

The following items have additions, deletions or alterations to restrictions, notes and/or cautions.

2641B **IPILIMUMAB**,
ipilimumab 50 mg/10 mL injection, 10 mL vial (Yervoy);
ipilimumab 200 mg/40 mL injection, 40 mL vial (Yervoy)

About the Supplement

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

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

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

This supplement is split into three parts:

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

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

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

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

Symbols used in the Efficient Funding of Chemotherapy supplement

- | | |
|------------------------------|--|
| * | An asterisk in the dispensed price column indicates that the manufacturer's pack does not coincide with the maximum quantity |
| ‡ | A double dagger in the maximum quantity column indicates where the maximum quantity has been determined to match the manufacturer's pack. These packs cannot be broken and the maximum quantity should be supplied and claimed |
| ^a or ^b | Located immediately before brand names of an item indicates that the brands are equivalent for the purposes of substitution. These brands may be interchanged without differences in clinical effect |

Remuneration arrangements

Fees payable per item claimed:

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

- Ready Prepared Dispensing Fee (\$7.02)
- Preparation fee (\$83.22)
- Distribution fee (\$25.92)
- Diluent fee (\$5.14)

Section 94 Approved Public Hospital Authority

- Preparation fee (\$83.22)

Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee (\$7.02)
- Preparation fee (\$83.22)
- Distribution fee (\$25.92) (not payable where the drug is trastuzumab)
- Diluent fee (\$5.14)

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)

6124

Previously untreated stage III or IV CD20 positive mantle cell lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- 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)

6075

Previously untreated stage III or IV indolent CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- 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.

Injection

10763L	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	200 mg	11	..	*1758.54	38.30	Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial) 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	..	*206.32	38.30	Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial) Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial) 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	..	*354.54	38.30	Holoxan [BX] (ifosfamide 1 g injection, 1 vial) 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	..	*2210.36	38.30	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	..	*137.15	38.30	Hospira Pty Limited [HH] (methotrexate 1 g/10 mL injection, 10 mL vial) Hospira Pty Limited [HH] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [HH] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [HH] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methaccord [EA] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Methotrexate MYX [OC] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methotrexate MYX [OC] (methotrexate 1 g/10 mL injection, 10 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

METHOTREXATE

Restricted benefit

Patients receiving treatment with a high dose regimen

Injection

7251P	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	20000 mg	..	..	*589.90	38.30	Hospira Pty Limited [HH] (methotrexate 1 g/10 mL injection, 10 mL vial) Hospira Pty Limited [HH] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [HH] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [HH] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methaccord [EA] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Methotrexate MYX [OC] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methotrexate MYX [OC] (methotrexate 1 g/10 mL injection, 10 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

PEMETREXED

Authority required (STREAMLINED)

4792

Locally advanced or metastatic non-small cell lung cancer

Clinical criteria:

- Patient must have received prior treatment with platinum-based chemotherapy. The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated

Doses greater than 500 mg per metre squared BSA are not PBS-subsidised

Authority required (STREAMLINED)

4789

Mesothelioma

Clinical criteria:

- The treatment must be in combination with cisplatin. The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated

Doses greater than 500 mg per metre squared BSA are not PBS-subsidised

Injection

7255W	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1100 mg	5	..	*3601.02	38.30	Alimta [LY] (pemetrexed 100 mg injection, 1 vial) Alimta [LY] (pemetrexed 500 mg injection, 1 vial) DBL Pemetrexed [HH] (pemetrexed 1 g injection, 1 vial) DBL Pemetrexed [HH] (pemetrexed 100 mg injection, 1 vial) DBL Pemetrexed [HH] (pemetrexed 500 mg injection, 1 vial) Pemetrexed APOTEX [TX] (pemetrexed 100 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 Juno [JU] (pemetrexed 100 mg injection, 1 vial) Pemetrexed Juno [JU] (pemetrexed 500 mg injection, 1 vial) Pemetrexed MYX [YN] (pemetrexed 1 g injection, 1 vial) Pemetrexed MYX [OC] (pemetrexed 100 mg injection, 1 vial) Pemetrexed MYX [OC] (pemetrexed 500 mg injection, 1 vial) Pemetrexed Sandoz [SZ] (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)

■ 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	..	*1358.06	38.30	Tomudex [HH] (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	..	*1355.22	38.30	Leustatin [JC] (cladribine 10 mg/10 mL injection, 10 mL vial) 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.

Authority required (STREAMLINED)

6248

B-cell chronic lymphocytic leukaemia

Clinical criteria:

- Patient must have advanced disease (Binet Stage B or C); OR
- Patient must have evidence of progressive Stage A disease, **AND**
- The treatment must be in combination with cyclophosphamide.

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

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

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

Injection

7233Q	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	55 mg	29	..	*211.14	38.30	Fludarabine ACT [EA] (fludarabine phosphate 50 mg injection, 1 vial) Fludarabine Ebew e [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	..	*801.70	38.30	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	..	*157.17	38.30	DBL Fluorouracil Injection BP [HH] (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials) DBL Fluorouracil Injection BP [HH] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)

■ 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	..	*127.82	38.30	DBL Fluorouracil Injection BP [HH] (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials) DBL Fluorouracil Injection BP [HH] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)

■ GEMCITABINE

Caution Pharmaceutical benefits containing gemcitabine may have different concentrations.

Note Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 1 g (as hydrochloride) in 25 mL, gemcitabine solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL and gemcitabine solution for injection 1 g (as hydrochloride) in 26.3 mL are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 2 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 2 g (as hydrochloride) in 50 mL and gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 5 mL, gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL and gemcitabine solution for injection 200 mg (as hydrochloride) in 5.3 mL are equivalent for the purposes of substitution.

Injection

7246J	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mg	17	..	*180.10	38.30	DBL Gemcitabine for Injection [HH] (gemcitabine 1 g injection, 1 vial)

DBL Gemcitabine for Injection [HH] (gemcitabine 2 g injection, 1 vial)
 DBL Gemcitabine for Injection [HH] (gemcitabine 200 mg injection, 1 vial)
 DBL Gemcitabine Injection [HH] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial)
 DBL Gemcitabine Injection [HH] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)
 DBL Gemcitabine Injection [HH] (gemcitabine 200 mg/5.3 mL injection, 5.3 mL vial)
 Gemaccord [EA] (gemcitabine 1 g injection, 1 vial)
 Gemaccord [EA] (gemcitabine 200 mg injection, 1 vial)
 Gemcitabine Actavis 2000 [EA] (gemcitabine 2 g injection, 1 vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 1 g injection, 1 vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 1 g/100 mL injection, 100 mL vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 200 mg injection, 1 vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 200 mg/20 mL injection, 20 mL vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 500 mg/50 mL injection, 50 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	..	*195.66	38.30	Hospira Pty Limited [HH] (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	..	*139.38	38.30	Hospira Pty Limited [HH] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)

■ VINOReLBINE

Injection

7263G	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	70 mg	7	..	*193.19	38.30	Hospira Pty Limited [HH] (vinorelbine 10 mg/mL injection, 1 mL vial) Hospira Pty Limited [HH] (vinorelbine 50 mg/5 mL injection, 5 mL vial) Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial) Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial) Vinorelbine Ebew e [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial) Vinorelbine Ebew e [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	..	*300.15	38.30	Etopophos [BQ] (etoposide 1 g injection, 1 vial) Etopophos [BQ] (etoposide 100 mg injection, 1 vial) Etoposide Ebew e [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials) Pfizer Australia Pty Ltd [PF] (etoposide 100 mg/5 mL injection, 5 mL vial)

Taxanes

■ CABAZITAXEL

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4662

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

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

Injection

7236W	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	55 mg	5	..	*3163.30	38.30	Jevtana [SW] (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1)

■ DOCETAXEL

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

Injection

10158P	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	250 mg	5	..	*200.73	38.30	DBL Docetaxel Concentrated Injection [HH] (docetaxel 160 mg/16 mL injection, 16 mL vial) DBL Docetaxel Concentrated Injection [HH] (docetaxel 20 mg/2 mL injection, 2 mL vial) DBL Docetaxel Concentrated Injection [HH] (docetaxel 80 mg/8 mL injection, 8 mL vial) Docetaxel Sandoz [SZ] (docetaxel 80 mg/8 mL injection, 8 mL vial) Oncotaxel 140 [EA] (docetaxel 140 mg/7 mL injection, 7 mL vial) Oncotaxel 80 [EA] (docetaxel 80 mg/4 mL injection, 4 mL vial)

■ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

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	..	*1281.55	38.30	Abraxane [TS] (nanoparticle albumin-bound paclitaxel 100 mg injection, 1 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	..	*2441.80	38.30	Abraxane [TS] (nanoparticle albumin-bound paclitaxel 100 mg injection, 1 vial)

■ PACLITAXEL
Injection

7254T	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	450 mg	3	..	*196.82	38.30	Anzatax [HH] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial) Anzatax [HH] (paclitaxel 150 mg/25 mL injection, 25 mL vial)

Anzatax [HH] (paclitaxel 300 mg/50 mL injection, 50 mL vial)
 Paclitaxel ACT [EF] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)
 Paclitaxel ACT [EF] (paclitaxel 150 mg/25 mL injection, 25 mL vial)
 Paclitaxel ACT [EF] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
 Paclitaxel ACT [EF] (paclitaxel 300 mg/50 mL injection, 50 mL vial)
 Paclitaxel Actavis [EA] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
 Paclitaxel Ebewe [SZ] (paclitaxel 150 mg/25 mL injection, 25 mL vial)
 Paclitaxel Ebewe [SZ] (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)
 Paclitaxel Ebewe [SZ] (paclitaxel 300 mg/50 mL injection, 50 mL vial)
 Paclitaxel Kabi [PK] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
 Paclitaxel Kabi [PK] (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	..	*143.26	38.30	Accord Doxorubicin [EA] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Doxorubicin Ebewe [SZ] (doxorubicin hydrochloride 100 mg/50 mL injection, 50 mL vial) Doxorubicin MYX [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Doxorubicin SZ [HX] (doxorubicin hydrochloride 10 mg/5 mL injection, 5 mL vial) Doxorubicin SZ [HX] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (doxorubicin hydrochloride 10 mg/5 mL injection, 5 mL vial) Hospira Pty Limited [HH] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)

■ DOXORUBICIN HYDROCHLORIDE-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	..	*1604.00	38.30	Caelyx [JC] (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial) Caelyx [JC] (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial) Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)

Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)

■ EPIRUBICIN

Injection/intravesical

7231N	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	220 mg	5	..	*298.75	38.30	DBL Epirubicin Hydrochloride Injection [HH] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirubicin ACT [EA] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial) Epirubicin ACT [EA] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirubicin ACT [EA] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Epirubicin SZ [HX] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Hospira Pty Limited [HH] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial) Hospira Pty Limited [HH] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Pharmorubicin [PF] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) 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	..	*386.95	38.30	Idarubicin Ebewe [SZ] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial) Idarubicin Ebewe [SZ] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial) Zavedos Solution [PF] (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 10 mg in 10 mL, 6) Zavedos Solution [PF] (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 5 mg in 5 mL, 3)

■ MITOZANTRONE

Injection

7252Q	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	30 mg	5	..	*228.34	38.30	Hospira Pty Limited [HH] (mitozantrone 20 mg/10 mL injection, 10 mL vial) Mitozantrone Ebewe [SZ] (mitozantrone 20 mg/10 mL injection, 10 mL vial) Onkotrone [BX] (mitozantrone 20 mg/10 mL injection, 10 mL vial) 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

7244G	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	30000 iu	11	..	*201.18	38.30	Bleo 15K [EA] (bleomycin sulfate 15 000 international units injection, 1 vial) CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial) Hospira Pty Limited [HH] (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	..	*193.28	38.30	Hospira Pty Limited [HH] (carboplatin 150 mg/15 mL injection, 15 mL vial) Hospira Pty Limited [HH] (carboplatin 450 mg/45 mL injection, 45 mL vial) Hospira Pty Limited [HH] (carboplatin 50 mg/5 mL injection, 5 mL vial)

■ CISPLATIN

Injection

7224F	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	220 mg	14	..	*167.27	38.30	Cisplatin Ebew e [SZ] (cisplatin 100 mg/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (cisplatin 100 mg/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (cisplatin 50 mg/50 mL injection, 50 mL vial)

■ OXALIPLATIN

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

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

Injection

7253R	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	300 mg	11	..	*181.35	38.30	DBL Oxaliplatin Concentrate [HH] (oxaliplatin 100 mg/20 mL injection, 20 mL vial) DBL Oxaliplatin Concentrate [HH] (oxaliplatin 50 mg/10 mL injection, 10 mL vial) Oxallicord [EA] (oxaliplatin 100 mg/20 mL injection, 20 mL vial) 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

■ 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	..	*3849.28	38.30	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)

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	..	*3849.28	38.30	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.

Authority required (STREAMLINED)

6338

Advanced carcinoma of cervix

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016, **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.

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.

Injection

10885X	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1800 mg	7	..	*7577.26	38.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)

■ BEVACIZUMAB

Note Special Pricing Arrangements apply.

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	..	*3849.28	38.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL 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

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	..	*21618.10	38.30	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

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 from a biopsy subsequent to the most recently delivered prior treatment with radiation, chemotherapy, biologics, immunotherapy or other agents;

(ii) The date of initial diagnosis of systemic anaplastic large cell lymphoma;

(iii) Dates of commencement and completion of front-line curative intent chemotherapy;

(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;

(v) a declaration of whether the patient has had, or is planned to have, a transplant

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	..	*21618.10	38.30	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	..	*2092.22	38.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)

Erbix [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	..	..	*3077.69	38.30	Erbix [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbix [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	..	..	*3077.69	38.30	Erbix [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbix [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	..	*2092.22	38.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

▪ **CETUXIMAB**

Note Special Pricing Arrangements apply.

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

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	..	*2092.22	38.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 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:

- (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.

Injection

2638W	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	360 mg	3	..	*48160.74	38.30	Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial) 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 A patient may only qualify for PBS-subsidised treatment under this restriction once.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4251**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Completion of induction treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The treatment must be for completion of induction treatment in a patient who commenced induction treatment with ipilimumab prior to 1 August 2013, **AND**
- The treatment must not exceed a total of 4 doses (combined PBS-subsidised and non-PBS-subsidised) 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.

For patients who commenced induction treatment with ipilimumab prior to 1 August 2013 prescribers should request the appropriate number of repeats to provide a total of 4 doses of ipilimumab (combined PBS-subsidised and non-PBS subsidised).

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.

Authority required (STREAMLINED)**4252**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Completion of re-induction treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction) received prior to 1 August 2013, **AND**
- The treatment must be for completion of re-induction treatment in a patient who commenced re-induction treatment with ipilimumab prior to 1 August 2013, **AND**
- The treatment must not exceed a total of 4 doses (combined PBS-subsidised and non-PBS-subsidised) 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.

For patients who commenced re-induction treatment with ipilimumab prior to 1 August 2013 prescribers should request the appropriate number of repeats to provide a maximum of 4 doses of ipilimumab (combined PBS-subsidised and non-PBS-subsidised).

Injection

2643D	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	360 mg	2	..	*48160.74	38.30	Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial) 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)

6111

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 of 3 mg per kg every 2 weeks.

Injection

10748Q	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	360 mg	11	..	*7702.26	38.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) 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)

6095

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 9 doses at a maximum dose of 3 mg per kg every 2 weeks.

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

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)

6070

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 9 doses at a maximum dose of 3 mg per kg every 2 weeks.

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

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)

6083

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathering 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 have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2016, **AND**

- Patient must not have received prior treatment with ipilimumab or any other PD-1 (programmed cell death-1) inhibitor 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**
- The treatment must not exceed a maximum dose of 3 mg per kg every 2 weeks.

Authority required (STREAMLINED)

6116

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathering treatment 2

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2016, **AND**
- Patient must not have received prior treatment with ipilimumab or any other PD-1 (programmed cell death-1) inhibitor 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**
- The treatment must not exceed a maximum dose of 3 mg per kg every 2 weeks.

Injection

10775D	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	360 mg	8	..	*7702.26	38.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

OBINUTUZUMAB

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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.

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

Chronic lymphocytic leukaemia (CLL)

Clinical criteria:

- Patient must require treatment for CD20 positive chronic lymphocytic leukaemia (CLL), **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 while on treatment.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; **AND**

(b) a completed CD20 positive Chronic Lymphocytic Leukaemia PBS Authority Application - Supporting Information Form which includes:

i) documentation that the patient has CD20 positive CLL (flow cytometry pathology report from blood or bone marrow, noting that this may be from some time earlier); **AND**

ii) a statement that the patient is previously untreated, is inappropriate for fludarabine based chemo immunotherapy, that treatment will be in combination with chlorambucil; **AND**

iii) documentation that the patient has a creatinine clearance 30 mL/min or greater; **AND**

iv) One of the following, either:

- A completed cumulative illness rating scale (CIRS) score form demonstrating that the patient has a score of greater than 6 (excluding CLL-induced illness or organ damage)

OR

-Documentation that the patient has a creatinine clearance less than 70 mL/min;

Injection

10418H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1000 mg	7	..	*5488.40	38.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

■ OFATUMUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4858**

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- Patient must be inappropriate for fludarabine based therapy, **AND**
- The treatment must be in combination with chlorambucil.

Injection

10237T	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1000 mg	5	..	*3554.29	38.30	Arzerra [NV] (ofatumumab 1 g/50 mL injection, 50 mL vial)

■ OFATUMUMAB

Note An initial dose of 1300 mg of PBS-subsidised ofatumumab must be made up of 3 vials of 100 mg and 1 vial of 1000 mg.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4828**

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), **AND**
- The condition must be previously untreated, **AND**
- The treatment must be in combination with chlorambucil, **AND**
- Patient must be inappropriate for fludarabine based therapy.

Injection

10239X	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1000 mg	5	..	*3554.29	38.30	Arzerra [NV] (ofatumumab 1 g/50 mL injection, 50 mL vial)

Injection

10240Y	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	300 mg	..	..	*1151.20	38.30	Arzerra [NV] (ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials)

■ PANITUMUMAB

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)**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	..	*6026.82	38.30	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial) Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

■ PANITUMUMAB

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

5526

Metastatic colorectal cancer
Treatment Phase: Initial Treatment

Clinical criteria:

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

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

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

Authority required (STREAMLINED)

5452

Metastatic colorectal cancer
Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

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

Injection

10508C	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	720 mg	9	..	*6026.82	38.30	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial) Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

■ PEMBROLIZUMAB

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

Note MANAGED ENTRY SCHEME

This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.

Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.

Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.

In the case of pembrolizumab, the relevant information is being collected from an ongoing clinical trial outside the PBS. Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS subsidy for this medicine.

For more information on Managed Entry Schemes, please visit

<http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions>.

For more information on the PBAC's consideration of this medicine and its MES, please visit

<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2015-03/pembrolizumab-psd-03-2015>.

Authority required (STREAMLINED)

5362

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 of 2 mg per kg every 3 weeks.

Injection

10424P	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	240 mg	7	..	*11427.40	38.30	Keytruda [MK] (pembrolizumab 50 mg injection, 1 vial)

▪ **PEMBROLIZUMAB**

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

Note MANAGED ENTRY SCHEME

This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.

Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.

Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.

In the case of pembrolizumab, the relevant information is being collected from an ongoing clinical trial outside the PBS.

Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS subsidy for this medicine.

For more information on Managed Entry Schemes, please visit

<http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions>.

For more information on the PBAC's consideration of this medicine and its MES, please visit

<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2015-03/pembrolizumab-psd-03-2015>.

Authority required (STREAMLINED)

6103

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 at a maximum dose of 2 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 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)

6093

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 at a maximum dose of 2 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 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)

6094

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathering 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 have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2015, **AND**
- Patient must not have received prior treatment with ipilimumab or any other PD-1 (programmed cell death-1) inhibitor 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**
- The treatment must not exceed a maximum dose of 2 mg per kg every 3 weeks.

Authority required (STREAMLINED)

6104

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathering treatment 2

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2015, **AND**
- Patient must not have received prior treatment with ipilimumab or any other PD-1 (programmed cell death-1) inhibitor 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**
- The treatment must not exceed a maximum dose of 2 mg per kg every 3 weeks.

Injection

10475H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	240 mg	5	..	*11427.40	38.30	Keytruda [MK] (pembrolizumab 50 mg injection, 1 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

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	..	*6352.06	38.30	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	..	*3236.68	38.30	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

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	..	..	*6352.06	38.30	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 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	..	*3202.13	38.30	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)

5998

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

Treatment Phase: Re-induction treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

6039

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

Treatment Phase: Re-induction treatment

Clinical criteria:

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

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

Injection

7257Y	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	800 mg	3	..	*3202.13	38.30	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 This drug is not PBS-subsidised for use as monotherapy.

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

Authority required (STREAMLINED)

4706

Chronic lymphocytic leukaemia (CLL)

Clinical criteria:

- The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), **AND**
- The treatment must be in combination with chemotherapy.

Injection

7259C	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1100 mg	5	..	*4357.41	38.30	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)

6309

Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be for induction treatment purposes only, **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 with no more than 8 doses in total.

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

Authority required (STREAMLINED)

6162

Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised chemotherapy, **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 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 with no more than 8 doses in total.

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

Authority required (STREAMLINED)

6034

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	..	*3202.13	38.30	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**

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

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: 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.

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).

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.

Injection

7264H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	500 mg	..	..	*3469.54	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)

■ 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

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: 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.

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).

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.

Injection

7266K	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1000 mg	..	..	*6843.70	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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).

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

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 PBS-subsidised treatment (Grandfather patient)

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) positivity, **AND**
- Patient must have been treated with this drug for this condition prior to 1 January 2016, **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.

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) positivity.

Injection

10575N	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	750 mg	3	..	*5057.38	38.30	Herceptin [RO] (trastuzumab 150 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

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	..	..	*6843.70	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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	..	*5057.38	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial)

Herceptin [RO] (trastuzumab 60 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).

Note Special Pricing Arrangements apply.

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	..	*6843.70	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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).

Note Special Pricing Arrangements apply.

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	..	*5057.38	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

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	..	..	*6843.70	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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

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	..	*1881.70	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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
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	..	*5057.38	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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
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).

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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	..	*7784.98	38.30	Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial) 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	..	*852.90	38.30	Phenasen [PL] (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	..	*852.90	38.30	Phenasen [PL] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

■ **BORTEZOMIB**

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

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

Applications for authority to prescribe should be forwarded to:

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

Note Special Pricing Arrangements apply.

Authority required

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 application and an application following completion of 8 treatment cycles, **AND**
- Patient must not receive more than 3 cycles of bortezomib under this restriction.

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

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

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

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

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

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

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

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

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

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

Injection

7269N	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	11	..	*1536.50	38.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

■ BORTEZOMIB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 application and an application following completion of 8 treatment cycles, **AND**
- Patient must not receive more than 3 cycles of bortezomib under this restriction.

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

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

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

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

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

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

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

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

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

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

Injection

7272R	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	11	..	*1536.50	38.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

■ BORTEZOMIB

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

Note Special Pricing Arrangements apply.

Authority required

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 PBS-subsidised thalidomide, lenalidomide or pomalidomide, **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.

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

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

Injection

7275X	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	15	..	*1536.49	38.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

■ BORTEZOMIB

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

Note Special Pricing Arrangements apply.

Authority required

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 PBS-subsidised thalidomide, lenalidomide or pomalidomide, **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.

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

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

Authority required

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

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 PBS-subsidised thalidomide, lenalidomide or pomalidomide, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

(1) a completed authority prescription form; and

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

(3) a signed patient acknowledgement.

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

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

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

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

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

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

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

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	..	*1536.49	38.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial)
						Velcade [JC] (bortezomib 3 mg injection, 1 vial)

■ BORTEZOMIB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, **AND**
 - Patient must not be receiving concomitant PBS-subsidised lenalidomide or pomalidomide, **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. Thalidomide treatment failure is defined as:

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

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

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

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

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

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

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

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

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

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

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

Authority required

Multiple myeloma

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

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 application and subsequent applications, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

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

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

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

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

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

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

(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

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

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

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

Injection

7268M	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	15	..	*1536.50	38.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial)
						Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

■ BORTEZOMIB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 lenalidomide or pomalidomide, **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.

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

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

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

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

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

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

Authority required

Multiple myeloma

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

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 application and subsequent applications, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

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

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

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

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

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

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

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

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

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

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

Injection

7271Q	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	15	..	*1536.50	38.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

• BORTEZOMIB

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

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 demonstrated progressive disease at the time of application, **AND**
- Patient must not have achieved a best confirmed response to bortezomib at the time of application, **AND**
- Patient must not be receiving PBS-subsidised thalidomide, lenalidomide or pomalidomide, **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 will not be approved if there is a gap of more than 6 months between the initial application and this application.

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

Authority required

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

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

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

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form, which includes a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology authority; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

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

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

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

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

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

Injection

7274W	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	19	..	*1536.49	38.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

■ ERIBULIN

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

Note Special Pricing Arrangements apply.

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	..	*1490.20	38.30	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	..	*283.50	38.30	Hospira Pty Limited [HH] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Hospira Pty Limited [HH] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinoccord [EA] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinoccord [EA] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) IRINOTECAN ACT [ED] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) IRINOTECAN ACT [ED] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) IRINOTECAN ACT [ED] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinotecan Ebew e [SZ] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinotecan Ebew e [SZ] (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 15 mL vial) Irinotecan Ebew e [SZ] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) Irinotecan Ebew e [SZ] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinotecan MYX [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)

TOPOTECAN

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	..	*167.26	38.30	Hycamtin [SZ] (topotecan 4 mg injection, 5 vials) Topotecan Agila [AF] (topotecan 4 mg injection, 1 vial)

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)

6124

Previously untreated stage III or IV CD20 positive mantle cell lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- 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)

6075

Previously untreated stage III or IV indolent CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- 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.

Injection

10760H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	200 mg	11	..	*1697.86	38.30	Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial) 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	..	*167.07	38.30	Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial) Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial) 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	..	*313.22	38.30	Holoxan [BX] (ifosfamide 1 g injection, 1 vial) 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	..	*2143.44	38.30	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	..	*98.87	38.30	Hospira Pty Limited [HH] (methotrexate 1 g/10 mL injection, 10 mL vial) Hospira Pty Limited [HH] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [HH] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [HH] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methaccord [EA] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Methotrexate MYX [OC] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methotrexate MYX [OC] (methotrexate 1 g/10 mL injection, 10 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

■ METHOTREXATE

Restricted benefit

Patients receiving treatment with a high dose regimen

Injection

4512L	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	20000 mg	..	..	*545.42	38.30	Hospira Pty Limited [HH] (methotrexate 1 g/10 mL injection, 10 mL vial) Hospira Pty Limited [HH] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [HH] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [HH] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methaccord [EA] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Methotrexate MYX [OC] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methotrexate MYX [OC] (methotrexate 1 g/10 mL injection, 10 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

■ PEMETREXED

Authority required (STREAMLINED)

4792

Locally advanced or metastatic non-small cell lung cancer

Clinical criteria:

- Patient must have received prior treatment with platinum-based chemotherapy. The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated

Doses greater than 500 mg per metre squared BSA are not PBS-subsidised

Authority required (STREAMLINED)

4789

Mesothelioma

Clinical criteria:

- The treatment must be in combination with cisplatin. The patient's body surface area (BSA) must be documented in the patient's medical records at the time the treatment cycle is initiated

Doses greater than 500 mg per metre squared BSA are not PBS-subsidised

Injection

4600D	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1100 mg	5	..	*3514.89	38.30	Alimta [LY] (pemetrexed 100 mg injection, 1 vial) Alimta [LY] (pemetrexed 500 mg injection, 1 vial) DBL Pemetrexed [HH] (pemetrexed 1 g injection, 1 vial) DBL Pemetrexed [HH] (pemetrexed 100 mg injection, 1 vial) DBL Pemetrexed [HH] (pemetrexed 500 mg injection, 1 vial) Pemetrexed APOTEX [TX] (pemetrexed 100 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 Juno [JU] (pemetrexed 100 mg injection, 1 vial) Pemetrexed Juno [JU] (pemetrexed 500 mg injection, 1 vial) Pemetrexed MYX [YN] (pemetrexed 1 g injection, 1 vial) Pemetrexed MYX [OC] (pemetrexed 100 mg injection, 1 vial) Pemetrexed MYX [OC] (pemetrexed 500 mg injection, 1 vial) Pemetrexed Sandoz [SZ] (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)

■ 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	..	*1302.90	38.30	Tomudex [HH] (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	..	*1300.10	38.30	Leustatin [JC] (cladribine 10 mg/10 mL injection, 10 mL vial) 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.

Authority required (STREAMLINED)

6248

B-cell chronic lymphocytic leukaemia

Clinical criteria:

- Patient must have advanced disease (Binet Stage B or C); OR
- Patient must have evidence of progressive Stage A disease, **AND**
- The treatment must be in combination with cyclophosphamide.

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

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

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

Injection

4393F	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	55 mg	29	..	*171.82	38.30	Fludarabine ACT [EA] (fludarabine phosphate 50 mg injection, 1 vial) Fludarabine Ebew e [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	..	*754.52	38.30	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	..	*118.59	38.30	DBL Fluorouracil Injection BP [HH] (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials) DBL Fluorouracil Injection BP [HH] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)

■ 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	..	*89.65	38.30	DBL Fluorouracil Injection BP [HH] (fluorouracil 1 g/20 mL injection, 5 x 20 mL vials) DBL Fluorouracil Injection BP [HH] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebew e [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials)

■ GEMCITABINE

Caution Pharmaceutical benefits containing gemcitabine may have different concentrations.

Note Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 200 mg (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 5 mL, gemcitabine solution concentrate for I.V. infusion 200 mg (as hydrochloride) in 20 mL and gemcitabine solution for injection 200 mg (as hydrochloride) in 5.3 mL are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 1 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 1 g (as hydrochloride) in 25 mL, gemcitabine solution concentrate for I.V. infusion 1000 mg (as hydrochloride) in 100 mL and gemcitabine solution for injection 1 g (as hydrochloride) in 26.3 mL are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the forms gemcitabine powder for I.V. infusion 2 g (as hydrochloride) (after reconstitution), gemcitabine solution concentrate for I.V. infusion 2 g (as hydrochloride) in 50 mL and gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.

Injection

4439P	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mg	17	..	*141.27	38.30	DBL Gemcitabine for Injection [HH] (gemcitabine 1 g injection, 1 vial)

DBL Gemcitabine for Injection [HH] (gemcitabine 2 g injection, 1 vial)
 DBL Gemcitabine for Injection [HH] (gemcitabine 200 mg injection, 1 vial)
 DBL Gemcitabine Injection [HH] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial)
 DBL Gemcitabine Injection [HH] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)
 DBL Gemcitabine Injection [HH] (gemcitabine 200 mg/5.3 mL injection, 5.3 mL vial)
 Gemaccord [EA] (gemcitabine 1 g injection, 1 vial)
 Gemaccord [EA] (gemcitabine 200 mg injection, 1 vial)
 Gemcitabine Actavis 2000 [EA] (gemcitabine 2 g injection, 1 vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 1 g injection, 1 vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 1 g/100 mL injection, 100 mL vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 200 mg injection, 1 vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 200 mg/20 mL injection, 20 mL vial)
 Gemcitabine Ebew e [SZ] (gemcitabine 500 mg/50 mL injection, 50 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	..	*156.56	38.30	Hospira Pty Limited [HH] (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	..	*101.06	38.30	Hospira Pty Limited [HH] (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	..	*154.12	38.30	Hospira Pty Limited [HH] (vinorelbine 10 mg/mL injection, 1 mL vial) Hospira Pty Limited [HH] (vinorelbine 50 mg/5 mL injection, 5 mL vial) Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial) Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial) Vinorelbine Ebew e [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial) Vinorelbine Ebew e [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	..	*259.62	38.30	Etopophos [BQ] (etoposide 1 g injection, 1 vial) Etopophos [BQ] (etoposide 100 mg injection, 1 vial) Etoposide Ebew e [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials) Pfizer Australia Pty Ltd [PF] (etoposide 100 mg/5 mL injection, 5 mL vial)

Taxanes

■ CABAZITAXEL

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4662

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

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

Injection

4376H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	55 mg	5	..	*3083.22	38.30	Jevtana [SW] (CABAZITAXEL Jevtana Concentrated injection 60 mg (as acetone solvate) in 1.5 mL, with diluent, 1)

■ DOCETAXEL

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

Injection

10148D	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	250 mg	5	..	*161.61	38.30	DBL Docetaxel Concentrated Injection [HH] (docetaxel 160 mg/16 mL injection, 16 mL vial) DBL Docetaxel Concentrated Injection [HH] (docetaxel 20 mg/2 mL injection, 2 mL vial) DBL Docetaxel Concentrated Injection [HH] (docetaxel 80 mg/8 mL injection, 8 mL vial) Docetaxel Sandoz [SZ] (docetaxel 80 mg/8 mL injection, 8 mL vial) Oncotaxel 140 [EA] (docetaxel 140 mg/7 mL injection, 7 mL vial) Oncotaxel 80 [EA] (docetaxel 80 mg/4 mL injection, 4 mL vial)

■ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

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	..	*1227.45	38.30	Abraxane [TS] (nanoparticle albumin-bound paclitaxel 100 mg injection, 1 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	..	*2371.68	38.30	Abraxane [TS] (nanoparticle albumin-bound paclitaxel 100 mg injection, 1 vial)

■ PACLITAXEL**Injection**

4567J	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	450 mg	3	..	*157.70	38.30	Anzatax [HH] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial) Anzatax [HH] (paclitaxel 150 mg/25 mL injection, 25 mL vial)

Anzatax [HH] (paclitaxel 300 mg/50 mL injection, 50 mL vial)
Paclitaxel ACT [EF] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)
Paclitaxel ACT [EF] (paclitaxel 150 mg/25 mL injection, 25 mL vial)
Paclitaxel ACT [EF] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
Paclitaxel ACT [EF] (paclitaxel 300 mg/50 mL injection, 50 mL vial)
Paclitaxel Actavis [EA] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
Paclitaxel Ebewe [SZ] (paclitaxel 150 mg/25 mL injection, 25 mL vial)
Paclitaxel Ebewe [SZ] (paclitaxel 30 mg/5 mL injection, 5 x 5 mL vials)
Paclitaxel Ebewe [SZ] (paclitaxel 300 mg/50 mL injection, 50 mL vial)
Paclitaxel Kabi [PK] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
Paclitaxel Kabi [PK] (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	..	*104.89	38.30	Accord Doxorubicin [EA] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Doxorubicin Ebewe [SZ] (doxorubicin hydrochloride 100 mg/50 mL injection, 50 mL vial) Doxorubicin MYX [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Doxorubicin SZ [HX] (doxorubicin hydrochloride 10 mg/5 mL injection, 5 mL vial) Doxorubicin SZ [HX] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (doxorubicin hydrochloride 10 mg/5 mL injection, 5 mL vial) Hospira Pty Limited [HH] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)

DOXORUBICIN HYDROCHLORIDE-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	..	*1545.44	38.30	Caelyx [JC] (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial) Caelyx [JC] (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial) Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride-pegylated liposomal 20 mg/10 mL injection, 1 x 10 mL vial)

Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride-pegylated liposomal 50 mg/25 mL injection, 1 x 25 mL vial)

■ EPIRUBICIN

Injection/intravesical

4375G	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	220 mg	5	..	*258.22	38.30	DBL Epirubicin Hydrochloride Injection [HH] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirubicin ACT [EA] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial) Epirubicin ACT [EA] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirubicin ACT [EA] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Epirubicin SZ [HX] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Hospira Pty Limited [HH] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial) Hospira Pty Limited [HH] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Pharmorubicin [PF] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) 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	..	*345.21	38.30	Idarubicin Ebewe [SZ] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial) Idarubicin Ebewe [SZ] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial) Zavedos Solution [PF] (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 10 mg in 10 mL, 6) Zavedos Solution [PF] (IDARUBICIN HYDROCHLORIDE Solution for I.V. injection 5 mg in 5 mL, 3)

■ MITOZANTRONE

Injection

4514N	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	30 mg	5	..	*188.78	38.30	Hospira Pty Limited [HH] (mitozantrone 20 mg/10 mL injection, 10 mL vial) Mitozantrone Ebewe [SZ] (mitozantrone 20 mg/10 mL injection, 10 mL vial) Onkotrone [BX] (mitozantrone 20 mg/10 mL injection, 10 mL vial) 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

4433H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	30000 iu	11	..	*162.00	38.30	Bleo 15K [EA] (bleomycin sulfate 15 000 international units injection, 1 vial) CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial) Hospira Pty Limited [HH] (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	..	*154.20	38.30	Hospira Pty Limited [HH] (carboplatin 150 mg/15 mL injection, 15 mL vial) Hospira Pty Limited [HH] (carboplatin 450 mg/45 mL injection, 45 mL vial) Hospira Pty Limited [HH] (carboplatin 50 mg/5 mL injection, 5 mL vial)

■ CISPLATIN

Injection

4319H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	220 mg	14	..	*128.56	38.30	Cisplatin Ebew e [SZ] (cisplatin 100 mg/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (cisplatin 100 mg/100 mL injection, 100 mL vial) Hospira Pty Limited [HH] (cisplatin 50 mg/50 mL injection, 50 mL vial)

■ OXALIPLATIN

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

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

Injection

4542C	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	300 mg	11	..	*142.44	38.30	DBL Oxaliplatin Concentrate [HH] (oxaliplatin 100 mg/20 mL injection, 20 mL vial) DBL Oxaliplatin Concentrate [HH] (oxaliplatin 50 mg/10 mL injection, 10 mL vial) Oxallicord [EA] (oxaliplatin 100 mg/20 mL injection, 20 mL vial) 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

■ 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	..	*3759.72	38.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 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	..	*3759.72	38.30	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.

Authority required (STREAMLINED)

6338

Advanced carcinoma of cervix

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 September 2016, **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.

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.

Injection

10881Q	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1800 mg	7	..	*7436.22	38.30	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)

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	..	*3759.72	38.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL 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

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	..	*21283.22	38.30	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

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 from a biopsy subsequent to the most recently delivered prior treatment with radiation, chemotherapy, biologics, immunotherapy or other agents;

(ii) The date of initial diagnosis of systemic anaplastic large cell lymphoma;

(iii) Dates of commencement and completion of front-line curative intent chemotherapy;

(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;

(v) a declaration of whether the patient has had, or is planned to have, a transplant

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	..	*21283.22	38.30	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	..	*2026.92	38.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)

Erbix [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	..	..	*2998.77	38.30	Erbix [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbix [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	..	..	*2998.77	38.30	Erbix [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbix [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	..	*2026.92	38.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

▪ **CETUXIMAB**

Note Special Pricing Arrangements apply.

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

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	..	*2026.92	38.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 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:

- (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.

Injection

2641B	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	360 mg	3	..	*47459.38	38.30	Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial) 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 A patient may only qualify for PBS-subsidised treatment under this restriction once.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4251

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Completion of induction treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- The treatment must be for completion of induction treatment in a patient who commenced induction treatment with ipilimumab prior to 1 August 2013, **AND**
- The treatment must not exceed a total of 4 doses (combined PBS-subsidised and non-PBS-subsidised) 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.

For patients who commenced induction treatment with ipilimumab prior to 1 August 2013 prescribers should request the appropriate number of repeats to provide a total of 4 doses of ipilimumab (combined PBS-subsidised and non-PBS subsidised).

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.

Authority required (STREAMLINED)

4252

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Completion of re-induction treatment

Clinical criteria:

- The treatment must be as monotherapy, **AND**
- Patient must have progressive disease after achieving an initial objective response to the most recent course of ipilimumab treatment (induction or re-induction) received prior to 1 August 2013, **AND**
- The treatment must be for completion of re-induction treatment in a patient who commenced re-induction treatment with ipilimumab prior to 1 August 2013, **AND**
- The treatment must not exceed a total of 4 doses (combined PBS-subsidised and non-PBS-subsidised) 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.

For patients who commenced re-induction treatment with ipilimumab prior to 1 August 2013 prescribers should request the appropriate number of repeats to provide a maximum of 4 doses of ipilimumab (combined PBS-subsidised and non-PBS-subsidised).

Injection

2663E	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	360 mg	2	..	*47459.38	38.30	Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial) 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)**6111**

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 of 3 mg per kg every 2 weeks.

Injection

10745M	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	360 mg	11	..	*7559.52	38.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) 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)**6095**

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 9 doses at a maximum dose of 3 mg per kg every 2 weeks.
The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

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)**6070**

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 9 doses at a maximum dose of 3 mg per kg every 2 weeks.
The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

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)**6083**

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathering 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 have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2016, **AND**

- Patient must not have received prior treatment with ipilimumab or any other PD-1 (programmed cell death-1) inhibitor 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**
- The treatment must not exceed a maximum dose of 3 mg per kg every 2 weeks.

Authority required (STREAMLINED)

6116

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathering treatment 2

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 May 2016, **AND**
- Patient must not have received prior treatment with ipilimumab or any other PD-1 (programmed cell death-1) inhibitor 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**
- The treatment must not exceed a maximum dose of 3 mg per kg every 2 weeks.

Injection

10764M	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	360 mg	8	..	*7559.52	38.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

OBINUTUZUMAB

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Prior Written Approval of Complex Drugs

Reply Paid 9826

HOBART TAS 7001

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.

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

Chronic lymphocytic leukaemia (CLL)

Clinical criteria:

- Patient must require treatment for CD20 positive chronic lymphocytic leukaemia (CLL), **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 while on treatment.

Applications for authorisation must be in writing and must include:

(a) a completed authority prescription form; **AND**

(b) a completed CD20 positive Chronic Lymphocytic Leukaemia PBS Authority Application - Supporting Information Form which includes:

i) documentation that the patient has CD20 positive CLL (flow cytometry pathology report from blood or bone marrow, noting that this may be from some time earlier); **AND**

ii) a statement that the patient is previously untreated, is inappropriate for fludarabine based chemo immunotherapy, that treatment will be in combination with chlorambucil; **AND**

iii) documentation that the patient has a creatinine clearance 30 mL/min or greater; **AND**

iv) One of the following, either:

- A completed cumulative illness rating scale (CIRS) score form demonstrating that the patient has a score of greater than 6 (excluding CLL-induced illness or organ damage)

OR

-Documentation that the patient has a creatinine clearance less than 70 mL/min;

Injection

10407R	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1000 mg	7	..	*5376.22	38.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

■ OFATUMUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4858**

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Continuing treatment

Clinical criteria:

- The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), **AND**
- Patient must have previously been issued with an authority prescription for this drug, **AND**
- Patient must not have progressive disease, **AND**
- Patient must be inappropriate for fludarabine based therapy, **AND**
- The treatment must be in combination with chlorambucil.

Injection

10236R	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1000 mg	5	..	*3468.81	38.30	Arzerra [NV] (ofatumumab 1 g/50 mL injection, 50 mL vial)

■ OFATUMUMAB

Note An initial dose of 1300 mg of PBS-subsidised ofatumumab must be made up of 3 vials of 100 mg and 1 vial of 1000 mg.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)**4828**

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), **AND**
- The condition must be previously untreated, **AND**
- The treatment must be in combination with chlorambucil, **AND**
- Patient must be inappropriate for fludarabine based therapy.

Injection

10252N	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1000 mg	5	..	*3468.81	38.30	Arzerra [NV] (ofatumumab 1 g/50 mL injection, 50 mL vial)

Injection

10249K	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	300 mg	..	..	*1098.90	38.30	Arzerra [NV] (ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials)

■ PANITUMUMAB

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)**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	..	*5907.22	38.30	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial) Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

▪ **PANITUMUMAB**

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

5526

Metastatic colorectal cancer
Treatment Phase: Initial Treatment

Clinical criteria:

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

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

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

Authority required (STREAMLINED)

5452

Metastatic colorectal cancer
Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

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

Injection

10513H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	720 mg	9	..	*5907.22	38.30	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial) Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

▪ **PEMBROLIZUMAB**

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

Note MANAGED ENTRY SCHEME

This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.

Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.

Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.

In the case of pembrolizumab, the relevant information is being collected from an ongoing clinical trial outside the PBS. Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS subsidy for this medicine.

For more information on Managed Entry Schemes, please visit

<http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions>.

For more information on the PBAC's consideration of this medicine and its MES, please visit

<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2015-03/pembrolizumab-psd-03-2015>.

Authority required (STREAMLINED)**5362**

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 of 2 mg per kg every 3 weeks.

Injection

10436G	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	240 mg	7	..	*11233.22	38.30	Keytruda [MK] (pembrolizumab 50 mg injection, 1 vial)

■ PEMBROLIZUMAB

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

Note MANAGED ENTRY SCHEME

This medicine has been listed on the PBS via a Managed Entry Scheme (MES). This MES provides a mechanism to address the uncertainty over the size of the additional clinical benefit of this medicine while providing early access to those patients for whom there is a high clinical need.

Information about the benefits of this medicine in clinical practice will be collected, analysed and presented to the Pharmaceutical Benefits Advisory Committee (PBAC) for consideration in the near future.

Prescribers and patients must be aware that if a drug listed via a MES does not prove as beneficial in clinical practice as appeared in the clinical data presented to the PBAC, it may subsequently have its restriction modified, or may be removed from the PBS by the Commonwealth or at the request of the sponsor.

In the case of pembrolizumab, the relevant information is being collected from an ongoing clinical trial outside the PBS.

Details of these arrangements are included in an information sheet that must be provided by the prescribing doctor to each patient receiving PBS subsidy for this medicine.

For more information on Managed Entry Schemes, please visit

<http://www.pbs.gov.au/info/publication/factsheets/shared/framework-for-introduction-of-managed-entry-scheme-for-PBAC-submissions>.

For more information on the PBAC's consideration of this medicine and its MES, please visit

<http://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/psd/2015-03/pembrolizumab-psd-03-2015>.

Authority required (STREAMLINED)**6103**

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 at a maximum dose of 2 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 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)**6093**

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 at a maximum dose of 2 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 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)

6094

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathering 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 have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2015, **AND**
- Patient must not have received prior treatment with ipilimumab or any other PD-1 (programmed cell death-1) inhibitor 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**
- The treatment must not exceed a maximum dose of 2 mg per kg every 3 weeks.

Authority required (STREAMLINED)

6104

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Grandfathering treatment 2

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 September 2015, **AND**
- Patient must not have received prior treatment with ipilimumab or any other PD-1 (programmed cell death-1) inhibitor 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**
- The treatment must not exceed a maximum dose of 2 mg per kg every 3 weeks.

Injection

10493G	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	240 mg	5	..	*11233.22	38.30	Keytruda [MK] (pembrolizumab 50 mg injection, 1 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

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	..	..	*6227.96	38.30	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

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	..	*6227.96	38.30	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	..	*3155.59	38.30	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 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	..	*3121.51	38.30	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)

5998

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

Treatment Phase: Re-induction treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

6039

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

Treatment Phase: Re-induction treatment

Clinical criteria:

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

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

Injection

4614W	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	800 mg	3	..	*3121.51	38.30	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 This drug is not PBS-subsidised for use as monotherapy.

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

Authority required (STREAMLINED)

4706

Chronic lymphocytic leukaemia (CLL)

Clinical criteria:

- The condition must be CD20 positive chronic lymphocytic leukaemia (CLL), **AND**
- The treatment must be in combination with chemotherapy.

Injection

4615X	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1100 mg	5	..	*4260.85	38.30	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)

6309

Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be for induction treatment purposes only, **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 with no more than 8 doses in total.

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

Authority required (STREAMLINED)

6162

Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised chemotherapy, **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 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 with no more than 8 doses in total.

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

Authority required (STREAMLINED)

6009

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	..	*3121.51	38.30	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

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

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: 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.

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).

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.

Injection

4632T	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	500 mg	..	..	*3410.80	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)

■ 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

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: 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.

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).

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.

Injection

4650R	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1000 mg	..	..	*6738.38	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) 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

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	..	..	*6738.38	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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	..	*4976.72	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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).

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

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 PBS-subsidised treatment (Grandfather patient)

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) positivity, **AND**
- Patient must have been treated with this drug for this condition prior to 1 January 2016, **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.

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) positivity.

Injection

10595P	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	750 mg	3	..	*4976.72	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

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	..	..	*6738.38	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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).

Note Special Pricing Arrangements apply.

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	..	*4976.72	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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).

Note Special Pricing Arrangements apply.

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	..	*6738.38	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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

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	..	*1844.88	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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. 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	..	*4976.72	38.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 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
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

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	..	*7641.10	38.30	Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial) 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	..	*804.72	38.30	Phenasen [PL] (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	..	*804.72	38.30	Phenasen [PL] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

■ BORTEZOMIB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 application and an application following completion of 8 treatment cycles, **AND**
- Patient must not receive more than 3 cycles of bortezomib under this restriction.

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

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

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

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

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

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

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

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

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

Injection

4712B	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	11	..	*1478.88	38.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

■ BORTEZOMIB

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

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

Applications for authority to prescribe should be forwarded to:

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

Note Special Pricing Arrangements apply.

Authority required

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 application and an application following completion of 8 treatment cycles, **AND**
- Patient must not receive more than 3 cycles of bortezomib under this restriction.

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

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

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

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

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

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

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

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

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

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

Injection

4725Q	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	11	..	*1478.88	38.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

■ BORTEZOMIB

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

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Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 PBS-subsidised thalidomide, lenalidomide or pomalidomide, **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.

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

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

Injection

4732C	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	15	..	*1478.88	38.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

■ BORTEZOMIB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 PBS-subsidised thalidomide, lenalidomide or pomalidomide, **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.

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

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

Authority required

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

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 PBS-subsidised thalidomide, lenalidomide or pomalidomide, **AND**
 - Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.
- The authority application must be made in writing and must include:

(1) a completed authority prescription form; and

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

(3) a signed patient acknowledgement.

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

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) in oligo-secretory and non-secretory myeloma patients only, the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

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

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

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

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

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

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	..	*1478.88	38.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial)
					Velcade [JC] (bortezomib 3 mg injection, 1 vial)

■ BORTEZOMIB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 have experienced treatment failure after a trial of at least four (4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease, **AND**
- Patient must not be receiving concomitant PBS-subsidised lenalidomide or pomalidomide, **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. Thalidomide treatment failure is defined as:

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

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

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

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

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

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

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

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

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

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

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

Authority required

Multiple myeloma

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

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 application and subsequent applications, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

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

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

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

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

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

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

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

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

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

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

Injection

4706Q	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	15	..	*1478.88	38.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

■ BORTEZOMIB

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

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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

Authority required

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 lenalidomide or pomalidomide, **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.

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

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application - Supporting Information Form which includes details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters will be used to assess response; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously provided; and

(4) a signed patient acknowledgment.

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

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

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

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

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

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

Authority required

Multiple myeloma

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

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 application and subsequent applications, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

(1) a completed authority prescription form; and

(2) a completed Multiple Myeloma bortezomib Authority Application Supporting Information form; and

(3) diagnostic reports demonstrating the patient has achieved at least a partial response.

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

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

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

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

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

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

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

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

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

Injection

4713C

Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
3000 mcg	15	..	*1478.88	38.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

■ BORTEZOMIB

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

Note Special Pricing Arrangements apply.

Authority required

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 demonstrated progressive disease at the time of application, **AND**
 - Patient must not have achieved a best confirmed response to bortezomib at the time of application, **AND**
 - Patient must not be receiving PBS-subsidised thalidomide, lenalidomide or pomalidomide, **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 will not be approved if there is a gap of more than 6 months between the initial application and this application.

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

Authority required

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

Injection

4429D	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3000 mcg	19	..	*1478.88	38.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

■ ERIBULIN

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

Note Special Pricing Arrangements apply.

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	..	*1433.22	38.30	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	..	*243.22	38.30	Hospira Pty Limited [HH] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Hospira Pty Limited [HH] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinoccord [EA] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinoccord [EA] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) IRINOTECAN ACT [ED] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) IRINOTECAN ACT [ED] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) IRINOTECAN ACT [ED] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) Irinotecan Alphapharm [AF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinotecan Ebew e [SZ] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinotecan Ebew e [SZ] (irinotecan hydrochloride trihydrate 300 mg/15 mL injection, 15 mL vial) Irinotecan Ebew e [SZ] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) Irinotecan Ebew e [SZ] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinotecan MYX [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)

■ TOPOTECAN

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	..	*128.55	38.30	Hycamtin [SZ] (topotecan 4 mg injection, 5 vials) Topotecan Agila [AF] (topotecan 4 mg injection, 1 vial)

Related Pharmaceutical Benefits for Public Hospital use

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ALIMENTARY TRACT AND METABOLISM

ANTIEMETICS AND ANTINAUSEANTS

ANTIEMETICS AND ANTINAUSEANTS

Serotonin (5HT₃) antagonists

GRANISETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.
- Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

granisetron 2 mg tablet, 1

5898K	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	2	..	..	*16.58	17.77	Kytril [RO]

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	..	..	2.42	3.61	^a Granisetron-AFT [AE] ^a Granisetron Kabi [PK]	^a GRANISETRON APOTEX [TX] ^a Kytril [RO]

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.

netupitant 300 mg + palonosetron 500 microgram capsule, 1

10714X	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	±1	5	..	103.01	38.30	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 tablet, 4

5967C	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	4.17	5.36	^a APO-Ondansetron [TX] ^a Ondansetron-DRLA [RZ] ^a Onsetron 4 [ZP]	^a Ondansetron AN [EA] ^a Ondansetron SZ [HX] ^a Zofran [AS]

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	38.30	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	..	..	6.54	7.73	^a APO-Ondansetron [TX] ^a Ondansetron-DRLA [RZ] ^a Onsetron 8 [ZP]	^a Ondansetron AN [EA] ^a Ondansetron SZ [HX] ^a 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	..	..	.36	1.55	^a Ondansetron Alphapharm [AF] ^a Onsetron [ZP]	^a Ondansetron-Clarix [AE]

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	..	..	.57	1.76	^a Ondansetron Alphapharm [AF] ^a Onsetron [ZP]	^a Ondansetron-Clarix [AE]

■ 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 Tablet (orally disintegrating) 4 mg, 4

5857G	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	4.17	5.36	^a Ondansetron AN ODT [EA] ^a Ondansetron ODT GH [GQ] ^a Onsetron ODT 4 [ED]	^a Ondansetron ODT-DRLA [RZ] ^a Ondansetron SZ ODT [HX]

ONDANSETRON Tablet (orally disintegrating) 8 mg, 4

5858H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer	Brand Name and Manufacturer
	1	..	..	6.54	7.73	^a Ondansetron AN ODT [EA] ^a Ondansetron ODT GH [GQ] ^a Onsetron ODT 8 [ED]	^a Ondansetron ODT-DRLA [RZ] ^a Ondansetron SZ ODT [HX]

ondansetron 4 mg wafer, 4

5969E	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1	..	^b 2.79	6.96	5.36	^a Zofran Zydix [AS]

ondansetron 8 mg wafer, 4

5970F	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1	..	^b 2.79	9.33	7.73	^a Zofran Zydix [AS]

■ PALONOSETRON

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

Note This drug is not PBS-subsidised for administration with oral 5-HT₃ antagonists.

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	33.83	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	5.76	Tropisetron-AFT [AE]

Other antiemetics**■ APREPITANT**

Note Aprepitant 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)**4223**

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)**4216**

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)**6464**

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 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

Authority required (STREAMLINED)**6383**

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of aprepitant 165 mg will be authorised per cycle of cytotoxic chemotherapy.
Concomitant use of a 5HT3 antagonist should not occur with aprepitant on days 2 and 3 of any chemotherapy cycle.

aprepitant 165 mg capsule, 1

2550F	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1	5	..	97.16	38.30	Emend [MK]

■ ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

■ ANTINEOPLASTIC AGENTS

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

■ RITUXIMAB

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

Authority required (STREAMLINED)

6008

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	..	2703.78	38.30	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	..	2703.78	38.30	Mabthera SC [RO]

■ RITUXIMAB

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

Authority required (STREAMLINED)

5998

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

Treatment Phase: Re-induction treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

6039

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

Treatment Phase: Re-induction treatment

Clinical criteria:

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

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

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	2	..	2703.78	38.30	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)
6317

Previously untreated aggressive CD20 positive non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised chemotherapy, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be for induction treatment purposes only, **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 with no more than 8 doses in total.

Authority required (STREAMLINED)
6162

Previously untreated symptomatic indolent CD20 positive non-Hodgkin's lymphoma in combination with chemotherapy

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised chemotherapy, **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 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 with no more than 8 doses in total.

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	6	..	2703.78	38.30	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

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	..	2795.85	38.30	Herceptin 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

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: 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.

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). 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.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10744L	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1	..	..	2795.85	38.30	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

Applications for authority to prescribe should be forwarded to:

Department of Human Services

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note Special Pricing Arrangements apply.

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	..	..	2795.85	38.30	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).

Note Special Pricing Arrangements apply.

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	..	2795.85	38.30	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).

Note Special Pricing Arrangements apply.

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	..	2795.85	38.30	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)

3899

Myeloproliferative disease with excessive thrombocytosis

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

5997P	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	5	4	..	*283.00	38.30	Roferon-A [RO]

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	..	*424.55	38.30	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)

3895

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

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	..	*424.65	38.30	Roferon-A [RO]

interferon alfa-2a 6 million units/0.5 mL injection, 0.5 mL syringe

5948C	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	5	5	..	*283.00	38.30	Roferon-A [RO]

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	..	*424.55	38.30	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)

3180

Hairy cell leukaemia

Authority required (STREAMLINED)

3899

Myeloproliferative disease with 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	..	*424.65	38.30	Roferon-A [RO]

■ INTERFERON ALFA-2B

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

Authority required (STREAMLINED)**3180**

Hairy cell leukaemia

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL

5893E	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3	4	..	*509.40	38.30	Intron A Redipen [MK]

■ INTERFERON ALFA-2B

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

Authority required (STREAMLINED)**3898**

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

Authority required (STREAMLINED)**3895**

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

interferon alfa-2b 18 million units/1.2 mL injection, 1.2 mL

5953H	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*509.40	38.30	Intron A Redipen [MK]

interferon alfa-2b 30 million units/1.2 mL injection, 1.2 mL

5956L	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3	5	..	*849.03	38.30	Intron A Redipen [MK]

Other immunostimulants**■ BACILLUS CALMETTE AND GUERIN-CONNAUGHT STRAIN****Restricted benefit**

Carcinoma in situ of the urinary bladder

Bacillus Calmette and Guerin-Connaught strain 660 million colony forming units injection [81 mg vial] (&) inert substance diluent [3 mL vial], 1 pack

5901N	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	3	1	..	*384.75	38.30	ImmuCyst [SW]

■ BACILLUS CALMETTE AND GUERIN-TICE STRAIN**Restricted benefit**

Primary and relapsing superficial urothelial carcinoma of the bladder

Bacillus Calmette and Guerin-Tice strain 500 million colony forming units injection, 3 vials

5902P	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1	1	..	467.24	38.30	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	37.17	Calcium Folate Ebew e [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	38.30	^a Calcium Folate Ebew e [SZ]	^a Leucovorin Calcium (Hospira Pty Limited) [HH]

■ 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, 10 x 5 mL ampoules

1899Y	Max. Amount	No. of Rpts	Premium \$	DPMA \$	MRVSN \$	Brand Name and Manufacturer
	1	2	..	38.90	38.30	^a Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

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	38.30	^a Leucovorin Calcium (Hospira Pty Limited) [HH]

▪ FOLINIC ACID

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

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	38.30	^a Calcium Folate Ebew e [SZ]

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	38.30	^a Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

▪ 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	38.30	Leucovorin Calcium (Hospira Pty Limited) [HH]

▪ 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	..	176.17	38.30	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	..	77.80	38.30	Uromitexan [BX]

Index of Manufacturers' Code

Code	Manufacturer
AE	AFT Pharmaceuticals Pty Ltd
AF	Alphapharm Pty Ltd
AN	Amgen Australia Pty Limited
AS	Aspen Pharmacare Australia Pty Limited
BQ	Bristol-Myers Squibb Australia Pty Ltd
BX	Baxter Healthcare Pty Limited
EA	Amneal Pharmaceuticals Pty Ltd
ED	Amneal Pharmaceuticals Pty Ltd
EF	Amneal Pharmaceuticals Pty Ltd
EI	Eisai Australia Pty Ltd
FB	Pierre Fabre Medicament Australia Pty Ltd
GQ	Generic Health Pty Ltd
HH	Hospira Pty Limited
HX	Sandoz Pty Ltd
JC	Janssen-Cilag Pty Ltd
JU	Juno Pharmaceuticals Pty Ltd
LR	Cipla Australia Pty Ltd
LY	Eli Lilly Australia Pty Ltd
MF	Mundipharma Pty Limited
MK	Merck Sharp & Dohme (Australia) Pty Ltd
NV	Novartis Pharmaceuticals Australia Pty Limited
OA	Orphan Australia Pty Ltd
OC	Accord Healthcare Pty Ltd
OE	Omegapharm Pty Ltd
PF	Pfizer Australia Pty Ltd
PK	Fresenius Kabi Australia Pty Limited
PL	The Trustee for Virgo Unit Trust (trading as Phebra)
RA	Ranbaxy Australia Pty Limited
RO	Roche Products Pty Ltd
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd
SE	Servier Laboratories (Aust.) Pty Ltd
SG	Merck Serono Australia Pty Ltd
SW	sanofi-aventis Australia Pty Ltd
SZ	Sandoz Pty Ltd
TB	Teva Pharma Australia Pty Limited
TK	Takeda Pharmaceuticals Australia Pty Ltd
TS	Specialised Therapeutics Australia Pty Ltd
TX	Apotex Pty Ltd
YN	Mayne Pharma International Pty Ltd
ZP	Medis Pharma Pty Ltd

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