Australian Government

Department of Health

PBS

Schedule of Pharmaceutical Benefits

Efficient Funding of Chemotherapy

Effective 1 June 2019

Contents

Summary of Changes

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

Additions

Addition – Item

11701W **BLEOMYCIN SULFATE**,
bleomycin sulfate 15 000 international units injection, 1 vial *(Bleomycin for Injection, USP)*

Addition – Brand

7255W *Pemetrexed SUN, RA* – **PEMETREXED**, pemetrexed 100 mg injection, 1 vial

7255W *Pemetrexed SUN, RA* – **PEMETREXED**, pemetrexed 500 mg injection, 1 vial

7255W *Pemetrexed SUN, RA* – **PEMETREXED**, pemetrexed 1 g injection, 1 vial

Deletions

Deletion – Brand

7255W *Pemetrexed Sandoz, SZ* – **PEMETREXED**, pemetrexed 500 mg injection, 1 vial

Advance Notices

1 September 2019

Deletion – Brand

10237T *Arzerra, NV* – **OFATUMUMAB**, ofatumumab 1 g/50 mL injection, 50 mL vial

10239X *Arzerra, NV* – **OFATUMUMAB**, ofatumumab 1 g/50 mL injection, 50 mL vial

10240Y *Arzerra, NV* – **OFATUMUMAB**, ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials

Efficient Funding of Chemotherapy (Public Hospital)

Additions

Addition – Item

11704B **BLEOMYCIN SULFATE**,
bleomycin sulfate 15 000 international units injection, 1 vial *(Bleomycin for Injection, USP)*

Addition – Brand

4600D *Pemetrexed SUN, RA* – **PEMETREXED**, pemetrexed 100 mg injection, 1 vial

4600D *Pemetrexed SUN, RA* – **PEMETREXED**, pemetrexed 500 mg injection, 1 vial

4600D *Pemetrexed SUN, RA* – **PEMETREXED**, pemetrexed 1 g injection, 1 vial

Deletions

Deletion – Brand

4600D *Pemetrexed Sandoz, SZ* – **PEMETREXED**, pemetrexed 500 mg injection, 1 vial

Advance Notices

1 September 2019

Deletion – Brand

10236R *Arzerra, NV* – **OFATUMUMAB**, ofatumumab 1 g/50 mL injection, 50 mL vial

10249K *Arzerra, NV* – **OFATUMUMAB**, ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials

10252N *Arzerra, NV* – **OFATUMUMAB**, ofatumumab 1 g/50 mL injection, 50 mL vial

Related Pharmaceutical Benefits for Public Hospital use

Advance Notices

1 July 2019

Deletion – Brand

2550F *Emend, MK* – **APREPITANT**, aprepitant 165 mg capsule, 1

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 ($7.29)
- Preparation fee ($84.44)
- Distribution fee ($26.65)
- Diluent fee ($5.28)

Section 94 Approved Public Hospital Authority

- Preparation fee ($84.44)

Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee ($7.29)
- Preparation fee ($84.44)
- Distribution fee ($26.65) (not payable where the drug is trastuzumab)
- Diluent fee ($5.28)

Pharmaceutical Benefits Schedules

Chemotherapy items for Private Hospital use

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

BENDAMUSTINE

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

Authority required (STREAMLINED)

7972

Previously untreated stage III or IV mantle cell lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be CD20 positive, **AND**
- The treatment must be in combination with rituximab, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- Patient must not receive more than 6 cycles (12 doses) of treatment under this restriction, **AND**
- Patient must not be eligible for stem cell transplantation.

Authority required (STREAMLINED)

7943

Previously untreated stage II bulky or stage III or IV indolent non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be CD20 positive, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- The treatment must be in combination with rituximab or obinutuzumab, **AND**
- The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.

Authority required (STREAMLINED)

7944

Follicular lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

- The condition must be CD20 positive, **AND**
- The condition must be refractory to treatment with rituximab for this condition, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for re-induction treatment purposes only, **AND**
- The treatment must be in combination with obinutuzumab, **AND**
- The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10763L	200 mg	11	..	*1760.90	40.30	Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial) Ribomustin [JC] (bendamustine hydrochloride 25 mg injection, 1 vial)

CYCLOPHOSPHAMIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7226H	2800 mg	17	..	*196.35	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7248L	4000 mg	19	..	*323.06	40.30	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	..	*2003.82	40.30	Muphoran [SE] (fotemustine 208 mg injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack)

ANTIMETABOLITES

Folic acid analogues

▪ METHOTREXATE

Injection

7250N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
250 mg	5	..	*149.51	40.30	Hospira Pty Limited [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) Hospira Pty Limited [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Accord [OD] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

▪ METHOTREXATE

Restricted benefit

Patients receiving treatment with a high dose regimen

Injection

7251P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
20000 mg	..	..	*887.62	40.30	Hospira Pty Limited [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) Hospira Pty Limited [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Accord [OD] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

▪ 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)

7195

Mesothelioma

Clinical criteria:

- The treatment must be in combination 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

Injection

7255W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1100 mg	5	..	*209.14	40.30	Alimta [LY] (pemetrexed 100 mg injection, 1 vial) Alimta [LY] (pemetrexed 500 mg injection, 1 vial) DBL Pemetrexed [PF] (pemetrexed 1 g injection, 1 vial) DBL Pemetrexed [PF] (pemetrexed 100 mg injection, 1 vial) DBL Pemetrexed [PF] (pemetrexed 500 mg injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 100 mg injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 500 mg injection, 1 vial) Pemetrexed APOTEX [TX] (pemetrexed 500 mg injection, 1 vial) PEMETREXED-DRLA [RZ] (pemetrexed 100 mg injection, 1 vial) Pemetrexed DRLA [RZ] (pemetrexed 500 mg injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 1 g injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 100 mg injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 500 mg injection, 1 vial) Reladdin [AF] (pemetrexed 100 mg injection, 1 vial) Reladdin [AF] (pemetrexed 500 mg injection, 1 vial) Tevatrexed [TB] (pemetrexed 100 mg injection, 1 vial) Tevatrexed [TB] (pemetrexed 500 mg injection, 1 vial)

▪ PRALATREXATE

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

Authority required

Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

Injection

11271F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
80 mg	5	..	*4544.70	40.30	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

▪ PRALATREXATE

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

Authority required

Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11278N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
80 mg	11	..	*4544.70	40.30	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

▪ RALTITREXED

Authority required (STREAMLINED)

6228

Advanced colorectal cancer

Clinical criteria:

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

Injection

7256X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7 mg	8	..	*1181.10	40.30	Tomudex [PF] (raltitrexed 2 mg injection, 1 vial)

Purine analogues

▪ CLADRIBINE

Authority required (STREAMLINED)

6265

Hairy cell leukaemia

Injection

7225G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
17 mg	6	..	*1178.66	40.30	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.

Injection

7233Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
55 mg	29	..	*188.24	40.30	Fludarabine ACT [JU] (fludarabine phosphate 50 mg injection, 1 vial) Fludarabine AMNEAL [JU] (fludarabine phosphate 50 mg injection, 1 vial) Fludarabine Ebewe [SZ] (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)

Pyrimidine analogues

▪ CYTARABINE

Injection

7227J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7000 mg	15	..	*932.86	40.30	Pfizer Australia Pty Ltd [PF] (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)

▪ FLUOROURACIL

Restricted benefit

Patients requiring administration of fluorouracil by intravenous infusion

Injection

7234R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5500 mg	11	..	*163.21	40.30	DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials) Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial) Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)

▪ FLUOROURACIL

Restricted benefit

Patients requiring administration of fluorouracil by intravenous injection

Injection

7239B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	23	..	*130.85	40.30	DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials) Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)

						Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)

▪ 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 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 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 form gemcitabine powder for I.V. infusion 2 g (as hydrochloride) (after reconstitution), and pharmaceutical benefits that have the form gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7246J	3000 mg	17	..	*187.59	40.30	DBL Gemcitabine Injection [PF] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial) DBL Gemcitabine Injection [PF] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

▪ VINBLASTINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7261E	20 mg	17	..	*198.02	40.30	Hospira Pty Limited [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)

▪ VINCRISTINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7262F	2 mg	7	..	*141.74	40.30	Hospira Pty Limited [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)

▪ VINORELBINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7263G	70 mg	7	..	*195.55	40.30	Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial) Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial) Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial) Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial)

Podophyllotoxin derivatives

▪ ETOPOSIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7237X	440 mg	14	..	*319.86	40.30	Etopophos [BQ] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial) Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials) Pfizer Australia Pty Ltd [PF] (etoposide 100 mg/5 mL injection, 5 mL vial)

Taxanes

▪ CABAZITAXEL

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4662

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7236W	55 mg	5	..	*3013.56	40.30	Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack)

▪ DOCETAXEL

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10158P	250 mg	5	..	*221.50	40.30	DBL Docetaxel Concentrated Injection [PF] (docetaxel 160 mg/16 mL injection, 16 mL vial) DBL Docetaxel Concentrated Injection [PF] (docetaxel 80 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 160 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 80 mg/4 mL injection, 4 mL vial) Docetaxel Sandoz [SZ] (docetaxel 80 mg/8 mL injection, 8 mL vial)

▪ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Authority required (STREAMLINED)

6106

Metastatic breast cancer

Authority required (STREAMLINED)

6119

HER2 positive breast cancer

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7270P	580 mg	5	..	*2444.16	40.30	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

▪ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Note Special Pricing Arrangements apply.

Note Not for use as neoadjuvant or adjuvant therapy.

Authority required (STREAMLINED)

4657

Stage IV (metastatic) adenocarcinoma of the pancreas

Clinical criteria:

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10150F	275 mg	11	..	*1283.91	40.30	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

▪ PACLITAXEL

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7254T	450 mg	3	..	*199.18	40.30	Anzatax [PF] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial) Anzatax [PF] (paclitaxel 150 mg/25 mL injection, 25 mL vial) Anzatax [PF] (paclitaxel 300 mg/50 mL injection, 50 mL vial) Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial)

Paclitaxel ACT [JU] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)
Paclitaxel ACT [JU] (paclitaxel 150 mg/25 mL injection, 25 mL vial)
Paclitaxel ACT [JU] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
Paclitaxel ACT [JU] (paclitaxel 300 mg/50 mL injection, 50 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)
Paclitaxin [TB] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)
Paclitaxin [TB] (paclitaxel 150 mg/25 mL injection, 25 mL vial)
Paclitaxin [TB] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
Paclitaxin [TB] (paclitaxel 300 mg/50 mL injection, 50 mL vial)

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

▪ DOXORUBICIN

Injection/intravesical

7229L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
135 mg	11	..	*175.53	40.30	Adriamycin [PF] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Adriamycin [PF] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Doxorubicin ACC [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)

▪ DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

Authority required (STREAMLINED)

4786

Advanced epithelial ovarian cancer

Clinical criteria:

- Patient must have failed a first-line platinum-based chemotherapy regimen.

Authority required (STREAMLINED)

4791

Metastatic breast cancer

Clinical criteria:

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

Authority required (STREAMLINED)

4787

Metastatic breast cancer

Clinical criteria:

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

Injection

7230M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
100 mg	5	..	*1202.54	40.30	Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial) Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial) Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial) Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)

▪ EPIRUBICIN

Injection/intravesical

7231N	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	220 mg	5	..	*205.01	40.30	Epirube [TB] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirube [TB] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Epirubicin Accord [OC] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirubicin ACT [JU] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial) Epirubicin ACT [JU] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirubicin ACT [JU] (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	..	*257.64	40.30	Idarubicin Ebewe [SZ] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial) Zavedos Solution [PF] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial) Zavedos Solution [PF] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial)

▪ MITOZANTRONE

Injection

7252Q	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	30 mg	5	..	*217.56	40.30	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

11701W	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	30000 iu	11	..	*166.92	40.30	Bleomycin for Injection, USP [QY] (bleomycin sulfate 15 000 international units injection, 1 vial)

Injection

7244G	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	30000 iu	11	..	*166.92	40.30	Bleo 15K [JU] (bleomycin sulfate 15 000 international units injection, 1 vial) CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial) Hospira Pty Limited [PF] (bleomycin sulfate 15 000 international units injection, 1 vial)

OTHER ANTINEOPLASTIC AGENTS

Platinum compounds

▪ CARBOPLATIN

Injection

7222D	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	900 mg	5	..	*195.64	40.30	Carboplatin Accord [OC] (carboplatin 450 mg/45 mL injection, 45 mL vial)

						Hospira Pty Limited [PF] (carboplatin 150 mg/15 mL injection, 15 mL vial) Hospira Pty Limited [PF] (carboplatin 450 mg/45 mL injection, 45 mL vial)

▪ CISPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7224F	220 mg	14	..	*169.63	40.30	Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial) Cisplatin Accord [OC] (cisplatin 50 mg/50 mL injection, 50 mL vial) Hospira Pty Limited [PF] (cisplatin 100 mg/100 mL injection, 100 mL vial) Hospira Pty Limited [PF] (cisplatin 50 mg/50 mL injection, 50 mL vial)

▪ OXALIPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7253R	300 mg	11	..	*183.71	40.30	DBL Oxaliplatin Concentrate [PF] (oxaliplatin 100 mg/20 mL injection, 20 mL vial) Oxaliplatin Accord [OC] (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

▪ ATEZOLIZUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6999

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

7572

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have received treatment with this drug for this condition prior to 1 April 2018, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have had a WHO performance status of 0 or 1 at the time non-PBS subsidised treatment with this drug for this condition was initiated.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11297N	1200 mg	7	..	*7704.63	40.30	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7539

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11309F	1200 mg	5	..	*7704.63	40.30	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ AVELUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8947

Stage IV (metastatic) Merkel Cell Carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11679Q	1200 mg	8	..	*8381.82	40.30	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

▪ AVELUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8856

Stage IV (metastatic) Merkel Cell Carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a total of 12 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11685B	1200 mg	11	..	*8381.82	40.30	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

▪ BEVACIZUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4584

Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with bevacizumab for this condition, **AND**
- Patient must not have progressive disease, **AND**
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks, **AND**
- The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10114H	900 mg	11	..	*3851.64	40.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial)

	Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

▪ BEVACIZUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

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	..	*3851.64	40.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

▪ BEVACIZUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6337

Advanced carcinoma of cervix

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a Gynaecologic Oncology Group (GOG) performance status of 0 or 1, **AND**
- The condition must not be amenable to curative treatment with surgery; OR
- The condition must not be amenable to curative radiation therapy, **AND**
- The condition must be previously untreated with this drug, **AND**
- Patient must not have received prior chemotherapy; OR
- Patient must have received prior chemotherapy with radiation therapy, **AND**
- The treatment must be in combination with platinum-based chemotherapy plus paclitaxel.

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

The patient's Gynaecologic Oncology Group (GOG) performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Authority required (STREAMLINED)

6353

Advanced carcinoma of cervix

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

10885X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1800 mg	7	..	*7579.62	40.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

▪ BEVACIZUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

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	..	*3851.64	40.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

▪ BLINATUMOMAB

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

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

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

Note Special Pricing Arrangements apply.

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

Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- The condition must not be present in the central nervous system or testis, **AND**
- The condition must be Philadelphia chromosome negative, **AND**
- Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 1 line of salvage therapy, **AND**
- The condition must have more than 5% blasts in bone marrow, **AND**
- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

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

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

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

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

(1) a completed authority prescription form;

(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and

(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and

(4) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.

Injection

11116C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
651 mcg	..	..	*70814.22	40.30	Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack)

▪ BLINATUMOMAB

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

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Induction treatment - balance of supply

Clinical criteria:

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

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

An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.

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

Injection

11119F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	..	..	*82595.98	40.30	Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack)

▪ BLINATUMOMAB

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

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

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

Note Special Pricing Arrangements apply.

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

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

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

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Consolidation treatment

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11115B	784 mcg	2	..	*82595.98	40.30	Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

Authority required

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not have progressive disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10180T	200 mg	11	..	*19998.06	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11067L	200 mg	11	..	*19998.06	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

Injection

11086L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	..	*19998.06	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Note Special Pricing Arrangements apply.

Authority required

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form; and

(b) a completed Systemic anaplastic large cell lymphoma Brentuximab PBS Authority Application - Supporting Information Form which includes the following:

(i) a histology report including evidence of the tumour's CD30 positivity;

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

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

(iv) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory.

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

Injection

10172J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	3	..	*19998.06	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma
Treatment Phase: Initial treatment
Clinical criteria:

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

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form;
(b) a completed Hodgkin lymphoma brentuximab PBS Authority Application; and
(c) a signed patient acknowledgement.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11080E	200 mg	3	..	*19998.06	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

Authority required
Relapsed or Refractory Hodgkin lymphoma
Treatment Phase: Initial treatment
Clinical criteria:

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

Applications for authorisation of initial treatment must be in writing and must include:
(a) a completed authority prescription form;
(b) a completed Hodgkin lymphoma brentuximab PBS Authority Application; and
(c) a signed patient acknowledgement.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11089P	200 mg	3	..	*19998.06	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required
CD30 positive cutaneous T-cell lymphoma
Treatment Phase: Initial treatment
Clinical criteria:

- Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma, **AND**

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

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

(a) a completed authority prescription form; and

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

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

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

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

Injection

11651F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
180 mg	3	..	*19998.06	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

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

Authority required

CD30 positive cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved an objective response with this drug, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The treatment must not exceed 12 cycles under this restriction.

An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria.

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

Injection

11661R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
180 mg	11	..	*19998.06	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ CETUXIMAB

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

Authority required (STREAMLINED)

4788

Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with radiotherapy, **AND**
- Patient must be unable to tolerate cisplatin; OR
- Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.

Injection

7240C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
550 mg	5	..	*1897.49	40.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

▪ CETUXIMAB

Note 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	..	..	*2784.41	40.30	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.

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	..	..	*2784.41	40.30	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)
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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10265G	550 mg	18	..	*1897.49	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7273T	550 mg	11	..	*1897.49	40.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

▪ INOTUZUMAB OZOGAMICIN

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

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

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

Note Special Pricing Arrangements apply.

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

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

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

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Consolidation treatment

Clinical criteria:

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

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

The treatment must not exceed 0.5mg per m^2 for all doses within a treatment cycle

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

Injection

11668D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2820 mcg	4	..	*40001.97	40.30	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

▪ INOTUZUMAB OZOGAMICIN

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

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

Note Special Pricing Arrangements apply.

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

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

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

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

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have a documented history of relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- Patient must have a documented history of receiving intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 2 lines of salvage therapy, **AND**
- The condition must be Philadelphia chromosome negative, **AND**
- The condition must be CD22-positive, **AND**
- Patient must have a documented history of more than 5% blasts in bone marrow, **AND**
- Patient must have received treatment with this drug for this condition prior to 1 May 2019, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

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

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

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

Patients who have received up to three treatment cycles as induction therapy with this drug for this condition prior to 1 May 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.

Patients who have received at least one treatment cycle as consolidation therapy with this drug for this condition prior to 1 May 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.

Patients who fail to demonstrate a complete remission (CR) or complete remission with incomplete haematological recovery (CRi) after 3 cycles of PBS-subsidised treatment with this agent must cease PBS-subsidised treatment with this agent.

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

(1) a completed authority prescription form;

(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and

(3) evidence that the condition is CD22-positive; and

(4) date of most recent inotuzumab ozogamicin dose, if this was for induction or consolidation therapy, and how many treatment cycle(s) of PBS-subsidised inotuzumab ozogamicin will be required for completion of induction or consolidation therapy; and

(5) date of latest chemotherapy prior to receiving non-PBS subsidised inotuzumab ozogamicin, and if it was the initial chemotherapy regimen or for salvage therapy and what line of salvage; and

(6) a copy of bone marrow biopsy report prior to receiving non-PBS subsidised inotuzumab ozogamicin.

Injection

11689F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3384 mcg	1	..	*53294.74	40.30	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

▪ INOTUZUMAB OZOGAMICIN

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

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

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

Note Special Pricing Arrangements apply.

Note Patients are eligible to receive a loading dose for the first dose of a treatment cycle while receiving induction treatment. Two prescriptions are required, the first prescription for the loading dose at a dose no higher than 0.8mg per m^2, and the second prescription for two doses at a dose no higher than 0.5mg per m^2. Both prescriptions must be submitted with the initial application.

Note Once a patient achieves complete remission or complete remission with partial haematological recovery, a new prescription must be written under the consolidation treatment phase.

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

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

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

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

(1) two completed authority prescription forms;

(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and

(3) evidence that the condition is CD22-positive; and

(4) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and

(5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.

The treatment must not exceed 0.8mg per m^2 for the first dose of a treatment cycle (Day 1), and 0.5mg per m^2 for subsequent doses (Days 8 and 15) within a treatment cycle.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11673J	3384 mcg	2	..	*53294.74	40.30	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

▪ IPILIMUMAB

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

8569

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11647B	120 mg	2	..	*17237.70	40.30	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

8555

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11644W	120 mg	3	..	*17237.70	40.30	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6562

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior treatment with ipilimumab, **AND**
- The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.

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

Note For patients who commence therapy with ipilimumab:
(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)

6585

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Re-induction treatment

Clinical criteria:

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

An initial objective response to treatment is defined as either:

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

(ii) a partial or complete response.

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

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

Authority required (STREAMLINED)

8206

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

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

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

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

Authority required (STREAMLINED)

8142

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

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

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

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

Authority required (STREAMLINED)

8178

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**

- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

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

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

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

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

Authority required (STREAMLINED)

8180

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

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

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

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

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

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

Injection

2638W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	3	..	*45761.10	40.30	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)

8552

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11157F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7704.62	40.30	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)

8568

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Maintenance treatment

Clinical criteria:

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

Maintenance treatment with nivolumab must not exceed 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.

Injection

11626X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7704.62	40.30	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)

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.

Authority required (STREAMLINED)

8143

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Maintenance treatment

Clinical criteria:

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

Maintenance treatment with nivolumab must not exceed 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.

Injection

10748Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7704.62	40.30	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 In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7567

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

11143L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7704.62	40.30	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)

6999

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

6997

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Grandfathering treatment

Clinical criteria:

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

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

Injection

11152Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7704.62	40.30	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.

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)

7864

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

11434T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7704.62	40.30	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 In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

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.

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.

Injection

10775D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7704.62	40.30	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.

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

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required (STREAMLINED)

8581

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial Treatment

Clinical criteria:

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

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

Injection

11159H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7704.62	40.30	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)

7787

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

7802

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

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 August 2018, **AND**
- Patient must have had a WHO performance status of 0 or 1, **AND**
- The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy, prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**

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

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

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

Injection

11425H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7704.62	40.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ NIVOLUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

8573

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

Injection

11627Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	3	..	*7704.62	40.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ NIVOLUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

8571

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Grandfather patients

Clinical criteria:

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

- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition; OR
- The treatment must be as monotherapy as maintenance for this condition.

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11635J	360 mg	2	..	*7704.62	40.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ NIVOLUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8182

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.

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

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

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

Authority required (STREAMLINED)

8141

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.

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

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

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

Authority required (STREAMLINED)

8146

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018; OR
- Patient must have received monotherapy with nivolumab as maintenance for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition; OR

- Patient must not have developed disease progression while being treated with monotherapy with nivolumab as maintenance for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition; OR
- The treatment must be as monotherapy as maintenance for this condition.

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

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

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

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

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

Authority required (STREAMLINED)

8220

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

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

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

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

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

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

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

Injection

11532Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	3	..	*2650.65	40.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ OBINUTUZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage II bulky or Stage III/IV follicular lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have previously received PBS subsidised treatment with this drug under the previously untreated initial restriction; OR
- Patient must have previously received PBS subsidised treatment with this drug under the previously untreated grandfather restriction, **AND**
- The condition must be CD20 positive, **AND**
- Patient must have demonstrated a partial or complete response to PBS subsidised induction treatment with this drug for this condition, **AND**
- The treatment must be maintenance therapy, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**

- The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11455X	1000 mg	5	..	*5490.76	40.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

Authority required

Follicular lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11473W	1000 mg	5	..	*5490.76	40.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

Authority required

Stage II bulky or Stage III/IV follicular lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be CD20 positive, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- The treatment must not exceed 10 doses for induction treatment with this drug for this condition.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or

ii) the rituximab-refractory re-induction restriction; or

iii) the previously untreated grandfather restriction; or

iv) the rituximab-refractory grandfather restriction.

Authority required

Stage II bulky or Stage III/IV follicular lymphoma

Treatment Phase: Grandfather treatment - previously untreated setting

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2018, **AND**
- The condition must be CD20 positive, **AND**
- The condition must have been untreated prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must be in combination with chemotherapy for induction treatment, **AND**
- The treatment must not exceed 10 doses for induction treatment with this drug for this condition; OR

- Patient must have demonstrated a partial or complete response to induction treatment with this drug for this condition for maintenance treatment, **AND**
- The treatment must be the sole PBS subsidised treatment for maintenance treatment; AND
- The treatment must not exceed 12 doses or 2 years duration of maintenance treatment, whichever comes first.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or

ii) the rituximab-refractory re-induction restriction; or

iii) the previously untreated grandfather restriction; or

iv) the rituximab-refractory grandfather restriction.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11456Y	1000 mg	9	..	*5490.76	40.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required

Follicular lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

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

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

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or

ii) the rituximab-refractory re-induction restriction; or

iii) the previously untreated grandfather restriction; or

iv) the rituximab-refractory grandfather restriction.

Authority required

Follicular lymphoma

Treatment Phase: Grandfather treatment - rituximab refractory

Clinical criteria:

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

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

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or

ii) the rituximab-refractory re-induction restriction; or

iii) the previously untreated grandfather restriction; or

iv) the rituximab-refractory grandfather restriction.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11460E	1000 mg	7	..	*5490.76	40.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

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

Note Special Pricing Arrangements apply.
Note Obinutuzumab is not to be used as monotherapy or in combination with anti-cancer drugs other than chlorambucil.
Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.

Authority required (STREAMLINED)
8184
Chronic lymphocytic leukaemia (CLL)
Clinical criteria:

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

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

Injection

10418H	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1000 mg	7	..	*5490.76	40.30	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	..	*3556.65	40.30	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

10240Y	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	300 mg	..	..	*1153.56	40.30	Arzerra [NV] (ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials)

Injection

10239X	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1000 mg	5	..	*3556.65	40.30	Arzerra [NV] (ofatumumab 1 g/50 mL injection, 50 mL vial)

▪ PANITUMUMAB

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

Authority required (STREAMLINED)
5439

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

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

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

Authority required (STREAMLINED)

5447

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10069Y	720 mg	5	..	*3969.74	40.30	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 Panitimumab 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10508C	720 mg	9	..	*3969.74	40.30	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.

Authority required (STREAMLINED)

6801

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10424P	240 mg	7	..	*11429.76	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) Keytruda [MK] (pembrolizumab 50 mg injection, 1 vial)

▪ PEMBROLIZUMAB

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

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

Authority required (STREAMLINED)

6806

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.

Authority required (STREAMLINED)

6817

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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10475H	240 mg	5	..	*11429.76	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) Keytruda [MK] (pembrolizumab 50 mg injection, 1 vial)

▪ PEMBROLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form;

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

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

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

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

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment - Grandfathered patients

Clinical criteria:

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

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

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

(a) a completed authority prescription form;

(b) a completed Hodgkin lymphoma pembrolizumab PBS Authority Application for Grandfathered patients.

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

Injection

11352L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*9168.54	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) Keytruda [MK] (pembrolizumab 50 mg injection, 1 vial)

▪ PEMBROLIZUMAB

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

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

Authority required (STREAMLINED)

8563

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy; OR
- The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; OR
- The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not exceed a total of 7 doses at a maximum dose of 200 mg every 3 weeks for this condition under this restriction.

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

Authority required (STREAMLINED)

8543

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

8542

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

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 March 2019, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy prior to initiating treatment with this drug for this condition; OR
- The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer prior to initiating treatment with this drug for this condition; OR
- The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer prior to initiating treatment with this drug for this condition, **AND**
- Patient must have a WHO performance status of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed 35 cycles in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks with this drug for this condition.

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

Injection

11632F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*9168.54	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

Authority required (STREAMLINED)

8122

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

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously been treated for this condition in the metastatic setting, **AND**

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must express programmed cell death ligand 1 (PD-L1) with a tumour score of at least 50% in the tumour sample; AND
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, **AND**
- The treatment must not exceed a total of 7 doses at a maximum dose of 200 mg every 3 weeks for this condition under this restriction.

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

Authority required (STREAMLINED)

8123

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

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 November 2018, **AND**
- Patient must not have had been treated for this condition in the metastatic setting prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS subsidised treatment with this drug for this condition, **AND**
- The condition must express programmed cell death ligand 1 (PD-L1) with a tumour score of at least 50% in the tumour sample prior to initiation of non-PBS subsidised treatment with this drug for this condition; AND
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, **AND**
- The treatment must not exceed 35 doses in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks, with this drug for this condition.

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

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

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

Authority required (STREAMLINED)

8124

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11492W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*9168.54	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PERTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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	..	*6354.42	40.30	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ PERTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be in combination with trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

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

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

The treatment must not exceed a lifetime total of one continuous course. However, short treatment breaks are permitted. A patient who has a treatment break of less than 6 weeks in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug. A patient who has a treatment break of more than 6 weeks in PBS-subsidised treatment with this drug is not eligible to receive PBS-subsidised treatment with this drug.

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

Injection

10308M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
420 mg	3	..	*3239.04	40.30	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ PERTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10334X	840 mg	..	..	*6354.42	40.30	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ RITUXIMAB

Authority required (STREAMLINED)

7400

Previously untreated or relapsed/refractory CD20 positive lymphoid cancer

Treatment Phase: Induction or re-induction therapy

Clinical criteria:

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7257Y	800 mg	7	..	*2629.42	40.30	Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

6011

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

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7258B	800 mg	7	..	*2629.42	40.30	Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

7399

Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7259C	800 mg	5	..	*2629.42	40.30	Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

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

Authority required (STREAMLINED)

6161

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

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10193L	800 mg	11	..	*2629.42	40.30	Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ TRASTUZUMAB

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

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

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

(a) a completed authority prescription form; and

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

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

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

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

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

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

Injection

7264H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
500 mg	..	..	*3133.73	40.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

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

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

(a) a completed authority prescription form; and

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

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

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

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

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

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

Injection

7266K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	..	..	*6170.43	40.30	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

10589H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	..	..	*6170.43	40.30	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	..	*4562.77	40.30	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	..	*6170.43	40.30	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	..	*4562.77	40.30	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	..	..	*6170.43	40.30	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	..	*1704.69	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7267L	750 mg	3	..	*4562.77	40.30	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

10281D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
450 mg	8	..	*7787.34	40.30	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	..	*855.26	40.30	Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

▪ ARSENIC

Authority required (STREAMLINED)

4793

Acute promyelocytic leukaemia

Treatment Phase: Induction and consolidation treatment

Clinical criteria:

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

Authority required (STREAMLINED)

5997

Acute promyelocytic leukaemia

Clinical criteria:

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

Injection

7241D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
18 mg	89	..	*855.26	40.30	Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7962

Multiple myeloma

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

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

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

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

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

Injection

7269N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	11	..	*1397.34	40.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7960

Multiple myeloma

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

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

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

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

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

Injection

7272R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	11	..	*1397.34	40.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7992

Symptomatic multiple myeloma

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

Details of the histological diagnosis of multiple myeloma must be documented in the patient's medical records.

Injection

7275X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	15	..	*1397.34	40.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7940

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

- Patient must have received an initial authority prescription for bortezomib for newly diagnosed symptomatic multiple myeloma and be ineligible for high dose chemotherapy, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have achieved a best confirmed response to bortezomib at the time of prescribing, **AND**

- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with a corticosteroid and melphalan or cyclophosphamide, **AND**
- Patient must not receive more than 5 cycles of treatment with bortezomib under this restriction.

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

Authority required (STREAMLINED)

7941

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

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

Injection

7274W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	19	..	*1397.34	40.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7963

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

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

Authority required (STREAMLINED)

7984

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

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

Details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response must be documented in the patient's medical records. Disease activity parameters include current diagnostic reports of at least one of the following:

(a) the level of serum monoclonal protein; or

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

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

(d) bone marrow aspirate or trephine; or

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

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

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

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be documented in the patient's medical records for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be documented in the patient's medical records.

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

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

Injection

7238Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	31	..	*1397.34	40.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7961

Multiple myeloma

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

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

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

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

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

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

Details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

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

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

(d) bone marrow aspirate or trephine; or

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

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

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

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

Authority required (STREAMLINED)

7974

Multiple myeloma

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

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Injection

7268M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	15	..	*1397.34	40.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7938

Multiple myeloma

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

Clinical criteria:

- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have progressive disease, **AND**
- Patient must have previously been treated with PBS-subsidised bortezomib, **AND**
- Patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

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

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

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

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

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

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

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

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

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

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

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

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

Details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters that will be used to assess response, and diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously documented must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

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

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

(d) bone marrow aspirate or trephine; or

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

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

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

As these parameters must be used to determine response, results for either (a) or (b) or (c) must be documented in the patient's medical records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records.

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

Authority required (STREAMLINED)

7939

Multiple myeloma

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

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7271Q	3000 mcg	15	..	*1397.34	40.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

▪ CARFILZOMIB

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

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

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

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

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

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

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

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).
Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Multiple myeloma
Treatment Phase: Grandfathering
Clinical criteria:

- Patient must have received treatment with this drug for this condition prior to 1 January 2018, **AND**
- Patient must have a documented histological diagnosis, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have had documented progressive disease after at least one prior therapy prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- Patient must not receive more than three cycles of treatment under this restriction.

Progressive disease is defined as at least 1 of the following:
(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or
(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or
(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or
(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or
(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or
(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or
(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).
Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.
A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Injection

11230C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	17	..	*2697.06	40.30	Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial)

▪ ERIBULIN

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

Authority required (STREAMLINED)

4649
Locally advanced or metastatic breast cancer
Clinical criteria:

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

Injection

10140Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3 mg	13	..	*853.74	40.30	Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

▪ ERIBULIN

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

Authority required (STREAMLINED)

7258
Advanced (unresectable and/or metastatic) liposarcoma
Treatment Phase: Initial treatment
Clinical criteria:

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

- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Authority required (STREAMLINED)

7280

Advanced (unresectable and/or metastatic) liposarcoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease while being treated with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11199K	3 mg	7	..	*853.74	40.30	Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

▪ IRINOTECAN

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7249M	800 mg	11	..	*189.42	40.30	Hospira Pty Limited [PF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Hospira Pty Limited [PF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) IRINOTECAN ACT [JU] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) IRINOTECAN ACT [JU] (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 500 mg/25 mL injection, 25 mL vial) Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)

▪ TOPOTECAN

Authority required (STREAMLINED)

6238

Advanced metastatic ovarian cancer

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7260D	3500 mcg	17	..	*156.19	40.30	Hycamtin [SZ] (topotecan 4 mg injection, 5 vials)

Chemotherapy items for Public Hospital use

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

BENDAMUSTINE

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

Authority required (STREAMLINED)

7972

Previously untreated stage III or IV mantle cell lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be CD20 positive, **AND**
- The treatment must be in combination with rituximab, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- Patient must not receive more than 6 cycles (12 doses) of treatment under this restriction, **AND**
- Patient must not be eligible for stem cell transplantation.

Authority required (STREAMLINED)

7943

Previously untreated stage II bulky or stage III or IV indolent non-Hodgkin's lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be CD20 positive, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- The treatment must be in combination with rituximab or obinutuzumab, **AND**
- The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.

Authority required (STREAMLINED)

7944

Follicular lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

- The condition must be CD20 positive, **AND**
- The condition must be refractory to treatment with rituximab for this condition, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for re-induction treatment purposes only, **AND**
- The treatment must be in combination with obinutuzumab, **AND**
- The treatment must not exceed 6 cycles (12 doses) with this drug under this restriction.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10760H	200 mg	11	..	*1699.08	40.30	Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial) Ribomustin [JC] (bendamustine hydrochloride 25 mg injection, 1 vial)

CYCLOPHOSPHAMIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4327R	2800 mg	17	..	*156.14	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4448D	4000 mg	19	..	*281.08	40.30	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	..	*1938.64	40.30	Muphoran [SE] (fotemustine 208 mg injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack)

ANTIMETABOLITES

Folic acid analogues

▪ METHOTREXATE

Injection

4502Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
250 mg	5	..	*109.94	40.30	Hospira Pty Limited [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) Hospira Pty Limited [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Accord [OD] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

▪ METHOTREXATE

Restricted benefit

Patients receiving treatment with a high dose regimen

Injection

4512L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
20000 mg	..	..	*837.84	40.30	Hospira Pty Limited [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) Hospira Pty Limited [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) Hospira Pty Limited [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methaccord [EA] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Accord [OD] (METHOTREXATE Injection 50 mg in 2 mL, 1) Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

▪ 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)

7195

Mesothelioma

Clinical criteria:

- The treatment must be in combination 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

Injection

4600D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1100 mg	5	..	*168.73	40.30	Alimta [LY] (pemetrexed 100 mg injection, 1 vial) Alimta [LY] (pemetrexed 500 mg injection, 1 vial) DBL Pemetrexed [PF] (pemetrexed 1 g injection, 1 vial) DBL Pemetrexed [PF] (pemetrexed 100 mg injection, 1 vial) DBL Pemetrexed [PF] (pemetrexed 500 mg injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 100 mg injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 500 mg injection, 1 vial) Pemetrexed APOTEX [TX] (pemetrexed 500 mg injection, 1 vial) PEMETREXED-DRLA [RZ] (pemetrexed 100 mg injection, 1 vial) Pemetrexed DRLA [RZ] (pemetrexed 500 mg injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 1 g injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 100 mg injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 500 mg injection, 1 vial) Reladdin [AF] (pemetrexed 100 mg injection, 1 vial) Reladdin [AF] (pemetrexed 500 mg injection, 1 vial) Tevatrexed [TB] (pemetrexed 100 mg injection, 1 vial) Tevatrexed [TB] (pemetrexed 500 mg injection, 1 vial)

▪ PRALATREXATE

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

Authority required

Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11272G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
80 mg	11	..	*4444.44	40.30	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

▪ PRALATREXATE

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

Authority required

Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

Injection

11293J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
80 mg	5	..	*4444.44	40.30	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

▪ RALTITREXED

Authority required (STREAMLINED)

6228

Advanced colorectal cancer

Clinical criteria:

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

Injection

4610P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7 mg	8	..	*1127.28	40.30	Tomudex [PF] (raltitrexed 2 mg injection, 1 vial)

Purine analogues

▪ CLADRIBINE

Authority required (STREAMLINED)

6265

Hairy cell leukaemia

Injection

4326Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
17 mg	6	..	*1124.88	40.30	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.

Injection

4393F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
55 mg	29	..	*148.12	40.30	Fludarabine ACT [JU] (fludarabine phosphate 50 mg injection, 1 vial) Fludarabine AMNEAL [JU] (fludarabine phosphate 50 mg injection, 1 vial) Fludarabine Ebewe [SZ] (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials)

Pyrimidine analogues

▪ CYTARABINE

Injection

4357H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7000 mg	15	..	*882.44	40.30	Pfizer Australia Pty Ltd [PF] (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)

▪ FLUOROURACIL

Restricted benefit

Patients requiring administration of fluorouracil by intravenous infusion

Injection

4394G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5500 mg	11	..	*123.44	40.30	DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials) Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial) Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)

▪ FLUOROURACIL

Restricted benefit

Patients requiring administration of fluorouracil by intravenous injection

Injection

4431F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	23	..	*91.53	40.30	DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) DBL Fluorouracil Injection BP [PF] (fluorouracil 500 mg/10 mL injection, 5 x 10 mL vials) Fluorouracil Accord [OC] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Accord [OC] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Accord [OC] (fluorouracil 5 g/100 mL injection, 100 mL vial)

						Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 1 g/20 mL injection, 20 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) Fluorouracil Ebewe [SZ] (fluorouracil 5 g/100 mL injection, 100 mL vial)

▪ 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 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 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 form gemcitabine powder for I.V. infusion 2 g (as hydrochloride) (after reconstitution), and pharmaceutical benefits that have the form gemcitabine solution for injection 2 g (as hydrochloride) in 52.6 mL are equivalent for the purposes of substitution.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4439P	3000 mg	17	..	*147.49	40.30	DBL Gemcitabine Injection [PF] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial) DBL Gemcitabine Injection [PF] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

▪ VINBLASTINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4618C	20 mg	17	..	*157.78	40.30	Hospira Pty Limited [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)

▪ VINCRISTINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4619D	2 mg	7	..	*102.28	40.30	Hospira Pty Limited [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)

▪ VINORELBINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4620E	70 mg	7	..	*155.34	40.30	Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial) Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial) Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial) Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial)

Podophyllotoxin derivatives

▪ ETOPOSIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4428C	440 mg	14	..	*277.94	40.30	Etopophos [BQ] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial) Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials) Pfizer Australia Pty Ltd [PF] (etoposide 100 mg/5 mL injection, 5 mL vial)

Taxanes

▪ CABAZITAXEL

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4662

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

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

Injection

4376H	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	55 mg	5	..	*2934.44	40.30	Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack)

▪ DOCETAXEL

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

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

Injection

10148D	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	250 mg	5	..	*180.92	40.30	DBL Docetaxel Concentrated Injection [PF] (docetaxel 160 mg/16 mL injection, 16 mL vial) DBL Docetaxel Concentrated Injection [PF] (docetaxel 80 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 160 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 80 mg/4 mL injection, 4 mL vial) Docetaxel Sandoz [SZ] (docetaxel 80 mg/8 mL injection, 8 mL vial)

▪ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Authority required (STREAMLINED)

6106

Metastatic breast cancer

Authority required (STREAMLINED)

6119

HER2 positive breast cancer

Injection

4531L	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	580 mg	5	..	*2372.90	40.30	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

▪ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Note Special Pricing Arrangements apply.

Note Not for use as neoadjuvant or adjuvant therapy.

Authority required (STREAMLINED)

4657

Stage IV (metastatic) adenocarcinoma of the pancreas

Clinical criteria:

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

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

Injection

10165B	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	275 mg	11	..	*1228.67	40.30	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

▪ PACLITAXEL

Injection

4567J	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	450 mg	3	..	*158.92	40.30	Anzatax [PF] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial) Anzatax [PF] (paclitaxel 150 mg/25 mL injection, 25 mL vial) Anzatax [PF] (paclitaxel 300 mg/50 mL injection, 50 mL vial) Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial)

Paclitaxel ACT [JU] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)
Paclitaxel ACT [JU] (paclitaxel 150 mg/25 mL injection, 25 mL vial)
Paclitaxel ACT [JU] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
Paclitaxel ACT [JU] (paclitaxel 300 mg/50 mL injection, 50 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)
Paclitaxin [TB] (paclitaxel 100 mg/16.7 mL injection, 16.7 mL vial)
Paclitaxin [TB] (paclitaxel 150 mg/25 mL injection, 25 mL vial)
Paclitaxin [TB] (paclitaxel 30 mg/5 mL injection, 5 mL vial)
Paclitaxin [TB] (paclitaxel 300 mg/50 mL injection, 50 mL vial)

Public

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	..	*135.59	40.30	Adriamycin [PF] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Adriamycin [PF] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Doxorubicin ACC [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)

▪ DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

Authority required (STREAMLINED)

4786

Advanced epithelial ovarian cancer

Clinical criteria:

- Patient must have failed a first-line platinum-based chemotherapy regimen.

Authority required (STREAMLINED)

4791

Metastatic breast cancer

Clinical criteria:

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

Authority required (STREAMLINED)

4787

Metastatic breast cancer

Clinical criteria:

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

Injection

4364Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
100 mg	5	..	*1148.42	40.30	Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial) Caelyx [JC] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial) Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial) Liposomal Doxorubicin SUN [RA] (doxorubicin hydrochloride (as pegylated liposomal) 50 mg/25 mL injection, 25 mL vial)

▪ EPIRUBICIN

Injection/intravesical

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4375G	220 mg	5	..	*164.67	40.30	Epirube [TB] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirube [TB] (epirubicin hydrochloride 50 mg/25 mL injection, 25 mL vial) Epirubicin Accord [OC] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirubicin ACT [JU] (epirubicin hydrochloride 100 mg/50 mL injection, 50 mL vial) Epirubicin ACT [JU] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial) Epirubicin ACT [JU] (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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4440Q	30 mg	5	..	*216.56	40.30	Idarubicin Ebewe [SZ] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial) Zavedos Solution [PF] (idarubicin hydrochloride 10 mg/10 mL injection, 10 mL vial) Zavedos Solution [PF] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial)

▪ MITOZANTRONE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4514N	30 mg	5	..	*177.04	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11704B	30000 iu	11	..	*127.10	40.30	Bleomycin for Injection, USP [QY] (bleomycin sulfate 15 000 international units injection, 1 vial)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4433H	30000 iu	11	..	*127.10	40.30	Bleo 15K [JU] (bleomycin sulfate 15 000 international units injection, 1 vial) CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial) Hospira Pty Limited [PF] (bleomycin sulfate 15 000 international units injection, 1 vial)

OTHER ANTINEOPLASTIC AGENTS

Platinum compounds

▪ CARBOPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4309T	900 mg	5	..	*155.42	40.30	Carboplatin Accord [OC] (carboplatin 450 mg/45 mL injection, 45 mL vial)

						Hospira Pty Limited [PF] (carboplatin 150 mg/15 mL injection, 15 mL vial) Hospira Pty Limited [PF] (carboplatin 450 mg/45 mL injection, 45 mL vial)

▪ CISPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4319H	220 mg	14	..	*129.78	40.30	Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial) Cisplatin Accord [OC] (cisplatin 50 mg/50 mL injection, 50 mL vial) Hospira Pty Limited [PF] (cisplatin 100 mg/100 mL injection, 100 mL vial) Hospira Pty Limited [PF] (cisplatin 50 mg/50 mL injection, 50 mL vial)

▪ OXALIPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4542C	300 mg	11	..	*143.66	40.30	DBL Oxaliplatin Concentrate [PF] (oxaliplatin 100 mg/20 mL injection, 20 mL vial) Oxaliplatin Accord [OC] (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

▪ ATEZOLIZUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6999

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

7572

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have received treatment with this drug for this condition prior to 1 April 2018, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have had a WHO performance status of 0 or 1 at the time non-PBS subsidised treatment with this drug for this condition was initiated.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11277M	1200 mg	7	..	*7560.74	40.30	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7539

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

Injection

11284X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	5	..	*7560.74	40.30	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ AVELUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8856

Stage IV (metastatic) Merkel Cell Carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a total of 12 doses at a maximum dose of 10 mg per kg every 2 weeks under this restriction.

Injection

11671G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	11	..	*8228.60	40.30	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

▪ AVELUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8947

Stage IV (metastatic) Merkel Cell Carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

11695M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	8	..	*8228.60	40.30	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

▪ BEVACIZUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

4814

Advanced International Federation of Gynecology and Obstetrics (FIGO) Stage IIIB, IIIC or Stage IV epithelial ovarian, fallopian tube or primary peritoneal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be suboptimally debulked (maximum diameter of any gross residual disease greater than 1 cm) only if the patient presents with Stage IIIB or Stage IIIC disease, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The condition must be previously untreated, **AND**
- The treatment must be commenced in combination with platinum-based chemotherapy, **AND**
- The treatment must not exceed a dose of 7.5 mg per kg every 3 weeks, **AND**
- The treatment must not exceed a lifetime total of 18 cycles of bevacizumab for epithelial ovarian, fallopian tube or primary peritoneal cancer.

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

Injection

10115J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
900 mg	5	..	*3760.94	40.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

▪ BEVACIZUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

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	..	*3760.94	40.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

▪ BEVACIZUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6337

Advanced carcinoma of cervix

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have a Gynaecologic Oncology Group (GOG) performance status of 0 or 1, **AND**
- The condition must not be amenable to curative treatment with surgery; OR
- The condition must not be amenable to curative radiation therapy, **AND**
- The condition must be previously untreated with this drug, **AND**
- Patient must not have received prior chemotherapy; OR
- Patient must have received prior chemotherapy with radiation therapy, **AND**
- The treatment must be in combination with platinum-based chemotherapy plus paclitaxel.

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

The patient's Gynaecologic Oncology Group (GOG) performance status and body weight must be documented in the patient's medical records at the time the treatment cycle is initiated.

Authority required (STREAMLINED)

6353

Advanced carcinoma of cervix

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

10881Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1800 mg	7	..	*7437.44	40.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

▪ BEVACIZUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

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	..	*3760.94	40.30	Avastin [RO] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Avastin [RO] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

▪ BLINATUMOMAB

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

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

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

Note Special Pricing Arrangements apply.

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

Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**
- The condition must not be present in the central nervous system or testis, **AND**
- The condition must be Philadelphia chromosome negative, **AND**
- Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 1 line of salvage therapy, **AND**
- The condition must have more than 5% blasts in bone marrow, **AND**
- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

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

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

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

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

(1) a completed authority prescription form;

(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and

(3) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and

(4) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11118E	651 mcg	..	..	*69798.92	40.30	Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack)

▪ BLINATUMOMAB

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

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Induction treatment - balance of supply

Clinical criteria:

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

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

An amount of 784 mcg will be sufficient for a continuous infusion of blinatumomab over 28 days in cycle 2.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11120G	784 mcg	..	..	*81418.00	40.30	Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack)

▪ BLINATUMOMAB

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

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

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

Note Special Pricing Arrangements apply.

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

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

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

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Consolidation treatment

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11117D	784 mcg	2	..	*81418.00	40.30	Blincyto [AN] (blinatumomab 38.5 microgram injection [1 vial] (&) inert substance solution [10 mL vial], 1 pack)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

Authority required

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not have progressive disease, **AND**
- Patient must have previously been issued with an authority prescription for this drug.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10171H	200 mg	11	..	*19684.44	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11087M	200 mg	11	..	*19684.44	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

Injection

11096B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	..	*19684.44	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Note Special Pricing Arrangements apply.

Authority required

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form; and

(b) a completed Systemic anaplastic large cell lymphoma Brentuximab PBS Authority Application - Supporting Information Form which includes the following:

(i) a histology report including evidence of the tumour's CD30 positivity;

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

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

(iv) a declaration of whether the patient's disease is relapsed or refractory, and the date and means by which the patient's disease was assessed as being relapsed or refractory.

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

Injection

10166C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	3	..	*19684.44	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form;

(b) a completed Hodgkin lymphoma brentuximab PBS Authority Application; and

(c) a signed patient acknowledgement.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11073T	200 mg	3	..	*19684.44	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form;

(b) a completed Hodgkin lymphoma brentuximab PBS Authority Application; and

(c) a signed patient acknowledgement.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11079D	200 mg	3	..	*19684.44	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

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

Authority required

CD30 positive cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have pathologically confirmed CD30 positive cutaneous T-cell lymphoma, **AND**

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

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

(a) a completed authority prescription form; and

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11660Q	180 mg	3	..	*19684.44	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

Note Special Pricing Arrangements apply.

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

Authority required

CD30 positive cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved an objective response with this drug, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The treatment must not exceed 12 cycles under this restriction.

An objective response is defined as the demonstration of response by clinical observation of skin lesions, or response by positron-emission tomography (PET) and/or computed tomography (CT) standard criteria.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11664X	180 mg	11	..	*19684.44	40.30	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ CETUXIMAB

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

Authority required (STREAMLINED)

4788

Stage III, IVa or IVb squamous cell cancer of the larynx, oropharynx or hypopharynx

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with radiotherapy, **AND**
- Patient must be unable to tolerate cisplatin; OR
- Patient must have a contraindication to cisplatin according to the TGA-approved Product Information.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4435K	550 mg	5	..	*1833.78	40.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

▪ CETUXIMAB

Note 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	..	..	*2708.46	40.30	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.

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	..	..	*2708.46	40.30	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)

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10262D	550 mg	18	..	*1833.78	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4731B	550 mg	11	..	*1833.78	40.30	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

▪ INOTUZUMAB OZOGAMICIN

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

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

Note Special Pricing Arrangements apply.

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

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

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

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

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have a documented history of relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**

- Patient must have a documented history of receiving intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 2 lines of salvage therapy, **AND**
- The condition must be Philadelphia chromosome negative, **AND**
- The condition must be CD22-positive, **AND**
- Patient must have a documented history of more than 5% blasts in bone marrow, **AND**
- Patient must have received treatment with this drug for this condition prior to 1 May 2019, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

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

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

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

Patients who have received up to three treatment cycles as induction therapy with this drug for this condition prior to 1 May 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.

Patients who have received at least one treatment cycle as consolidation therapy with this drug for this condition prior to 1 May 2019 must have achieved a complete remission or a complete remission with partial haematological recovery in order to continue with PBS-subsidised treatment with this drug.

Patients who fail to demonstrate a complete remission (CR) or complete remission with incomplete haematological recovery (CRi) after 3 cycles of PBS-subsidised treatment with this agent must cease PBS-subsidised treatment with this agent.

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

(1) a completed authority prescription form;

(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and

(3) evidence that the condition is CD22-positive; and

(4) date of most recent inotuzumab ozogamicin dose, if this was for induction or consolidation therapy, and how many treatment cycle(s) of PBS-subsidised inotuzumab ozogamicin will be required for completion of induction or consolidation therapy; and

(5) date of latest chemotherapy prior to receiving non-PBS subsidised inotuzumab ozogamicin, and if it was the initial chemotherapy regimen or for salvage therapy and what line of salvage; and

(6) a copy of bone marrow biopsy report prior to receiving non-PBS subsidised inotuzumab ozogamicin.

Injection

11674K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3384 mcg	1	..	*52521.40	40.30	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

▪ INOTUZUMAB OZOGAMICIN

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

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

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

Note Special Pricing Arrangements apply.

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

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

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

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Consolidation treatment

Clinical criteria:

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

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

The treatment must not exceed 0.5mg per m^2 for all doses within a treatment cycle

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

Injection

11680R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2820 mcg	4	..	*39412.16	40.30	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

▪ INOTUZUMAB OZOGAMICIN

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

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

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

Note Special Pricing Arrangements apply.

Note Patients are eligible to receive a loading dose for the first dose of a treatment cycle while receiving induction treatment. Two prescriptions are required, the first prescription for the loading dose at a dose no higher than 0.8mg per m^2, and the second prescription for two doses at a dose no higher than 0.5mg per m^2. Both prescriptions must be submitted with the initial application.

Note Once a patient achieves complete remission or complete remission with partial haematological recovery, a new prescription must be written under the consolidation treatment phase.

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

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

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

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

Authority required

Acute lymphoblastic leukaemia (ALL)

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

(1) two completed authority prescription forms;

(2) a completed Acute Lymphoblastic Leukaemia PBS Authority Application - Supporting Information Form; and

(3) evidence that the condition is CD22-positive; and

(4) date of most recent chemotherapy, and if this was the initial chemotherapy regimen or salvage therapy, including what line of salvage; and

(5) a copy of the most recent bone marrow biopsy report of no more than one month old at the time of application.

The treatment must not exceed 0.8mg per m^2 for the first dose of a treatment cycle (Day 1), and 0.5mg per m^2 for subsequent doses (Days 8 and 15) within a treatment cycle.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11696N	3384 mcg	2	..	*52521.40	40.30	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

▪ IPILIMUMAB

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

8569

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11641Q	120 mg	2	..	*16962.20	40.30	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

8555

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11628B	120 mg	3	..	*16962.20	40.30	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

6562

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior treatment with ipilimumab, **AND**
- The treatment must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.

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

Note For patients who commence therapy with ipilimumab:
(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)

6585

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Re-induction treatment

Clinical criteria:

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

An initial objective response to treatment is defined as either:

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

(ii) a partial or complete response.

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

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

Authority required (STREAMLINED)

8206

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

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

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

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

Authority required (STREAMLINED)

8142

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

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

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

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

Authority required (STREAMLINED)

8178

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**

- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

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

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

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

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

Authority required (STREAMLINED)

8180

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal,

AND

- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018, **AND**
- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

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

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

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

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

Injection

2641B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	3	..	*45091.80	40.30	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)

8552

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11160J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7560.74	40.30	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)

8568

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Maintenance treatment

Clinical criteria:

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

Maintenance treatment with nivolumab must not exceed 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.

Injection

11642R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7560.74	40.30	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)

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.

Authority required (STREAMLINED)

8143

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Maintenance treatment

Clinical criteria:

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

Maintenance treatment with nivolumab must not exceed 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.

Injection

10745M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7560.74	40.30	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)

6999

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

6997

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Grandfathering treatment

Clinical criteria:

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

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

Injection

11153B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7560.74	40.30	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 In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7567

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

11158G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7560.74	40.30	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.

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)

7864

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

11435W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7560.74	40.30	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 In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

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.

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.

Injection

10764M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7560.74	40.30	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.

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

Note Response Evaluation Criteria In Solid Tumours (RECIST) is defined as follows:
Complete response (CR) is disappearance of all target lesions.
Partial response (PR) is a 30% decrease in the sum of the longest diameter of target lesions.
Progressive disease (PD) is a 20% increase in the sum of the longest diameter of target lesions.
Stable disease (SD) is small changes that do not meet above criteria.

Authority required (STREAMLINED)

8581

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial Treatment

Clinical criteria:

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

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

Injection

11150W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7560.74	40.30	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)

7787

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

7802

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

Treatment Phase: Grandfather treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 August 2018, **AND**
- Patient must have had a WHO performance status of 0 or 1, **AND**

- The condition must have progressed within 6 months of the last dose of prior platinum based chemotherapy, prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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

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

Injection

11411N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	11	..	*7560.74	40.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ NIVOLUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

8571

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Grandfather patients

Clinical criteria:

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

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

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

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

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

Injection

11631E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	2	..	*7560.74	40.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ NIVOLUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

8573

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11636K	360 mg	3	..	*7560.74	40.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ NIVOLUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8182

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.

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

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

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

Authority required (STREAMLINED)

8141

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be positive for a BRAF V600 mutation, **AND**
- The condition must have progressed following treatment with a BRAF inhibitor (with or without a MEK inhibitor); OR
- Patient must be contraindicated to treatment with a BRAF inhibitor according to the TGA approved Product Information; OR
- Patient must have developed intolerance to a BRAF inhibitor of a severity necessitating permanent treatment withdrawal, **AND**
- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for this condition, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition.

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

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

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

Authority required (STREAMLINED)

8146

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

- The condition must be negative for a BRAF V600 mutation, **AND**
- Patient must have received combined therapy with ipilimumab and nivolumab as induction for this condition prior to 1 December 2018; OR
- Patient must have received monotherapy with nivolumab as maintenance for this condition prior to 1 December 2018, **AND**
- Patient must not have previously received treatment with ipilimumab or a programmed cell death factor 1 (PD-1) inhibitor prior to initiating combined therapy with ipilimumab and nivolumab as induction for this condition, **AND**

- Patient must not have developed disease progression while being treated with combined therapy with ipilimumab and nivolumab as induction for this condition; OR
- Patient must not have developed disease progression while being treated with monotherapy with nivolumab as maintenance for this condition, **AND**
- Patient must have had an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1 prior to initiating treatment with this drug for this condition, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with ipilimumab as induction for this condition; OR
- The treatment must be as monotherapy as maintenance for this condition.

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

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

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

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

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

Authority required (STREAMLINED)

8220

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment - Grandfather patients

Clinical criteria:

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

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

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

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

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

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

Injection

11543M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	3	..	*2576.54	40.30	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ OBINUTUZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required

Stage II bulky or Stage III/IV follicular lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have previously received PBS subsidised treatment with this drug under the previously untreated initial restriction; OR
- Patient must have previously received PBS subsidised treatment with this drug under the previously untreated grandfather restriction, **AND**
- The condition must be CD20 positive, **AND**
- Patient must have demonstrated a partial or complete response to PBS subsidised induction treatment with this drug for this condition, **AND**

- The treatment must be maintenance therapy, **AND**
- The treatment must be the sole PBS subsidised treatment for this condition, **AND**
- The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11462G	1000 mg	5	..	*5377.44	40.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

Authority required

Follicular lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11468N	1000 mg	5	..	*5377.44	40.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

Authority required

Follicular lymphoma

Treatment Phase: Re-induction treatment

Clinical criteria:

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

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

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or

ii) the rituximab-refractory re-induction restriction; or

iii) the previously untreated grandfather restriction; or

iv) the rituximab-refractory grandfather restriction.

Authority required

Follicular lymphoma

Treatment Phase: Grandfather treatment - rituximab refractory

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2018, **AND**
- The condition must be CD20 positive, **AND**

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

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

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or

ii) the rituximab-refractory re-induction restriction; or

iii) the previously untreated grandfather restriction; or

iv) the rituximab-refractory grandfather restriction.

Injection

11457B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	7	..	*5377.44	40.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

Authority required

Stage II bulky or Stage III/IV follicular lymphoma

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be CD20 positive, **AND**
- The condition must be previously untreated, **AND**
- The condition must be symptomatic, **AND**
- The treatment must be for induction treatment purposes only, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- The treatment must not exceed 10 doses for induction treatment with this drug for this condition.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or

ii) the rituximab-refractory re-induction restriction; or

iii) the previously untreated grandfather restriction; or

iv) the rituximab-refractory grandfather restriction.

Authority required

Stage II bulky or Stage III/IV follicular lymphoma

Treatment Phase: Grandfather treatment - previously untreated setting

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 October 2018, **AND**
- The condition must be CD20 positive, **AND**
- The condition must have been untreated prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must be in combination with chemotherapy for induction treatment, **AND**
- The treatment must not exceed 10 doses for induction treatment with this drug for this condition; OR
- Patient must have demonstrated a partial or complete response to induction treatment with this drug for this condition for maintenance treatment, **AND**
- The treatment must be the sole PBS subsidised treatment for maintenance treatment; AND
- The treatment must not exceed 12 doses or 2 years duration of maintenance treatment, whichever comes first.

A patient may only qualify for PBS subsidised initiation treatment once in a lifetime under:

i) the previously untreated induction treatment restriction; or

ii) the rituximab-refractory re-induction restriction; or

iii) the previously untreated grandfather restriction; or

iv) the rituximab-refractory grandfather restriction.

Injection

11458C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	9	..	*5377.44	40.30	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

Authority required (STREAMLINED)

8184

Chronic lymphocytic leukaemia (CLL)

Clinical criteria:

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10407R	1000 mg	7	..	*5377.44	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10236R	1000 mg	5	..	*3470.03	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10249K	300 mg	..	..	*1100.12	40.30	Arzerra [NV] (ofatumumab 100 mg/5 mL injection, 3 x 5 mL vials)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10252N	1000 mg	5	..	*3470.03	40.30	Arzerra [NV] (ofatumumab 1 g/50 mL injection, 50 mL vial)

▪ PANITUMUMAB

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

Authority required (STREAMLINED)

5439

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

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

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

Authority required (STREAMLINED)

5447

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

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

Injection

10082P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
720 mg	5	..	*3877.42	40.30	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 Panitimumab 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	..	*3877.42	40.30	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.

Authority required (STREAMLINED)

6801

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	..	*11234.44	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) Keytruda [MK] (pembrolizumab 50 mg injection, 1 vial)

▪ PEMBROLIZUMAB

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

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

Authority required (STREAMLINED)

6806

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.

Authority required (STREAMLINED)

6817

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.

Injection

10493G	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	240 mg	5	..	*11234.44	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) Keytruda [MK] (pembrolizumab 50 mg injection, 1 vial)

▪ PEMBROLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form;

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

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

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition.

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

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

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment - Grandfathered patients

Clinical criteria:

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

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

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

(a) a completed authority prescription form;

(b) a completed Hodgkin lymphoma pembrolizumab PBS Authority Application for Grandfathered patients.

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

Reply Paid 9826
HOBART TAS 7001

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11330H	200 mg	6	..	*9004.44	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial) Keytruda [MK] (pembrolizumab 50 mg injection, 1 vial)

▪ PEMBROLIZUMAB

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

Authority required (STREAMLINED)

8563

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

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy; OR
- The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; OR
- The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- The treatment must not exceed a total of 7 doses at a maximum dose of 200 mg every 3 weeks for this condition under this restriction.

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

Authority required (STREAMLINED)

8543

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

8542

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

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have received non-PBS treatment with this drug for this condition prior to 1 March 2019, **AND**
- The treatment must be the sole PBS-subsidised treatment for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy prior to initiating treatment with this drug for this condition; OR
- The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer prior to initiating treatment with this drug for this condition; OR
- The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer prior to initiating treatment with this drug for this condition, **AND**
- Patient must have a WHO performance status of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must not exceed 35 cycles in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks with this drug for this condition.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11646Y	200 mg	6	..	*9004.44	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8122

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

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must express programmed cell death ligand 1 (PD-L1) with a tumour score of at least 50% in the tumour sample; AND
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, **AND**
- The treatment must not exceed a total of 7 doses at a maximum dose of 200 mg every 3 weeks for this condition under this restriction.

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

Authority required (STREAMLINED)

8123

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

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to 1 November 2018, **AND**
- Patient must not have had been treated for this condition in the metastatic setting prior to initiating non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS subsidised treatment with this drug for this condition, **AND**
- The condition must express programmed cell death ligand 1 (PD-L1) with a tumour score of at least 50% in the tumour sample prior to initiation of non-PBS subsidised treatment with this drug for this condition; AND
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material, **AND**
- The treatment must not exceed 35 doses in total or up to 24 months of treatment, at a dose of 200 mg every 3 weeks, with this drug for this condition.

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

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

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

Authority required (STREAMLINED)

8124

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11494Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*9004.44	40.30	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PERTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

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

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form; and

(b) a completed Late stage metastatic breast cancer Initial PBS authority application form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification in the primary tumour or a metastatic lesion by in situ hybridisation (ISH) and tick a box to state the person has Stage IV disease; and

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

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

Injection

10267J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
840 mg	..	..	*6229.18	40.30	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ PERTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Authority required

HER2 positive breast cancer

Treatment Phase: Grandfathering treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition before 1 July 2015; OR
- Patient must have received non-PBS-subsidised trastuzumab for this condition before 1 July 2015, **AND**
- Patient must not have received non-PBS-subsidised treatment with trastuzumab for this condition before 1 July 2014, **AND**
- Patient must not have received prior therapy with trastuzumab emtansine or lapatinib for this condition, **AND**
- The treatment must be in combination with trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

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

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

Injection

10309N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
840 mg	1	..	*6229.18	40.30	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ PERTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

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

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously been issued with an authority prescription for this drug for this condition, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be in combination with trastuzumab, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

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

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

The treatment must not exceed a lifetime total of one continuous course. However, short treatment breaks are permitted. A patient who has a treatment break of less than 6 weeks in PBS-subsidised treatment with this drug for reasons other than disease progression is eligible to continue to receive PBS-subsidised treatment with this drug. A patient who has a treatment break of more than 6 weeks in PBS-subsidised treatment with this drug is not eligible to receive PBS-subsidised treatment with this drug.

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

Injection

10333W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
420 mg	3	..	*3156.81	40.30	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ RITUXIMAB

Authority required (STREAMLINED)

7400

Previously untreated or relapsed/refractory CD20 positive lymphoid cancer

Treatment Phase: Induction or re-induction therapy

Clinical criteria:

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

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

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

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

Injection

4614W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	7	..	*2555.64	40.30	Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

6011

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

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

4613T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	7	..	*2555.64	40.30	Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

7399

Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

4615X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	5	..	*2555.64	40.30	Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

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

Authority required (STREAMLINED)

6161

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

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

10179R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	11	..	*2555.64	40.30	Mabthera [RO] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Mabthera [RO] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ TRASTUZUMAB

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

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

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**

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

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

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

(a) a completed authority prescription form; and

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

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

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

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

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

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

Injection

4632T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
500 mg	..	..	*3079.25	40.30	Herceptin [RO] (trastuzumab 150 mg injection, 1 vial) Herceptin [RO] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

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

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

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

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

(a) a completed authority prescription form; and

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

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

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

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

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

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

Reply Paid 9826
HOBART TAS 7001

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4650R	1000 mg	..	..	*6074.05	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10581X	1000 mg	..	..	*6074.05	40.30	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	..	*4488.57	40.30	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	..	..	*6074.05	40.30	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	..	*4488.57	40.30	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	..	*6074.05	40.30	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	..	*1669.93	40.30	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	..	*4488.57	40.30	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10282E	450 mg	8	..	*7642.32	40.30	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	..	*805.94	40.30	Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

▪ ARSENIC

Authority required (STREAMLINED)

4793

Acute promyelocytic leukaemia

Treatment Phase: Induction and consolidation treatment

Clinical criteria:

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

Authority required (STREAMLINED)

5997

Acute promyelocytic leukaemia

Clinical criteria:

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

Injection

4371C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
18 mg	89	..	*805.94	40.30	Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7962

Multiple myeloma

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

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

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

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

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

Injection

4712B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	11	..	*1340.53	40.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7960

Multiple myeloma

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

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

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

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

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

Injection

4725Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	11	..	*1340.53	40.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7992

Symptomatic multiple myeloma

Clinical criteria:

- Patient must be newly diagnosed, **AND**
- Patient must be eligible for high dose chemotherapy and autologous stem cell transplantation, **AND**
- Patient must not be receiving concomitant PBS-subsidised thalidomide or its analogues, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

Details of the histological diagnosis of multiple myeloma must be documented in the patient's medical records.

Injection

4732C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	15	..	*1340.53	40.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7940

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

7941

Symptomatic multiple myeloma

Treatment Phase: Continuing PBS-subsidised treatment

Clinical criteria:

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

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

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

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

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

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

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

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

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

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

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

Injection

4429D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	19	..	*1340.53	40.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7963

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

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

Authority required (STREAMLINED)

7984

Symptomatic multiple myeloma

Treatment Phase: Initial PBS-subsidised treatment

Clinical criteria:

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

Details of the histological diagnosis of multiple myeloma, the name of the nephrologist who has reviewed the patient and the date of review, a copy of the current pathology reports reporting Glomerular Filtration Rate from an Approved Pathology Authority, and nomination of the disease activity parameter(s) that will be used to assess response must be documented in the patient's medical records. Disease activity parameters include current diagnostic reports of at least one of the following:

(a) the level of serum monoclonal protein; or

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

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

(d) bone marrow aspirate or trephine; or

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

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

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

As these parameters will be used to determine response, results for either (a) or (b) or (c) should be documented in the patient's medical records for all patients.

Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be documented in the patient's medical records.

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

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

Injection

4403R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	31	..	*1340.53	40.30	Velcade [JC] (bortezomib 1 mg injection, 1 vial) Velcade [JC] (bortezomib 3 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7961

Multiple myeloma

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

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a primary stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

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

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

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

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

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Authority required (STREAMLINED)

7974

Multiple myeloma

Treatment Phase: Treatment of Progressive disease - Continuing PBS-subsidised treatment

Clinical criteria:

- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have previously received 4 treatment cycles of bortezomib for progressive disease, **AND**
- Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib, **AND**
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, **AND**
- Patient must not have a gap of more than 6 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

Diagnostic reports must be no more than one month old at the time of prescribing.

A response assessment prior to cycle 5 must be documented in the patient's medical records.

Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.

Note Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4706Q	3000 mcg	15	..	*1340.53	40.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

▪ BORTEZOMIB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

7938

Multiple myeloma

Treatment Phase: Retreatment of Progressive disease - Initial PBS-subsidised treatment

Clinical criteria:

- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have progressive disease, **AND**
- Patient must have previously been treated with PBS-subsidised bortezomib, **AND**
- Patient must have experienced at least a partial response to the most recent course of PBS-subsidised bortezomib therapy, **AND**
- Patient must not be receiving concomitant PBS-subsidised carfilzomib, thalidomide or its analogues, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

Details of the basis of the current diagnosis of progressive disease and nomination of which disease activity parameters that will be used to assess response, and diagnostic reports demonstrating the patient has achieved at least a partial response to the most recent course of PBS-subsidised bortezomib, if not previously documented must be documented in the patient's medical records.

Confirmation of eligibility for treatment with current diagnostic reports of at least one of the following must be documented in the patient's medical records:

(a) the level of serum monoclonal protein; or

(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or

(c) the serum level of free kappa and lambda light chains; or

(d) bone marrow aspirate or trephine; or

(e) if present, the size and location of lytic bone lesions (not including compression fractures); or

(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or

(g) if present, the level of hypercalcaemia, corrected for albumin concentration.

As these parameters must be used to determine response, results for either (a) or (b) or (c) must be documented in the patient's medical records. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) must be documented in the patient's medical records.

Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be documented in the patient's medical records.

Authority required (STREAMLINED)

7939

Multiple myeloma

Treatment Phase: Retreatment of Progressive disease - Continuing PBS-subsidised treatment

Clinical criteria:

- The treatment must be as monotherapy; OR
- The treatment must be in combination with a corticosteroid and/or cyclophosphamide, **AND**
- Patient must have previously received 4 treatment cycles of bortezomib in the current treatment course, **AND**
- Patient must have demonstrated at the completion of cycle 4 at least a partial response to bortezomib, **AND**
- Patient must not have received 2 treatment cycles after first achieving a confirmed complete response, **AND**

- Patient must not have a gap of more than 6 months between the initial PBS-subsidised treatment with this drug for this condition and continuing PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not receive more than 4 cycles of treatment with bortezomib under this restriction.

Diagnostic reports demonstrating the patient has achieved at least a partial response must be documented in the patient's medical records.

If serum M protein is measurable, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 50% reduction in the level of serum M protein (monoclonal protein).

If urine Bence-Jones protein levels are being used to monitor disease activity, partial response (PR) compared with baseline (prior to treatment with bortezomib) is defined as at least a 90% reduction in 24-hour urinary light chain M protein excretion or to less than 200 mg per 24 hours.

If serum M protein is unmeasurable as in non-secretory/oligo-secretory multiple myeloma, partial response compared with baseline is defined as at least a 50% reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If serum M protein and urine Bence-Jones protein and serum FLC are unmeasurable/unavailable, partial response compared with baseline is defined as:

(a) at least a 50% reduction in bone marrow plasma cells; or

(b) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response); or

(c) at least a 50% reduction in the size of soft tissue plasmacytoma (by clinical or applicable radiographic examination, i.e. MRI or CT-Scan); or

(d) normalisation of corrected serum calcium to less than or equal to 2.65 mmol per L.

Diagnostic reports must be no more than one month old at the time of prescribing.

A response assessment prior to cycle 5 must be documented in the patient's medical records.

Confirmation of complete response requires 2 determinations a minimum of 6 weeks apart.

Note Patients who fail to demonstrate at least a partial response after 8 cycles will not be eligible to receive further PBS-subsidised treatment with bortezomib.

Injection

4713C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	15	..	*1340.53	40.30	Velcade [JC] (bortezomib 3 mg injection, 1 vial) Velcade [JC] (bortezomib 3.5 mg injection, 1 vial)

▪ CARFILZOMIB

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum amount or number of units may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Multiple myeloma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have progressive disease after at least one prior therapy, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant, **AND**
- Patient must not have previously received this drug for this condition, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- Patient must not receive more than three cycles of treatment under this restriction.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must not develop disease progression while receiving treatment with this drug for this condition, **AND**

- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- Patient must not receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required

Multiple myeloma

Treatment Phase: Grandfathering

Clinical criteria:

- Patient must have received treatment with this drug for this condition prior to 1 January 2018, **AND**
- Patient must have a documented histological diagnosis, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must have had documented progressive disease after at least one prior therapy prior to commencing non-PBS subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- Patient must have undergone or be ineligible for a stem cell transplant, **AND**
- Patient must not be receiving concomitant PBS-subsidised bortezomib, thalidomide or its analogues, **AND**
- Patient must not receive more than three cycles of treatment under this restriction.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

A patient may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a Grandfathered patient must qualify under the Continuing treatment criteria.

Injection

11229B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	17	..	*2622.32	40.30	Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial)

▪ ERIBULIN

Note A patient who has progressive disease with eribulin is no longer eligible for PBS-subsidised eribulin.

Authority required (STREAMLINED)

4649

Locally advanced or metastatic breast cancer

Clinical criteria:

- Patient must have progressive disease, **AND**
- Patient must have failed at least two prior chemotherapeutic regimens for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Injection

10144X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3 mg	13	..	*804.44	40.30	Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

▪ ERIBULIN

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7258

Advanced (unresectable and/or metastatic) liposarcoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have an ECOG performance status of 2 or less, **AND**
- The condition must be dedifferentiated, myxoid, round-cell or pleomorphic subtype, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline and ifosfamide (unless contraindicated) for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Authority required (STREAMLINED)

7280

Advanced (unresectable and/or metastatic) liposarcoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease while being treated with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11212D	3 mg	7	..	*804.44	40.30	Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

▪ IRINOTECAN

Note In first-line usage, effectiveness and tolerance may be improved when irinotecan is combined with an infusional 5-fluorouracil regimen.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4451G	800 mg	11	..	*149.32	40.30	Hospira Pty Limited [PF] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Hospira Pty Limited [PF] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial) Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) IRINOTECAN ACT [JU] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) IRINOTECAN ACT [JU] (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 500 mg/25 mL injection, 25 mL vial) Irinotecan Kabi [PK] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) MEDITAB IRINOTECAN [LR] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial) Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Omegapharm Irinotecan [OE] (irinotecan hydrochloride trihydrate 40 mg/2 mL injection, 2 mL vial)

▪ TOPOTECAN

Authority required (STREAMLINED)

6238

Advanced metastatic ovarian cancer

Clinical criteria:

- Patient must have failed prior therapy which included a platinum compound.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4617B	3500 mcg	17	..	*116.52	40.30	Hycamtin [SZ] (topotecan 4 mg injection, 5 vials)

Related Pharmaceutical Benefits for Public Hospital use

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 3 mg/3 mL injection, 3 mL ampoule

5899L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	1.92	3.15	[a] Granisetron-AFT [AE] [a] Kytril [IX]	[a] Granisetron Kabi [PK]

granisetron 2 mg tablet, 1

5898K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2	..	..	*16.58	17.81	Kytril [IX]

NETUPITANT + PALONOSETRON

Note No increase in the maximum number of repeats may be authorised.

Note No increase in the maximum quantity or number of units may be authorised.

Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Authority required (STREAMLINED)

5991

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

5994

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6937

Nausea and vomiting

Clinical criteria:

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6879

Nausea and vomiting

Clinical criteria:

Related

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 capsule of 300 mg netupitant/0.5 mg palonosetron fixed dose combination will be authorised per cycle of cytotoxic chemotherapy.

netupitant 300 mg + palonosetron 500 microgram capsule, 1

10714X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
‡1	5	..	97.16	40.30	Akynzeo [MF]

▪ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

ondansetron 4 mg tablet, 4

5967C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	3.41	4.64	[a] APO-Ondansetron [TX]	[a] Ondansetron AN [EA]
					[a] Ondansetron APOTEX [GX]	[a] Ondansetron-DRLA [RZ]
					[a] Ondansetron Mylan Tablets [AF]	[a] Ondansetron SZ [HX]
					[a] Onsetron 4 [ZP]	[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	40.30	Zofran syrup 50 mL [AS]

ondansetron 8 mg tablet, 4

5968D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	5.35	6.58	[a] APO-Ondansetron [TX]	[a] Ondansetron AN [EA]
					[a] Ondansetron APOTEX [GX]	[a] Ondansetron-DRLA [RZ]
					[a] Ondansetron Mylan Tablets [AF]	[a] Ondansetron SZ [HX]
					[a] Onsetron 8 [ZP]	[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 8 mg/4 mL injection, 4 mL ampoule

5972H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	.51	1.74	[a] Ondansetron Alphapharm [AF]	[a] Onsetron [ZP]

ondansetron 4 mg/2 mL injection, 2 mL ampoule

5971G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	.32	1.55	[a] Ondansetron Alphapharm [AF]	[a] Onsetron [ZP]

▪ ONDANSETRON

Note Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron 4 mg wafer are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron 8 mg wafer are equivalent for the purposes of substitution.

Restricted benefit

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

ondansetron 4 mg wafer, 4

5969E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	..	[B]2.28	5.69	4.64	[a] Zofran Zydis [AS]

ondansetron 4 mg orally disintegrating tablet, 4

5857G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	3.41	4.64	[a] Ondansetron AN ODT [EA] [a] Ondansetron ODT-DRLA [RZ] [a] Ondansetron SZ ODT [HX]	[a] Ondansetron Mylan ODT [AF] [a] Ondansetron ODT GH [GQ]

ondansetron 8 mg wafer, 4

5970F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	..	[B]2.28	7.63	6.58	[a] Zofran Zydis [AS]

ondansetron 8 mg orally disintegrating tablet, 4

5858H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	5.35	6.58	[a] Ondansetron AN ODT [EA] [a] Ondansetron ODT-DRLA [RZ] [a] Ondansetron SZ ODT [HX]	[a] Ondansetron Mylan ODT [AF] [a] Ondansetron ODT GH [GQ]

▪ PALONOSETRON

Note No increase in the maximum quantity or number of units may be authorised.

Note This drug is not PBS-subsidised for administration with oral 5-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	33.87	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	5.80	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	..	87.44	40.30	Emend [MK]

▪ FOSAPREPITANT

Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Note No increase in the maximum quantity or number of units may be authorised.

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6886

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following agents: altretamine; carmustine; cisplatin when a single dose constitutes a cycle of chemotherapy; cyclophosphamide at a dose of 1500 mg per square metre per day or greater; dacarbazine; procarbazine when a single dose constitutes a cycle of chemotherapy; streptozocin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6891

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat breast cancer, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone, **AND**
- Patient must be scheduled to be co-administered cyclophosphamide and an anthracycline.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Authority required (STREAMLINED)

6887

Nausea and vomiting

Clinical criteria:

- The condition must be associated with moderately emetogenic cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must have had a prior episode of chemotherapy induced nausea or vomiting, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes any 1 of the following intravenous chemotherapy agents: arsenic trioxide; azacitidine; cyclophosphamide at a dose of less than 1500 mg per square metre per day; cytarabine at a dose of greater than 1 g per square metre per day; dactinomycin; daunorubicin; doxorubicin; epirubicin; fotemustine; idarubicin; ifosfamide; irinotecan; melphalan; methotrexate at a dose of 250 mg to 1 g per square metre; raltitrexed.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

Authority required (STREAMLINED)

6852

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy, **AND**
- The treatment must be in combination with a 5-hydroxytryptamine receptor (5HT3) antagonist and dexamethasone on day 1 of a chemotherapy cycle, **AND**
- Patient must be scheduled to be administered a chemotherapy regimen that includes either carboplatin or oxaliplatin.

No more than 1 vial of fosaprepitant 150 mg injection will be authorised per cycle of cytotoxic chemotherapy.

Concomitant use of a 5HT3 antagonist should not occur with fosaprepitant on days 2 and 3 of any chemotherapy cycle.

fosaprepitant 150 mg injection, 1 vial

11103J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	5	..	97.16	40.30	Emend IV [MK]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

OTHER ANTINEOPLASTIC AGENTS

Monoclonal antibodies

RITUXIMAB

Authority required (STREAMLINED)

7400

Previously untreated or relapsed/refractory CD20 positive lymphoid cancer

Treatment Phase: Induction or re-induction therapy

Clinical criteria:

- The treatment must be for induction or re-induction for CD20 positive lymphoma; OR
- The treatment must be for induction or re-induction for CD20 positive chronic lymphocytic leukaemia; OR
- The treatment must be for induction or consolidation for CD20 positive acute lymphoblastic leukaemia, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must not receive more than the number of cycles of treatment recommended by standard guidelines for the partner chemotherapy under this restriction.

An initial dose of rituximab must be administered with rituximab intravenous injection. Subsequent doses may be administered with either intravenous or subcutaneous rituximab.

No more than 8 doses in total as per course of treatment will be allowed for lymphoma or chronic lymphocytic leukaemia.

No more than 12 doses in total as per course of treatment will be allowed for acute lymphoblastic leukaemia for induction course (including consolidation course).

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10741H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	6	..	2265.49	40.30	Mabthera SC [RO]

RITUXIMAB

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7399

Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, **AND**
- The treatment must be in combination with chemotherapy, **AND**
- Patient must be in complete remission, **AND**
- Patient must not receive more than 6 doses in total under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10708N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	5	..	2265.49	40.30	Mabthera SC [RO]

RITUXIMAB

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6011

Relapsed or refractory Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, **AND**

- Patient must have demonstrated a partial or complete response to re-induction treatment received immediately prior to this current Authority application, **AND**
- Patient must not receive more than 8 cycles or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10720F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	7	..	2265.49	40.30	Mabthera SC [RO]

▪ RITUXIMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

6161

Stage III or IV CD20 positive follicular B-cell non-Hodgkin's lymphoma

Treatment Phase: Maintenance therapy

Clinical criteria:

- Patient must have demonstrated a partial or complete response to induction treatment with either R-CHOP or R-CVP regimens for previously untreated follicular B-cell Non-Hodgkin's lymphoma, received immediately prior to this current Authority application, **AND**
- Patient must not have received bendamustine induction therapy, **AND**
- The treatment must be maintenance therapy, **AND**
- Patient must not receive more than 12 doses or 2 years duration of treatment, whichever comes first, under this restriction.

rituximab 1.4 g/11.7 mL injection, 11.7 mL vial

10710Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	11	..	2265.49	40.30	Mabthera SC [RO]

▪ TRASTUZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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	..	2516.27	40.30	Herceptin SC [RO]

▪ TRASTUZUMAB

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with adjuvant chemotherapy, **AND**
- Patient must have undergone surgery, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Authority required

Locally advanced HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

- Patient must commence treatment concurrently with neoadjuvant chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy.

HER2 positivity must be demonstrated by in situ hybridisation (ISH).

Authority applications for initial treatment must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Early Breast Cancer - PBS Supporting Information Form which includes:

(i) a copy of the pathology report from an Approved Pathology Authority confirming the presence of HER2 gene amplification by in situ hybridisation (ISH); and

(ii) a copy of the signed patient acknowledgement form.

Cardiac function must be tested by a suitable method including, for example, ECHO or MUGA, prior to seeking the initial authority approval and then at 3 monthly intervals during treatment.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
Applications for authority to prescribe should be forwarded to:
Department of Human Services
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

trastuzumab 600 mg/5 mL injection, 5 mL vial

10744L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	..	..	2516.27	40.30	Herceptin SC [RO]

▪ TRASTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au
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	..	..	2516.27	40.30	Herceptin SC [RO]

▪ TRASTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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	..	2516.27	40.30	Herceptin SC [RO]

▪ TRASTUZUMAB

Note No applications for increased maximum quantities will be authorised.

Note No applications for increased repeats will be authorised.

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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	..	2516.27	40.30	Herceptin SC [RO]

▪ IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Interferons

▪ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

6678

Myeloproliferative disease

Clinical criteria:

- Patient must have excessive thrombocytosis.

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

5998Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5	4	..	*363.00	40.30	Roferon-A [RO]

▪ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

6661

Low grade non-Hodgkin's lymphoma

Clinical criteria:

- The condition must have clinical features suggestive of a poor prognosis, **AND**
- The treatment must be in combination with anthracycline-based chemotherapy.

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

5946Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15	5	..	*363.15	40.30	Roferon-A [RO]

interferon alfa-2a 9 million units/0.5 mL injection, 0.5 mL syringe

5949D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5	5	..	*363.00	40.30	Roferon-A [RO]

▪ INTERFERON ALFA-2A

Caution Treatment with interferon alfa has been associated with depression and suicide in some patients. Patients with a history of suicidal ideation or depressive illness should be warned of the risks. Psychiatric status during therapy should be monitored.

Authority required (STREAMLINED)

6662

Hairy cell leukaemia

Authority required (STREAMLINED)

6678

Myeloproliferative disease

Clinical criteria:

- Patient must have excessive thrombocytosis.

interferon alfa-2a 3 million units/0.5 mL injection, 0.5 mL syringe

5945X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15	4	..	*363.15	40.30	Roferon-A [RO]

Other immunostimulants

▪ MYCOBACTERIUM BOVIS (BACILLUS CALMETTE AND GUERIN (BCG)) TICE STRAIN

Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis (Bacillus Calmette and Guerin (BCG)) Tice strain 500 million CFU injection, 3 vials

5902P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	1	..	399.49	40.30	OncoTICE [MK]

▪ VARIOUS

▪ ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Detoxifying agents for antineoplastic treatment

▪ FOLINIC ACID

folinic acid 1 g/100 mL injection, 100 mL vial

5863N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	1	..	35.98	37.21	Calcium Folinate Ebewe [SZ]

folinic acid 300 mg/30 mL injection, 30 mL vial

5870Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
4	1	..	*42.12	40.30	[a] Calcium Folinate Ebewe [SZ]	[a] Leucovorin Calcium (Hospira Pty Limited) [PF]

▪ FOLINIC ACID

Note For item codes 5890B and 1899Y, pharmaceutical benefits that have the form injection equivalent to 50 mg folinic acid in 5 mL are equivalent for the purposes of substitution.

folinic acid 50 mg/5 mL injection, 5 mL vial

5890B	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	10	2	..	*38.90	40.13	[a] Leucovorin Calcium (Hospira Pty Limited) [PF]

folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules

1899Y	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1	2	..	38.90	40.13	[a] Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

▪ FOLINIC ACID

Note For item codes 5886T and 1904F, pharmaceutical benefits that have the form injection equivalent to 100 mg folinic acid in 10 mL are equivalent for the purposes of substitution.

folinic acid 100 mg/10 mL injection, 10 mL vial

5886T	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	10	1	..	*43.80	40.30	[a] Calcium Folinate Ebewe [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	40.30	[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	40.30	Leucovorin Calcium (Hospira Pty Limited) [PF]

▪ MESNA

Restricted benefit

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

Clinical criteria:

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

mesna 400 mg/4 mL injection, 15 x 4 mL ampoules

5960Q	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1	5	..	66.52	40.30	Uromitexan [BX]

mesna 1 g/10 mL injection, 15 x 10 mL ampoules

5961R	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1	5	..	150.63	40.30	Uromitexan [BX]

Index of Manufacturers' Code

Code	Manufacturer
AE	AFT Pharmaceuticals (AU) 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
EI	Eisai Australia Pty Ltd
FB	Pierre Fabre Australia Pty Ltd
FF	Phebra Pty Ltd
GQ	Generic Health Pty Ltd
GX	Apotex Pty Ltd
HX	Sandoz Pty Ltd
IX	Clinect 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
OD	Accord Healthcare Pty Ltd
OE	Omegapharm Pty Ltd
PF	Pfizer Australia Pty Ltd
PK	Fresenius Kabi Australia Pty Limited
QY	Pro Pharmaceuticals Group Pty Ltd
RA	Sun Pharma ANZ Pty Ltd
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
ZP	Medis Pharma Pty Ltd

Generic/Proprietary Index