Australian Government

Department of Health and Aged Care

PBS

Schedule of Pharmaceutical Benefits

Efficient Funding of Chemotherapy

Effective 1 August 2022

Contents

Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits are effective from 1 August 2022. 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)

Deletions

Deletion – Item

7245H **FOTEMUSTINE**,
fotemustine 208 mg injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack *(Muphoran)*

Deletion – Note

11911X **DURVALUMAB**,
durvalumab 120 mg/2.4 mL injection, 2.4 mL vial *(Imfinzi)*;
durvalumab 500 mg/10 mL injection, 10 mL vial *(Imfinzi)*

Alterations

Alteration – Maximum Quantity

		From	*To*
11911X	**DURVALUMAB**, durvalumab 120 mg/2.4 mL injection, 2.4 mL vial *(Imfinzi)*; durvalumab 500 mg/10 mL injection, 10 mL vial *(Imfinzi)*	1200	1500

Alteration – Number of Repeats

		From	*To*
11911X	**DURVALUMAB**, durvalumab 120 mg/2.4 mL injection, 2.4 mL vial *(Imfinzi)*; durvalumab 500 mg/10 mL injection, 10 mL vial *(Imfinzi)*	8	4

Advance Notices

1 December 2022

Deletion – Brand

7236W *Jevtana, SW* – **CABAZITAXEL**, cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack

Efficient Funding of Chemotherapy (Public Hospital)

Deletions

Deletion – Item

4437M **FOTEMUSTINE**,
fotemustine 208 mg injection [1 vial] (&) inert substance diluent [4 mL ampoule], 1 pack *(Muphoran)*

Deletion – Note

11915D **DURVALUMAB**,
durvalumab 120 mg/2.4 mL injection, 2.4 mL vial *(Imfinzi)*;
durvalumab 500 mg/10 mL injection, 10 mL vial *(Imfinzi)*

Alterations

Alteration – Maximum Quantity

		From	*To*
11915D	**DURVALUMAB**, durvalumab 120 mg/2.4 mL injection, 2.4 mL vial *(Imfinzi)*; durvalumab 500 mg/10 mL injection, 10 mL vial *(Imfinzi)*	1200	1500

Alteration – Number of Repeats

		From	*To*
11915D	**DURVALUMAB**, durvalumab 120 mg/2.4 mL injection, 2.4 mL vial *(Imfinzi)*; durvalumab 500 mg/10 mL injection, 10 mL vial *(Imfinzi)*	8	4

Advance Notices

1 December 2022

Deletion – Brand

4376H *Jevtana, SW* – **CABAZITAXEL**, cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack

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 ($7.82)
- Preparation fee ($87.07)
- Distribution fee ($28.22)
- Diluent fee ($5.59)

Section 94 Approved Public Hospital Authority

- Preparation fee ($87.07)

Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee ($7.82)
- Preparation fee ($87.07)
- Distribution fee ($28.22) (not payable where the drug is trastuzumab)
- Diluent fee ($5.59)

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

10763L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	..	*1684.06	42.50	Ribomustin [JC] (bendamustine hydrochloride 100 mg injection, 1 vial) Ribomustin [JC] (bendamustine hydrochloride 25 mg injection, 1 vial)

CYCLOPHOSPHAMIDE

Injection

7226H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2800 mg	17	..	*201.39	42.50	Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial) Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial) Endoxan [BX] (cyclophosphamide 500 mg injection, 1 vial)

IFOSFAMIDE

Injection

7248L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4000 mg	19	..	*328.10	42.50	Holoxan [BX] (ifosfamide 1 g injection, 1 vial) Holoxan [BX] (ifosfamide 2 g injection, 1 vial)

ANTIMETABOLITES

Folic acid analogues

▪ METHOTREXATE

Injection

7250N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
250 mg	5	..	*154.55	42.50	DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) DBL Methotrexate [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) DBL Methotrexate [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) DBL Methotrexate [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Accord [OD] (methotrexate 50 mg/2 mL injection, 2 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

▪ METHOTREXATE

Restricted benefit

Patients receiving treatment with a high dose regimen

Injection

7251P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
20000 mg	..	..	*892.66	42.50	DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) DBL Methotrexate [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) DBL Methotrexate [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) DBL Methotrexate [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Accord [OD] (methotrexate 50 mg/2 mL injection, 2 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

▪ PEMETREXED

Injection

7255W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1100 mg	5	..	*231.27	42.50	Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 100 mg injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 500 mg injection, 1 vial) Pemetrexed APOTEX [TX] (pemetrexed 500 mg injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 1 g injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 100 mg injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 500 mg injection, 1 vial) 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11271F	80 mg	5	..	*4549.74	42.50	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11278N	80 mg	11	..	*4549.74	42.50	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

▪ RALTITREXED

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7256X	7 mg	8	..	*1186.14	42.50	Tomudex [PF] (raltitrexed 2 mg injection, 1 vial)

Purine analogues

▪ CLADRIBINE

Authority required (STREAMLINED)

6265

Hairy cell leukaemia

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7225G	17 mg	6	..	*1183.70	42.50	Leustatin [IX] (cladribine 10 mg/10 mL injection, 10 mL vial) Litak [AF] (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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7233Q	55 mg	29	..	*193.28	42.50	Fludarabine Ebewe [SZ] (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials) Fludarabine Juno [JO] (fludarabine phosphate 50 mg injection, 1 vial)

Pyrimidine analogues

▪ CYTARABINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7227J	7000 mg	15	..	*937.90	42.50	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7234R	5500 mg	11	..	*155.65	42.50	DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) 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 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	..	*133.60	42.50	DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) 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 5 g/100 mL injection, 100 mL vial)

▪ GEMCITABINE

Caution Pharmaceutical benefits containing gemcitabine may have different concentrations.

Injection

7246J	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	3000 mg	17	..	*192.63	42.50	DBL Gemcitabine Injection [PF] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial) DBL Gemcitabine Injection [PF] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

▪ VINBLASTINE

Injection

7261E	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	20 mg	17	..	*203.06	42.50	DBL Vinblastine [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)

▪ VINCRISTINE

Injection

7262F	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	2 mg	7	..	*146.78	42.50	DBL Vincristine Sulfate [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)

▪ VINORELBINE

Injection

7263G	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	70 mg	7	..	*200.59	42.50	Navelbine [FB] (vinorelbine 10 mg/mL injection, 1 mL vial) Navelbine [FB] (vinorelbine 50 mg/5 mL injection, 5 mL vial) Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial) Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial)

Podophyllotoxin derivatives

▪ ETOPOSIDE

Injection

7237X	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	440 mg	14	..	*324.90	42.50	Etopophos [LM] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial) Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)

Taxanes

▪ CABAZITAXEL

Authority required (STREAMLINED)

4662

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

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

Injection

7236W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
55 mg	5	..	*732.35	42.50	Cabazitaxel Ever Pharma [IT] (cabazitaxel 60 mg/6 mL injection, 6 mL vial) Cabazitaxel Juno [JU] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack) Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack) MSN Cabazitaxel [RQ] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack)

▪ DOCETAXEL

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

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

Injection

10158P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
250 mg	5	..	*196.34	42.50	DBL Docetaxel Concentrated Injection [PF] (docetaxel 160 mg/16 mL injection, 16 mL vial) DBL Docetaxel Concentrated Injection [PF] (docetaxel 80 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 160 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 80 mg/4 mL injection, 4 mL vial)

▪ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Authority required (STREAMLINED)

6106

Metastatic breast cancer

Authority required (STREAMLINED)

6119

HER2 positive breast cancer

Injection

7270P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
580 mg	5	..	*2217.18	42.50	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

▪ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Note Special Pricing Arrangements apply.

Note Not for use as neoadjuvant or adjuvant therapy.

Authority required (STREAMLINED)

4657

Stage IV (metastatic) adenocarcinoma of the pancreas

Clinical criteria:

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

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

Injection

10150F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
275 mg	11	..	*1172.94	42.50	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

▪ PACLITAXEL

Injection

7254T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
450 mg	3	..	*204.22	42.50	Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial) 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)

Topoisomerase 1 (TOP1) inhibitors

▪ IRINOTECAN

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

Injection

7249M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	11	..	*194.70	42.50	Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinotecan Accord [OC] (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

Injection

7260D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3500 mcg	17	..	*161.23	42.50	Hycamtin [SZ] (topotecan 4 mg injection, 5 vials) Topotecan Accord [OC] (topotecan 4 mg/4 mL injection, 5 x 4 mL vials)

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	..	*180.57	42.50	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7230M	100 mg	5	..	*1207.58	42.50	Caelyx [BX] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial) Caelyx [BX] (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
7231N	220 mg	5	..	*210.05	42.50	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)

▪ IDARUBICIN

Restricted benefit
Acute myelogenous leukaemia (AML)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7247K	30 mg	5	..	*310.68	42.50	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
7252Q	30 mg	5	..	*222.60	42.50	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

Restricted benefit
Germ cell neoplasms
Restricted benefit
Lymphoma

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7244G	30000 iu	11	..	*209.82	42.50	CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial) DBL Bleomycin Sulfate [PF] (bleomycin sulfate 15 000 international units injection, 1 vial)

MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES

CD20 (Clusters of Differentiation 20) inhibitors

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

Injection

11455X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	5	..	*5227.45	42.50	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.

Injection

11456Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	9	..	*5227.45	42.50	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.

Injection

11460E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	7	..	*5227.45	42.50	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, **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 therapy for this condition, **AND**
- The treatment must not exceed 12 doses or 2 years duration of treatment, whichever comes first, under this restriction, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Injection

11473W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	5	..	*5227.45	42.50	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11015

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: For combination use with venetoclax treatment cycles 1 to 6 inclusive in first-line therapy

Clinical criteria:

- The condition must be untreated, **AND**
- The treatment must be in combination with PBS-subsidised venetoclax.

Injection

12193R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	8	..	*5227.45	42.50	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

Authority required (STREAMLINED)

11052

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Combination use with chlorambucil only

Clinical criteria:

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

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

Injection

10418H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	7	..	*5227.45	42.50	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ RITUXIMAB

Authority required (STREAMLINED)

7400

Previously untreated or relapsed/refractory CD20 positive lymphoid cancer

Treatment Phase: Induction or re-induction therapy

Clinical criteria:

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

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

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

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

Injection

7257Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	7	..	*679.98	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

10227

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

Treatment Phase: Re-induction therapy

Clinical criteria:

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

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

Injection

11935E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	3	..	*679.98	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

9542

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

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, **AND**

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

Injection

7258B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	7	..	*679.98	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

7399

Previously untreated or Relapsed/refractory CD20 positive acute lymphoblastic leukaemia

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

7259C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	5	..	*679.98	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

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

Authority required (STREAMLINED)

9451

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

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

10193L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	11	..	*679.98	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

CD22 (Clusters of Differentiation 22) inhibitors

▪ INOTUZUMAB OZOGAMICIN

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

Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Note A complete remission is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a full recovery of peripheral blood counts with platelets of greater than 100,000 per microliter, and absolute neutrophil count (ANC) of greater than 1,000 per microliter.
Note A complete remission with partial haematological recovery is defined as bone marrow blasts of less than or equal to 5%, no evidence of disease and a partial recovery of peripheral blood counts with platelets of greater than 50,000 per microliter, and absolute neutrophil count (ANC) of greater than 500 per microliter.
Note Patients who fail to demonstrate a response to PBS-subsidised treatment with this agent at the time when an assessment is required must cease PBS-subsidised therapy with this agent.

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Consolidation treatment

Clinical criteria:

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

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

The treatment must not exceed 0.5mg per 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	..	*40007.01	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**

- Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 1 line of salvage therapy, **AND**
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
- The condition must be CD22-positive, **AND**
- The condition must have more than 5% blasts in bone marrow, **AND**
- The treatment must not be more than 3 treatment cycles under this restriction in a lifetime.

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

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

(1) two completed authority prescription forms;

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

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

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

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

The treatment must not exceed 0.8mg per 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

11673J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3384 mcg	2	..	*53299.78	42.50	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

CD38 (Clusters of Differentiation 38) inhibitors

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

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

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

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

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

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

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

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

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

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

Injection

12225K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	4	..	*11976.05	42.50	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial) Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)

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 receiving treatment with this drug for this condition.

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

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

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

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

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

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

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

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

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

Injection

12226L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	5	..	*11976.05	42.50	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial) Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.
Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised).

Treatment criteria:

- Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment.

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

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

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

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

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

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

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

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

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

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and 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 documented 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.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Injection

12230Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	8	..	*11976.05	42.50	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial) Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2021, **AND**
- Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

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

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

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

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

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

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

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

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

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

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and 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 documented 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.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Injection

12221F	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1920 mg	7	..	*11976.05	42.50	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial) Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

HER2 (Human Epidermal Growth Factor Receptor 2) inhibitors

▪ PERTUZUMAB

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

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

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

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, confirmed through a pathology report from an Approved Pathology Authority, **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.

Details (date, unique identifying number/code, or provider number) 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) must be provided at the time of application.

The pathology report must be documented in the patient's medical records.

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

Injection

10334X	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	840 mg	..	..	*6047.92	42.50	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ PERTUZUMAB

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

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

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

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

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10308M	420 mg	3	..	*3088.31	42.50	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ TRASTUZUMAB

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

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

Authority required (STREAMLINED)

10296

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7264H	500 mg	..	..	*933.34	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

Authority required (STREAMLINED)

10213

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

Clinical criteria:

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

Injection

7265J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
250 mg	9	..	*581.16	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

Authority required (STREAMLINED)

10294

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

Clinical criteria:

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

Injection

7267L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
750 mg	3	..	*1302.18	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

9349

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

10383L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
750 mg	3	..	*1302.18	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial)

Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial)
Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)
Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)
Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)
Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

Note No increase in the maximum number of repeats may be authorised.
Note Increased maximum quantity will be authorised where a patient's weight is greater than 125 kg.
Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

9353

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10402L	1000 mg	..	..	*1718.76	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

Note No increase in the maximum number of repeats may be authorised.
Note Increased maximum quantity will be authorised where a patient's weight is greater than 125 kg.
Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required (STREAMLINED)

9573

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10589H	1000 mg	..	..	*1718.76	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial)

Ogivri [AF] (trastuzumab 150 mg injection, 1 vial)
Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial)
Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)
Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

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

Authority required (STREAMLINED)

9571

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10597R	750 mg	3	..	*1302.18	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

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

Authority required (STREAMLINED)

10293

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7266K	1000 mg	..	..	*1718.76	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB EMTANSINE

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

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

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

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, confirmed through a pathology report from an Approved Pathology Authority, **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 the sole PBS-subsidised therapy 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.

The following information must be provided by the prescriber at the time of application:

(a) details (date, unique identifying number/code or provider number) 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).

(b) dates of treatment with trastuzumab and pertuzumab;

(c) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or

(d) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

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

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

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy 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.

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10281D	450 mg	8	..	*7409.20	42.50	Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial) Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)

▪ TRASTUZUMAB EMTANSINE

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

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

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial adjuvant treatment

Clinical criteria:

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

Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery.

The pathology report must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

(i) a completed authority prescription form; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Early HER2 positive breast cancer

Treatment Phase: Continuing adjuvant treatment

Clinical criteria:

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11956G	450 mg	6	..	*7409.20	42.50	Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial) Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)

EGFR (Epidermal Growth Factor Receptor) inhibitors

▪ CETUXIMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12470

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised encorafenib for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12817N	550 mg	11	..	*1902.53	42.50	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.

Authority required (STREAMLINED)

12483

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised encorafenib for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12821T	880 mg	..	..	*2789.45	42.50	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)

	Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL 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	..	*1902.53	42.50	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	..	..	*2789.45	42.50	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)

12045

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; OR
- The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC, **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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7242E	880 mg	..	..	*2789.45	42.50	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	..	*1902.53	42.50	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)

12016

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; OR
- Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC, **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	..	*1902.53	42.50	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 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)

12066

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; OR
- The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC, **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)

12035

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

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

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

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

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

Injection

10069Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
720 mg	5	..	*3974.78	42.50	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	..	*3974.78	42.50	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial) Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

PD-1/PDL-1 (Programmed cell death protein 1/death ligand 1) inhibitors

▪ ATEZOLIZUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10297

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11297N	1200 mg	7	..	*7330.62	42.50	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 Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10216

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

Treatment Phase: Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**
- Patient must have stable or responding disease.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11801D	1200 mg	7	..	*7330.62	42.50	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 Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10215

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment - 4 weekly treatment regimen

Clinical criteria:

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

Injection

11957H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	5	..	*10211.38	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10257

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

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

Clinical criteria:

- Patient must have experienced intolerance to combination treatment with bevacizumab, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Injection

12098R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	5	..	*10211.38	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10276

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

11309F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	5	..	*7330.62	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10206

Extensive-stage small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

Injection

11927R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	3	..	*7330.62	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10521

Extensive-stage small cell lung cancer

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

11928T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	4	..	*7330.62	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10312

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment - 4 weekly treatment regimen

Clinical criteria:

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

Injection

11940K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	3	..	*10211.38	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10509

Extensive-stage small cell lung cancer

Treatment Phase: Continuing treatment - 4 weekly treatment regimen

Clinical criteria:

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

Injection

12076N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	3	..	*10211.38	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10917

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

Treatment Phase: Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen

Treatment criteria:

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

Clinical criteria:

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

PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

Injection

12155R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	8	..	*7330.62	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10972

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

Treatment Phase: Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen

Clinical criteria:

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

PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

Injection

12159Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	5	..	*10211.38	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10182

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

Treatment Phase: Initial treatment 1

Treatment criteria:

- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

Clinical criteria:

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

Authority required (STREAMLINED)

10125

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

Treatment Phase: Initial treatment 2

Treatment criteria:

- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

Clinical criteria:

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

Injection

11792P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	5	..	*7330.62	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.
Note No increase in the maximum amount or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10915

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

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

Clinical criteria:

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

Treatment criteria:

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

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

Injection

12163E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	5	..	*10211.38	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial) Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

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

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10939

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

Treatment Phase: Initial treatment

Treatment criteria:

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

Clinical criteria:

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

Injection

12167J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	3	..	*7330.62	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ AVELUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

8947

Stage IV (metastatic) Merkel Cell Carcinoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

11679Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	8	..	*8386.86	42.50	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)
10023
Stage IV (metastatic) Merkel Cell Carcinoma
Treatment Phase: Continuing treatment
Clinical criteria:

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

Injection

11685B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	11	..	*8386.86	42.50	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

▪ DURVALUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)
10126
Unresectable Stage III non-small cell lung cancer
Treatment Phase: Initial treatment
Clinical criteria:

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

Authority required (STREAMLINED)
12271
Unresectable Stage III non-small cell lung cancer
Treatment Phase: Continuing treatment
Clinical criteria:

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

Injection

11911X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	4	..	*12220.65	42.50	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial) Imfinzi [AP] (durvalumab 500 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)
11477
Locally advanced or metastatic non-small cell lung cancer
Treatment Phase: Continuing treatment as second-line drug therapy
Clinical criteria:

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

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

Injection

11152Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9731.26	42.50	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)

9299

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11157F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9731.26	42.50	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)

9252

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11425H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9731.26	42.50	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)

9321

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Maintenance treatment

Clinical criteria:

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

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

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

Injection

11626X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9731.26	42.50	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)

9298

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

9214

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Maintenance treatment

Clinical criteria:

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

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

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

Injection

10748Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9731.26	42.50	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)

10155

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

10775D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	8	..	*9731.26	42.50	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)

11434

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment as second-line drug therapy

Clinical criteria:

- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy.

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11143L	480 mg	8	..	*9731.26	42.50	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)

9216

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11434T	480 mg	8	..	*9731.26	42.50	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 increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10195

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11532Y	120 mg	3	..	*2529.36	42.50	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)

9312

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial Treatment

Clinical criteria:

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

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

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

Injection

11159H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	8	..	*9731.26	42.50	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 A patient may only qualify for PBS-subsidised treatment under this restriction once.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11469

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

Treatment Phase: Grandfather treatment (treatment of a patient commenced on non-PBS-subsidised combination treatment as first-line drug therapy)

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021, **AND**
- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug 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 not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- Patient must not have received treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer prior to initiating treatment with this drug for this PBS indication, **AND**
- The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with platinum-based chemotherapy for the first two cycles, **AND**
- The treatment must be in combination with ipilimumab.

Injection

12312B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	13	..	*7330.64	42.50	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)

11392

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

Treatment Phase: Initial combination treatment (with ipilimumab) as first-line drug therapy

Clinical criteria:

- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must be in combination with platinum-based chemotherapy for the first two cycles, **AND**
- The treatment must be in combination with ipilimumab.

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)

11468

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

Treatment Phase: Continuing combination treatment (with ipilimumab) of first-line drug therapy

Clinical criteria:

- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with ipilimumab.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12315E	360 mg	13	..	*7330.64	42.50	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 increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

Note 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 An increase of number of repeats may be authorised up to 11 if the patient is receiving a weight based dosing of 3mg/kg every 2 weeks.

Authority required (STREAMLINED)

11985

Unresectable malignant mesothelioma

Clinical criteria:

- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with PBS-subsidised ipilimumab, unless an intolerance to ipilimumab of a severity necessitating permanent treatment withdrawal of ipilimumab, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a maximum total of 24 months in a lifetime for this condition.

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
12574T	360 mg	8	..	*7330.64	42.50	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 increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

Note Special Pricing Arrangements apply.

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

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemaglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

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	..	*7330.64	42.50	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 quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

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

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11906P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	5	..	*9731.26	42.50	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)

Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

Authority required (STREAMLINED)

10705

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10424P	200 mg	7	..	*7883.26	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

Authority required (STREAMLINED)

10701

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment - 6 weekly treatment regimen

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12123C	400 mg	3	..	*15637.82	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

Authority required (STREAMLINED)

10696

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10475H	200 mg	5	..	*7883.26	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

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

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

Authority required (STREAMLINED)

10689

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment - 6 weekly treatment regimen

Clinical criteria:

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

Injection

12122B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	2	..	*15637.82	42.50	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.

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

Authority required (STREAMLINED)

10681

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

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

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

Authority required (STREAMLINED)

10682

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

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction.

Injection

11492W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*7883.26	42.50	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.

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

Authority required (STREAMLINED)

9921

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

9894

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11632F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*7883.26	42.50	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.

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

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

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

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

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

12120X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	7	..	*7883.26	42.50	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.

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

Authority required (STREAMLINED)

10704

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

Treatment Phase: Initial treatment - 6 weekly treatment regimen

Clinical criteria:

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

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

Authority required (STREAMLINED)

10693

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

Treatment Phase: Continuing treatment - 6 weekly treatment regimen

Clinical criteria:

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

Injection

12121Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	3	..	*15637.82	42.50	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.

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

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment - 6 weekly treatment regimen

Clinical criteria:

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

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

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment - 6 weekly treatment regimen

Clinical criteria:

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

Injection

12125E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	3	..	*15637.82	42.50	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.
Note Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form;

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11352L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*7883.26	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

Authority required

Relapsed or refractory primary mediastinal B-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan, with the results retained in the patient's medical records, **AND**
- Patient must have been treated with rituximab-based chemotherapy for this condition, **AND**
- Patient must be experiencing relapsed/refractory disease, **AND**
- Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; OR
- Patient must have undergone an autologous stem cell transplant (ASCT); OR
- Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy, **AND**

- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

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

(a) a completed authority prescription form;

(b) a completed primary mediastinal B-cell lymphoma pembrolizumab PBS Authority Application, which includes:

(i) confirmation that histology results with PET/CT scans support a diagnosis of primary mediastinal B-cell lymphoma and are retained on the patient's medical records;

(ii) details of prior treatments for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Relapsed or refractory primary mediastinal B-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

12126F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*7883.26	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL 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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated for this PBS indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease), **AND**
- Patient must not have received prior treatment for colorectal cancer with each of: (i) a programmed cell death-1 (PD-1) inhibitor, (ii) a programmed cell death ligand-1 (PD-L1) inhibitor, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

Authority required

Unresectable or metastatic deficient mismatch repair (dMMR) 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 while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment in a lifetime for this condition.

Authority required

Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer

Treatment Phase: Transitioning from non-PBS to PBS subsided treatment - Grandfather treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 August 2021, **AND**
- Patient must not have received prior PBS funded treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for colorectal cancer, **AND**
- Patient must have been untreated for this indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease), prior to initiating treatment with this drug, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment in a lifetime 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 This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12605K	200 mg	6	..	*7883.26	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

VEGF/VEGFR (Vascular Endothelial Growth Factor) inhibitors

▪ BEVACIZUMAB

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12508H	1800 mg	7	..	*2355.44	42.50	Mvasi [AN] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Mvasi [AN] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

Other monoclonal antibodies and antibody drug conjugates

▪ BLINATUMOMAB

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

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

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

(4) if applicable, the date of completion of blinatumomab treatment for minimal residual disease and the date of the patient's subsequent relapse; and

(5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11116C	651 mcg	..	..	*70819.26	42.50	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 restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Acute lymphoblastic leukaemia

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**
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
- Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime.

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11119F	784 mcg	..	..	*82601.02	42.50	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 restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

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

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Consolidation treatment

Clinical criteria:

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

Injection

11115B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	2	..	*82601.02	42.50	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.

Authority required

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

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

Treatment criteria:

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

Clinical criteria:

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

(4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

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

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

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised initial treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission, **AND**

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

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

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11867N	784 mcg	1	..	*82601.02	42.50	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 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

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 be more than 12 treatment cycles under this restriction in a lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10180T	200 mg	11	..	*19009.38	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

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, **AND**
- Patient must have responded to PBS-subsidised treatment with this drug if previously used for initial treatment of CD30 positive peripheral T-cell lymphoma, non-cutaneous type.

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	..	*19009.38	42.50	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11067L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	..	*19009.38	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form; and

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

Injection

11080E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	3	..	*19009.38	42.50	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11086L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	..	*19009.38	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form; and

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

Injection

11089P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	3	..	*19009.38	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

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
11651F	180 mg	3	..	*19009.38	42.50	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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

CD30 positive cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11661R	180 mg	11	..	*19009.38	42.50	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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note This product is not PBS-subsidised for the treatment of previously untreated CD30 positive cutaneous T-cell lymphoma.

Authority required

CD30 positive peripheral T-cell lymphoma, non-cutaneous type

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone, **AND**
- Patient must have completed 6 initial cycles of PBS-subsidised treatment with this drug for this indication, **AND**
- Patient must have achieved at least a partial response to the 6 initial cycles of treatment with a combination of this drug and cyclophosphamide, doxorubicin and prednisone for this indication, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as:

(a) Positron emission tomography-based response: lymph nodes and extralymphatic sites - a score of 4 (uptake moderately > liver), or 5 (uptake markedly higher than liver and/or new lesions), with reduced uptake compared with baseline and residual mass(es) of any size; nonmeasured lesions - not applicable; organ enlargement - not applicable; new lesions - none; bone marrow - residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan; OR

(b) Computed tomography-based response: lymph nodes and extralymphatic sites - greater than or equal to 50% decrease in the sum of the product of the perpendicular diameters for multiple lesions, of up to six (6) target measurable nodes and extranodal sites; non-measured lesions - absent/normal, regressed but no increase; new lesions - none; bone marrow - not applicable.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12632W	200 mg	1	..	*19009.38	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note This product is not PBS-subsidised for the treatment of previously untreated CD30 positive cutaneous T-cell lymphoma.

Authority required

CD30 positive peripheral T-cell lymphoma, non-cutaneous type

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have histological confirmation of CD30 expression in at least 3% of malignant cells, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- The treatment must be for curative intent, **AND**
- The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone, **AND**
- The treatment must not be more than 6 treatment cycles under this restriction in a lifetime.

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

(a) a completed authority prescription form; and

(b) a completed Peripheral T-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 Peripheral T-cell lymphoma cell lymphoma.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12656D	200 mg	5	..	*19009.38	42.50	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ ELOTUZUMAB

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

Note Special Pricing Arrangements apply.

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

Authority required

Relapsed and/or refractory 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 lenalidomide and 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.

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

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

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

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

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

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

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

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

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

Injection

12990Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	9	..	*5148.03	42.50	Empliciti [BQ] (elotuzumab 300 mg injection, 1 vial) Empliciti [BQ] (elotuzumab 400 mg injection, 1 vial)

▪ ELOTUZUMAB

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

Note Special Pricing Arrangements apply.

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

Authority required

Relapsed and/or refractory 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 lenalidomide and dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

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

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

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

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

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

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

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

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

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

Injection

12995Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	5	..	*5148.03	42.50	Empliciti [BQ] (elotuzumab 300 mg injection, 1 vial) Empliciti [BQ] (elotuzumab 400 mg injection, 1 vial)

▪ GEMTUZUMAB OZOGAMICIN

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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Induction treatment

Clinical criteria:

- Patient must have confirmed CD33-positive AML prior to initiation of treatment, **AND**
- The condition must be de novo, **AND**
- The condition must be previously untreated at the time of initiation (except for prior essential treatment with hydroxyurea or leukapheresis for patients with hyperleukocytic AML), **AND**
- Patient must have confirmed intermediate/favourable cytogenetic risk; OR
- Patient must have unknown cytogenetic risk due to inconclusive test results, **AND**

- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The treatment must be in combination with standard intensive remission induction chemotherapy for this condition, which must include cytarabine and an anthracycline, **AND**
- The treatment must not be used in combination with a tyrosine kinase inhibitor, **AND**
- The condition must not be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive, **AND**
- Patient must not receive more than 1 induction cycle under this restriction in a lifetime.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12878T	5 mg	2	..	*9424.04	42.50	Mylotarg [PF] (gemtuzumab ozogamicin 5 mg injection, 1 vial)

▪ GEMTUZUMAB OZOGAMICIN

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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Consolidation treatment

Clinical criteria:

- Patient must have achieved a complete remission following induction treatment with this drug for this condition, **AND**
- The treatment must be in combination with standard intensive remission consolidation chemotherapy for this condition, which must include cytarabine and an anthracycline, **AND**
- Patient must not receive more than 2 consolidation cycles under this restriction in a lifetime.

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

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

Complete remission following induction is defined as fewer than 5% blasts in a normocellular marrow and an absolute neutrophil count of more than 1.0×10^9 cells/L with a platelet count of 100×10^9/L or more in the peripheral blood in the absence of transfusion.

Progressive disease is defined as the presence of any of the following:

a) Leukaemic cells in the CSF;

b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;

c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;

d) Extramedullary leukaemia.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12904E	5 mg	1	..	*9424.04	42.50	Mylotarg [PF] (gemtuzumab ozogamicin 5 mg injection, 1 vial)

▪ IPILIMUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11478

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

Treatment Phase: Initial combination treatment (with nivolumab) as first-line drug therapy

Clinical criteria:

- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must be in combination with platinum-based chemotherapy for the first two cycles, **AND**
- The treatment must be in combination with nivolumab.

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

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

Authority required (STREAMLINED)

11391

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

Treatment Phase: Continuing combination treatment (with nivolumab) of first-line drug therapy

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 receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with nivolumab.

Injection

12304N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	4	..	*17242.74	42.50	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11394

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

Treatment Phase: Grandfather treatment (treatment of a patient commenced on non-PBS-subsidised combination treatment as first-line drug therapy)

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021, **AND**
- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug 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 not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with platinum-based chemotherapy for the first two cycles, **AND**
- The treatment must be in combination with nivolumab.

Injection

12308T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	4	..	*17242.74	42.50	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

11930

Unresectable malignant mesothelioma

Clinical criteria:

- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with PBS-subsidised nivolumab for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a maximum total of 24 months in a lifetime for this condition.

Injection

12601F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	3	..	*17242.74	42.50	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

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

Note Special Pricing Arrangements apply.

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

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemaglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

Authority required (STREAMLINED)

8555

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

Injection

11644W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	3	..	*17242.74	42.50	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 increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

Authority required (STREAMLINED)

10122

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

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

Injection

2638W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	3	..	*45766.14	42.50	Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial) Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ SACITUZUMAB GOVITECAN

Caution This medicine contains a cytotoxic component and causes chemotherapy-like toxicity, in particular, it can cause severe or life-threatening neutropenia and severe diarrhoea. For further information, refer to the Product Information.

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)

12656

Unresectable locally advanced or metastatic triple-negative breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have progressive disease following two or more prior systemic therapies, at least one of them in the locally advanced or metastatic setting, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this PBS indication.

Injection

12944G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	7	..	*10666.29	42.50	Trodelvy [GI] (sacituzumab govitecan 180 mg injection, 1 vial)

▪ SACITUZUMAB GOVITECAN

Caution This medicine contains a cytotoxic component and causes chemotherapy-like toxicity, in particular, it can cause severe or life-threatening neutropenia and severe diarrhoea. For further information, refer to the Product Information.

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)

12669

Unresectable locally advanced or metastatic triple-negative breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

Authority required (STREAMLINED)

12670

Unresectable locally advanced or metastatic triple-negative breast cancer

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather treatment

Clinical criteria:

- Patient must must have received treatment with this drug for this PBS indication prior to 1 May 2022, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 1 prior to treatment initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this PBS indication.

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12965J	1200 mg	13	..	*10666.29	42.50	Trodelvy [GI] (sacituzumab govitecan 180 mg injection, 1 vial)

OTHER ANTINEOPLASTIC AGENTS

Platinum compounds

▪ CARBOPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7222D	900 mg	5	..	*200.68	42.50	Carboplatin Accord [OC] (carboplatin 450 mg/45 mL injection, 45 mL vial) DBL Carboplatin [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	..	*178.36	42.50	Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial) Cisplatin Accord [OC] (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	..	*188.75	42.50	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)

Proteasome inhibitors

▪ BORTEZOMIB

Restricted benefit

Multiple myeloma

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12219D	3000 mcg	15	..	*654.68	42.50	Bortezom [CR] (bortezomib 3.5 mg injection, 1 vial) Bortezomib Accord [OC] (bortezomib 1 mg injection, 1 vial) Bortezomib Accord [OC] (bortezomib 3.5 mg injection, 1 vial) Bortezomib-Dr.Reddy's [RI] (bortezomib 3.5 mg injection, 1 vial) Bortezomib Ever Pharma [IT] (bortezomib 2.5 mg/mL injection, 1 mL vial) Bortezomib Ever Pharma [IT] (bortezomib 3.5 mg/1.4 mL injection, 1.4 mL vial)

Bortezomib Juno [JU] (bortezomib 1 mg injection, 1 vial)
Bortezomib Juno [JU] (bortezomib 2.5 mg injection, 1 vial)
Bortezomib Juno [JU] (bortezomib 3.5 mg injection, 1 vial)
Bortezomib Sandoz [SZ] (bortezomib 3.5 mg injection, 1 vial)
BORTEZOMIB-TEVA [TB] (bortezomib 3.5 mg injection, 1 vial)
DBL Bortezomib [PF] (bortezomib 1 mg injection, 1 vial)
DBL Bortezomib [PF] (bortezomib 2.5 mg injection, 1 vial)
DBL Bortezomib [PF] (bortezomib 3 mg injection, 1 vial)
DBL Bortezomib [PF] (bortezomib 3.5 mg injection, 1 vial)
Velcade [JC] (bortezomib 1 mg injection, 1 vial)
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 (STREAMLINED)

12934

Multiple myeloma

Treatment Phase: Initial treatment - twice weekly treatment regimen

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 receive more than three cycles of treatment under this restriction.

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

12930

Multiple myeloma

Treatment Phase: Continuing treatment - twice weekly treatment regimen

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 receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.

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

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

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

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

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

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

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

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

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

Injection

11230C	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	120 mg	17	..	*2702.10	42.50	Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 60 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 (STREAMLINED)

12694

Multiple myeloma

Treatment Phase: Initial treatment - once weekly treatment regimen

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 receive more than three cycles of treatment under this restriction.

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

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

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

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

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

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

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

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

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

Authority required (STREAMLINED)

12849

Multiple myeloma

Treatment Phase: Continuing treatment - once weekly treatment regimen

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 receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.

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

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

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

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

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

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

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

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

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

Injection

12243J	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	160 mg	8	..	*3559.90	42.50	Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 60 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	..	*380.50	42.50	Arsenic Trioxide Accord [OC] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) Arsenic Trioxide-AFT [AE] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL ampoules) Arsenic Trioxide Juno [JU] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) 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	..	*380.50	42.50	Arsenic Trioxide Accord [OC] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) Arsenic Trioxide-AFT [AE] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL ampoules) Arsenic Trioxide Juno [JU] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

▪ 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	..	*822.27	42.50	Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

▪ ERIBULIN

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

Authority required (STREAMLINED)

7258

Advanced (unresectable and/or metastatic) liposarcoma

Treatment Phase: Initial treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Authority required (STREAMLINED)

7280

Advanced (unresectable and/or metastatic) liposarcoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

Population criteria:

- Patient must be aged 18 years or older.

Injection

11199K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3 mg	7	..	*822.27	42.50	Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

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	..	*1620.97	42.50	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	..	*158.77	42.50	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	..	*283.71	42.50	Holoxan [BX] (ifosfamide 1 g injection, 1 vial) Holoxan [BX] (ifosfamide 2 g injection, 1 vial)

ANTIMETABOLITES

Folic acid analogues

▪ METHOTREXATE

Injection

4502Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
250 mg	5	..	*112.57	42.50	DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) DBL Methotrexate [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) DBL Methotrexate [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) DBL Methotrexate [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Accord [OD] (methotrexate 50 mg/2 mL injection, 2 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

▪ METHOTREXATE

Restricted benefit

Patients receiving treatment with a high dose regimen

Injection

4512L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
20000 mg	..	..	*840.47	42.50	DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial) DBL Methotrexate [PF] (methotrexate 5 mg/2 mL injection, 5 x 2 mL vials) DBL Methotrexate [PF] (methotrexate 50 mg/2 mL injection, 5 x 2 mL vials) DBL Methotrexate [PF] (methotrexate 500 mg/20 mL injection, 20 mL vial) Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial) Methotrexate Accord [OD] (methotrexate 50 mg/2 mL injection, 2 mL vial) Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial) Pfizer Australia Pty Ltd [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)

▪ PEMETREXED

Injection

4600D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1100 mg	5	..	*188.23	42.50	Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 100 mg injection, 1 vial) Pemetrexed Accord [OD] (pemetrexed 500 mg injection, 1 vial) Pemetrexed APOTEX [TX] (pemetrexed 500 mg injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 1 g injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 100 mg injection, 1 vial) Pemetrexed SUN [RA] (pemetrexed 500 mg injection, 1 vial) 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11272G	80 mg	11	..	*4447.07	42.50	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11293J	80 mg	5	..	*4447.07	42.50	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

▪ RALTITREXED

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4610P	7 mg	8	..	*1129.91	42.50	Tomudex [PF] (raltitrexed 2 mg injection, 1 vial)

Purine analogues

▪ CLADRIBINE

Authority required (STREAMLINED)

6265

Hairy cell leukaemia

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4326Q	17 mg	6	..	*1127.51	42.50	Leustatin [IX] (cladribine 10 mg/10 mL injection, 10 mL vial) Litak [AF] (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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4393F	55 mg	29	..	*150.75	42.50	Fludarabine Ebewe [SZ] (fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials) Fludarabine Juno [JO] (fludarabine phosphate 50 mg injection, 1 vial)

Pyrimidine analogues

▪ CYTARABINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4357H	7000 mg	15	..	*885.07	42.50	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4394G	5500 mg	11	..	*113.69	42.50	DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) 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 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	..	*91.91	42.50	DBL Fluorouracil Injection BP [PF] (fluorouracil 2.5 g/50 mL injection, 50 mL vial) 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 5 g/100 mL injection, 100 mL vial)

▪ GEMCITABINE

Caution Pharmaceutical benefits containing gemcitabine may have different concentrations.

Injection

4439P	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	3000 mg	17	..	*150.12	42.50	DBL Gemcitabine Injection [PF] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial) DBL Gemcitabine Injection [PF] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

▪ VINBLASTINE

Injection

4618C	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	20 mg	17	..	*160.41	42.50	DBL Vinblastine [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)

▪ VINCRISTINE

Injection

4619D	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	2 mg	7	..	*104.91	42.50	DBL Vincristine Sulfate [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)

▪ VINORELBINE

Injection

4620E	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	70 mg	7	..	*157.97	42.50	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

4428C	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	440 mg	14	..	*280.57	42.50	Etopophos [LM] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial) Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)

Taxanes

▪ CABAZITAXEL

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	..	*682.39	42.50	Cabazitaxel Ever Pharma [IT] (cabazitaxel 60 mg/6 mL injection, 6 mL vial) Cabazitaxel Juno [JU] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack) Jevtana [SW] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack) MSN Cabazitaxel [RQ] (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	..	*153.77	42.50	DBL Docetaxel Concentrated Injection [PF] (docetaxel 160 mg/16 mL injection, 16 mL vial) DBL Docetaxel Concentrated Injection [PF] (docetaxel 80 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 160 mg/8 mL injection, 8 mL vial) Docetaxel Accord [OC] (docetaxel 80 mg/4 mL injection, 4 mL vial)

▪ NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Authority required (STREAMLINED)

6106

Metastatic breast cancer

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	..	*2146.69	42.50	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	..	*1116.88	42.50	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	..	*161.55	42.50	Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial) 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)

Topoisomerase 1 (TOP1) inhibitors

▪ IRINOTECAN

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

Injection

4451G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	11	..	*152.07	42.50	Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial) Irinotecan Accord [OC] (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

Injection

4617B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3500 mcg	17	..	*119.15	42.50	Hycamtin [SZ] (topotecan 4 mg injection, 5 vials) Topotecan Accord [OC] (topotecan 4 mg/4 mL injection, 5 x 4 mL vials)

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	..	*138.22	42.50	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4364Q	100 mg	5	..	*1151.05	42.50	Caelyx [BX] (doxorubicin hydrochloride (as pegylated liposomal) 20 mg/10 mL injection, 10 mL vial) Caelyx [BX] (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	..	*167.32	42.50	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)

▪ IDARUBICIN

Restricted benefit
Acute myelogenous leukaemia (AML)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4440Q	30 mg	5	..	*266.53	42.50	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	..	*179.67	42.50	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

Restricted benefit
Germ cell neoplasms
Restricted benefit
Lymphoma

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4433H	30000 iu	11	..	*167.07	42.50	CIPLA BLEOMYCIN [LR] (bleomycin sulfate 15 000 international units injection, 1 vial) DBL Bleomycin Sulfate [PF] (bleomycin sulfate 15 000 international units injection, 1 vial)

MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES

CD20 (Clusters of Differentiation 20) inhibitors

▪ 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.

Injection

11457B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	7	..	*5115.42	42.50	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.

Injection

11458C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	9	..	*5115.42	42.50	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: Maintenance therapy

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug under the previously untreated initial 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 therapy 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	..	*5115.42	42.50	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, **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 therapy 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	..	*5115.42	42.50	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

Note A patient may only qualify for PBS-subsidised treatment under this restriction once in a lifetime.
Note No increase in the maximum quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11015

Chronic lymphocytic leukaemia (CLL) or small lymphocytic lymphoma (SLL)

Treatment Phase: For combination use with venetoclax treatment cycles 1 to 6 inclusive in first-line therapy

Clinical criteria:

- The condition must be untreated, **AND**
- The treatment must be in combination with PBS-subsidised venetoclax.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12204H	1000 mg	8	..	*5115.42	42.50	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

▪ OBINUTUZUMAB

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

Authority required (STREAMLINED)

11052

Chronic lymphocytic leukaemia (CLL)

Treatment Phase: Combination use with chlorambucil only

Clinical criteria:

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

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

Injection

10407R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	7	..	*5115.42	42.50	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 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	..	*630.75	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

10227

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

Treatment Phase: Re-induction therapy

Clinical criteria:

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

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

Injection

11936F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	3	..	*630.75	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

Authority required (STREAMLINED)

9542

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

Treatment Phase: Maintenance therapy

Clinical criteria:

- The treatment must be maintenance therapy, **AND**

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

Injection

4613T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	7	..	*630.75	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

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	..	*630.75	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

▪ RITUXIMAB

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

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

Authority required (STREAMLINED)

9451

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

Treatment Phase: Maintenance therapy

Clinical criteria:

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

Injection

10179R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	11	..	*630.75	42.50	Riximyo [SZ] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Riximyo [SZ] (rituximab 500 mg/50 mL injection, 50 mL vial) Ruxience [PF] (rituximab 100 mg/10 mL injection, 10 mL vial) Ruxience [PF] (rituximab 500 mg/50 mL injection, 50 mL vial) Truxima [EW] (rituximab 100 mg/10 mL injection, 2 x 10 mL vials) Truxima [EW] (rituximab 500 mg/50 mL injection, 50 mL vial)

CD22 (Clusters of Differentiation 22) inhibitors

▪ INOTUZUMAB OZOGAMICIN

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

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

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

Note Special Pricing Arrangements apply.

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

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

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

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

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Consolidation treatment

Clinical criteria:

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

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

The treatment must not exceed 0.5mg per 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	..	*39414.79	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment

Clinical criteria:

- The condition must be relapsed or refractory B-precursor cell ALL, with an Eastern Cooperative Oncology Group (ECOG) performance status of 2 or less, **AND**

- Patient must have received intensive combination chemotherapy for initial treatment of ALL or for subsequent salvage therapy, **AND**
- Patient must not have received more than 1 line of salvage therapy, **AND**
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
- The condition must be CD22-positive, **AND**
- The condition must have more than 5% blasts in bone marrow, **AND**
- The treatment must not be more than 3 treatment cycles under this restriction in a lifetime.

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

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

(1) two completed authority prescription forms;

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

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

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

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

The treatment must not exceed 0.8mg per 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

11696N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3384 mcg	2	..	*52524.03	42.50	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

CD38 (Clusters of Differentiation 38) inhibitors

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

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

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

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

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

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

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

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

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

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

Injection

12220E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	4	..	*11770.87	42.50	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial) Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised).

Treatment criteria:

- Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment.

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

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

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

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

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

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

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

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

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

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and 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 documented 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.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Injection

12228N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	8	..	*11770.87	42.50	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial) Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)

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 receiving treatment with this drug for this condition.

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

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

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

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

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

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12231R	1920 mg	5	..	*11770.87	42.50	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial) Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Grandfather treatment - Transitioning from non-PBS to PBS-subsidised supply

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 January 2021, **AND**
- Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

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

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

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

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

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

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

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

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

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

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and 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 documented 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.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

Injection

12229P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	7	..	*11770.87	42.50	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial) Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

HER2 (Human Epidermal Growth Factor Receptor 2) inhibitors

▪ PERTUZUMAB

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

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

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

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, confirmed through a pathology report from an Approved Pathology Authority, **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.

Details (date, unique identifying number/code, or provider number) 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) must be provided at the time of application.

The pathology report must be documented in the patient's medical records.

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

Injection

10267J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
840 mg	..	..	*5924.57	42.50	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ PERTUZUMAB

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

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

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

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

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

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

Injection

10333W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
420 mg	3	..	*3005.82	42.50	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

▪ TRASTUZUMAB

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

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

Authority required (STREAMLINED)

10296

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (weekly regimen)

Clinical criteria:

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

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

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

Injection

4632T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
500 mg	..	..	*908.43	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

Authority required (STREAMLINED)

10213

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (weekly regimen)

Clinical criteria:

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

Injection

4639E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
250 mg	9	..	*561.11	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

Authority required (STREAMLINED)

10294

Early HER2 positive breast cancer

Treatment Phase: Continuing treatment (3 weekly regimen)

Clinical criteria:

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

Injection

4703M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
750 mg	3	..	*1272.17	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

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

Authority required (STREAMLINED)

9353

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

10391X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	..	..	*1683.01	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial)

					Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

Note Authority applications for increased quantities/ repeats (where relevant) may be made by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

9349

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

10401K	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	750 mg	3	..	*1272.17	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

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

Authority required (STREAMLINED)

9573

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

10581X	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1000 mg	..	..	*1683.01	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial)

						Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

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

Authority required (STREAMLINED)

9571

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10588G	750 mg	3	..	*1272.17	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB

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

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

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

Authority required (STREAMLINED)

10293

Early HER2 positive breast cancer

Treatment Phase: Initial treatment (3 weekly regimen)

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4650R	1000 mg	..	..	*1683.01	42.50	Herzuma [EW] (trastuzumab 150 mg injection, 1 vial) Herzuma [EW] (trastuzumab 440 mg injection [1 vial] (&) inert substance diluent [20 mL vial], 1 pack) Kanjinti [JU] (trastuzumab 150 mg injection, 1 vial) Kanjinti [JU] (trastuzumab 420 mg injection, 1 vial) Ogivri [AF] (trastuzumab 150 mg injection, 1 vial) Ontruzant [OQ] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 150 mg injection, 1 vial) Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)

▪ TRASTUZUMAB EMTANSINE

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

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

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

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, confirmed through a pathology report from an Approved Pathology Authority, **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 the sole PBS-subsidised therapy 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.

The following information must be provided by the prescriber at the time of application:

(a) details (date, unique identifying number/code or provider number) 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).

(b) dates of treatment with trastuzumab and pertuzumab;

(c) date of demonstration of progression following treatment with trastuzumab and pertuzumab; or

(d) date of demonstration of progression and date of completion of adjuvant trastuzumab treatment.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application.

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

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

Authority required

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for metastatic (Stage IV) HER2 positive breast cancer, **AND**
- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug, **AND**
- The treatment must be the sole PBS-subsidised therapy 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.

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

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

Injection

10282E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
450 mg	8	..	*7267.06	42.50	Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial) Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)

▪ TRASTUZUMAB EMTANSINE

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

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

Authority required

Early HER2 positive breast cancer

Treatment Phase: Initial adjuvant treatment

Clinical criteria:

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

Authority applications for initial treatment must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail and must include:

(a) details (date, unique identifying number/code or provider number) of the pathology report from an Approved Pathology Authority demonstrating evidence of residual invasive carcinoma in the breast and/or axillary lymph nodes following completion of surgery.

The pathology report must be documented in the patient's medical records.

If the application is submitted through HPOS upload or mail, it must include:

(i) a completed authority prescription form; and

(ii) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice)

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authorisation under this restriction should be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/hpos)
Alternatively, applications for authority to prescribe can be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Early HER2 positive breast cancer

Treatment Phase: Continuing adjuvant treatment

Clinical criteria:

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

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

Injection

11951B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
450 mg	6	..	*7267.06	42.50	Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial) Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)

EGFR (Epidermal Growth Factor Receptor) inhibitors

▪ CETUXIMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

12470

Metastatic colorectal cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised encorafenib for this condition.

Injection

12816M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
550 mg	11	..	*1836.41	42.50	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.

Authority required (STREAMLINED)

12483

Metastatic colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in combination with PBS-subsidised encorafenib for this condition.

Injection

12820R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
880 mg	..	..	*2711.09	42.50	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)

						Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL 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	..	*1836.41	42.50	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4312Y	880 mg	..	..	*2711.09	42.50	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)

12045

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; OR
- The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC, **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	..	..	*2711.09	42.50	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

10262D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
550 mg	18	..	*1836.41	42.50	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)

12016

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

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

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

Injection

4731B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
550 mg	11	..	*1836.41	42.50	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 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)

12066

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; OR
- The condition must have progressed following first-line treatment with pembrolizumab for dMMR mCRC, **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)

12035

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; OR
- Patient must have received an initial authority prescription for this drug for treatment of RAS wild-type metastatic colorectal cancer after failure of treatment with first-line pembrolizumab for dMMR mCRC, **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	..	*3880.05	42.50	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	..	*3880.05	42.50	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial) Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

PD-1/PDL-1 (Programmed cell death protein 1/death ligand 1) inhibitors

▪ ATEZOLIZUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10297

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

11277M	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1200 mg	7	..	*7189.56	42.50	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 Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10216

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

Treatment Phase: Continuing first-line treatment of metastatic disease - 3 weekly treatment regimen

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**
- Patient must have stable or responding disease.

Injection

11802E	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1200 mg	7	..	*7189.56	42.50	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 Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10215

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment - 4 weekly treatment regimen

Clinical criteria:

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

Injection

11930X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	5	..	*10030.55	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10257

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

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

Clinical criteria:

- Patient must have experienced intolerance to combination treatment with bevacizumab, **AND**
- Patient must have previously received PBS-subsidised treatment with this drug in this line of treatment, **AND**
- Patient must have stable or responding disease, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Injection

12097Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	5	..	*10030.55	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10276

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

11284X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	5	..	*7189.56	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10206

Extensive-stage small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

Injection

11926Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	3	..	*7189.56	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10521

Extensive-stage small cell lung cancer

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

11929W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	4	..	*7189.56	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10312

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment - 4 weekly treatment regimen

Clinical criteria:

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

Injection

11931Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	3	..	*10030.55	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10509

Extensive-stage small cell lung cancer

Treatment Phase: Continuing treatment - 4 weekly treatment regimen

Clinical criteria:

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

Injection

12078Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	3	..	*10030.55	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10917

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

Treatment Phase: Continuing treatment of hepatocellular carcinoma - 3 weekly treatment regimen

Treatment criteria:

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

Clinical criteria:

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

PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

Injection

12168K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	8	..	*7189.56	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10972

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

Treatment Phase: Continuing treatment where bevacizumab is discontinued - 4 weekly treatment regimen

Clinical criteria:

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

PBS supply of this drug must be through only one of the two continuing treatment regimens at any given time

Injection

12174R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	5	..	*10030.55	42.50	Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

Authority required (STREAMLINED)

10182

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

Treatment Phase: Initial treatment 1

Treatment criteria:

- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

Clinical criteria:

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

Authority required (STREAMLINED)

10125

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

Treatment Phase: Initial treatment 2

Treatment criteria:

- Patient must be undergoing combination treatment with bevacizumab and platinum-doublet chemotherapy.

Clinical criteria:

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

Injection

11807K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	5	..	*7189.56	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial)

▪ ATEZOLIZUMAB

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.
Note No increase in the maximum amount or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10915

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

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

Clinical criteria:

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

Treatment criteria:

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

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

Injection

12164F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1680 mg	5	..	*10030.55	42.50	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 mL vial) Tecentriq [RO] (atezolizumab 840 mg/14 mL injection, 14 mL vial)

▪ ATEZOLIZUMAB

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

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

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10939

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

Treatment Phase: Initial treatment

Treatment criteria:

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

Clinical criteria:

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

Injection

12171N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	3	..	*7189.56	42.50	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)

10023

Stage IV (metastatic) Merkel Cell Carcinoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

- The treatment must not exceed a maximum dose of 10 mg per kg every 2 weeks under this restriction.

Injection

11671G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	11	..	*8231.23	42.50	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	..	*8231.23	42.50	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

▪ DURVALUMAB

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10126

Unresectable Stage III non-small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

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

Authority required (STREAMLINED)

12271

Unresectable Stage III non-small cell lung cancer

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11915D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	4	..	*12012.07	42.50	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial) Imfinzi [AP] (durvalumab 500 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)

11477

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Continuing treatment as second-line drug therapy

Clinical criteria:

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

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

Injection

11153B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9557.05	42.50	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)

9299

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11160J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9557.05	42.50	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial) Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)

▪ NIVOLUMAB

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

9252

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11411N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9557.05	42.50	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)

9321

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Maintenance treatment

Clinical criteria:

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

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

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

Injection

11642R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9557.05	42.50	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)

9298

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

9214

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Maintenance treatment

Clinical criteria:

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

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

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

Injection

10745M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	11	..	*9557.05	42.50	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)

10155

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Injection

10764M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	8	..	*9557.05	42.50	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)

11434

Locally advanced or metastatic non-small cell lung cancer

Treatment Phase: Initial treatment as second-line drug therapy

Clinical criteria:

- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must have progressed on or after prior platinum based chemotherapy.

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11158G	480 mg	8	..	*9557.05	42.50	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)

9216

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11435W	480 mg	8	..	*9557.05	42.50	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 increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

10195

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11543M	120 mg	3	..	*2454.58	42.50	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)

9312

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Initial Treatment

Clinical criteria:

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

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

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

Injection

11150W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	8	..	*9557.05	42.50	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 A patient may only qualify for PBS-subsidised treatment under this restriction once.

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11469

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

Treatment Phase: Grandfather treatment (treatment of a patient commenced on non-PBS-subsidised combination treatment as first-line drug therapy)

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021, **AND**
- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug 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 not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- Patient must not have received treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer prior to initiating treatment with this drug for this PBS indication, **AND**
- The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with platinum-based chemotherapy for the first two cycles, **AND**
- The treatment must be in combination with ipilimumab.

Injection

12303M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	13	..	*7189.57	42.50	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)

11392

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

Treatment Phase: Initial combination treatment (with ipilimumab) as first-line drug therapy

Clinical criteria:

- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must be in combination with platinum-based chemotherapy for the first two cycles, **AND**
- The treatment must be in combination with ipilimumab.

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)

11468

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

Treatment Phase: Continuing combination treatment (with ipilimumab) of first-line drug therapy

Clinical criteria:

- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with ipilimumab.

Injection

12323N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	13	..	*7189.57	42.50	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 increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

Note 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 An increase of number of repeats may be authorised up to 11 if the patient is receiving a weight based dosing of 3mg/kg every 2 weeks.

Authority required (STREAMLINED)

11985

Unresectable malignant mesothelioma

Clinical criteria:

- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with PBS-subsidised ipilimumab, unless an intolerance to ipilimumab of a severity necessitating permanent treatment withdrawal of ipilimumab, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a maximum total of 24 months in a lifetime for this condition.

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

Injection

12602G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	8	..	*7189.57	42.50	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 increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

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

Note Special Pricing Arrangements apply.

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

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemaglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

Authority required (STREAMLINED)

8573

Stage IV clear cell variant renal cell carcinoma (RCC)

Treatment Phase: Induction treatment

Clinical criteria:

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

Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.
The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

Injection

11636K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	3	..	*7189.57	42.50	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 quantity or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.
Note Special Pricing Arrangements apply.

Authority required

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

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

Authority required

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11900H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	5	..	*9557.05	42.50	Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)

▪ PEMBROLIZUMAB

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

Authority required (STREAMLINED)

10705

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

10436G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	7	..	*7734.57	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

Authority required (STREAMLINED)

10701

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Continuing treatment - 6 weekly treatment regimen

Clinical criteria:

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

Injection

12124D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	3	..	*15382.07	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

Authority required (STREAMLINED)

10696

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

10493G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	5	..	*7734.57	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

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

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

Authority required (STREAMLINED)

10689

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Initial treatment - 6 weekly treatment regimen

Clinical criteria:

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

Injection

12128H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	2	..	*15382.07	42.50	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.

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

Authority required (STREAMLINED)

10681

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

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

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

Authority required (STREAMLINED)

10682

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

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction.

Injection

11494Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*7734.57	42.50	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.

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

Authority required (STREAMLINED)

9921

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

Treatment Phase: Initial treatment

Clinical criteria:

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

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

Authority required (STREAMLINED)

9894

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

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

11646Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*7734.57	42.50	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.

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

Authority required (STREAMLINED)

10704

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

Treatment Phase: Initial treatment - 6 weekly treatment regimen

Clinical criteria:

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

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

Authority required (STREAMLINED)

10693

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

Treatment Phase: Continuing treatment - 6 weekly treatment regimen

Clinical criteria:

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

Injection

12119W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	3	..	*15382.07	42.50	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.

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

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment - 6 weekly treatment regimen

Clinical criteria:

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

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

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment - 6 weekly treatment regimen

Clinical criteria:

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

Injection

12127G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	3	..	*15382.07	42.50	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.

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

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

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

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

Authority required

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Clinical criteria:

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

Injection

12130K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	7	..	*7734.57	42.50	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.

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

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form;

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11330H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*7734.57	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

▪ PEMBROLIZUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required

Relapsed or refractory primary mediastinal B-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form;

(b) a completed primary mediastinal B-cell lymphoma pembrolizumab PBS Authority Application, which includes:

(i) confirmation that histology results with PET/CT scans support a diagnosis of primary mediastinal B-cell lymphoma and are retained on the patient's medical records;

(ii) details of prior treatments for this condition.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Relapsed or refractory primary mediastinal B-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

12129J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	6	..	*7734.57	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL 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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

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

Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be untreated for this PBS indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease), **AND**
- Patient must not have received prior treatment for colorectal cancer with each of: (i) a programmed cell death-1 (PD-1) inhibitor, (ii) a programmed cell death ligand-1 (PD-L1) inhibitor, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test, **AND**
- The treatment must not exceed a total of 7 doses under this restriction.

Authority required

Unresectable or metastatic deficient mismatch repair (dMMR) 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 while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment in a lifetime for this condition.

Authority required

Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer

Treatment Phase: Transitioning from non-PBS to PBS subsided treatment - Grandfather treatment

Clinical criteria:

- Patient must have received non-PBS subsidised treatment with this drug for this condition prior to 1 August 2021, **AND**

- Patient must not have received prior PBS funded treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for colorectal cancer, **AND**
- Patient must have been untreated for this indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease), prior to initiating treatment with this drug, **AND**
- Patient must have stable or responding disease, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test, **AND**
- The treatment must not exceed a total of 35 cycles or up to 24 months of treatment in a lifetime 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 This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Injection

12615Y	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	200 mg	6	..	*7734.57	42.50	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

VEGF/VEGFR (Vascular Endothelial Growth Factor) inhibitors

▪ BEVACIZUMAB

Injection

12479T	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1800 mg	7	..	*2283.07	42.50	Mvasi [AN] (bevacizumab 100 mg/4 mL injection, 4 mL vial) Mvasi [AN] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

Other monoclonal antibodies and antibody drug conjugates

▪ BLINATUMOMAB

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

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

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

Note Special Pricing Arrangements apply.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment

Clinical criteria:

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

(4) if applicable, the date of completion of blinatumomab treatment for minimal residual disease and the date of the patient's subsequent relapse; and

(5) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application.

Injection

11118E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
651 mcg	..	..	*69801.55	42.50	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 restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

Acute lymphoblastic leukaemia

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**
- Patient must have previously received a tyrosine kinase inhibitor (TKI) if the condition is Philadelphia chromosome positive, **AND**
- Patient must have received insufficient therapy with this agent for this condition under the Induction treatment restriction to complete a maximum of 2 treatment cycles in a lifetime.

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

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

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

Injection

11120G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	..	..	*81420.63	42.50	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 restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

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

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

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

Authority required

Acute lymphoblastic leukaemia

Treatment Phase: Consolidation treatment

Clinical criteria:

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

- Patient must not receive PBS-subsidised treatment with this drug if progressive disease develops while on this drug.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11117D	784 mcg	2	..	*81420.63	42.50	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.

Authority required

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

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

Treatment criteria:

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

Clinical criteria:

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

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

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

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

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

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

(1) a completed authority prescription form; and

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

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

(4) the percentage blasts in bone marrow count that is no more than 4 weeks old at the time of application

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

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

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

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

Treatment criteria:

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

Clinical criteria:

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

- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

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

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

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

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

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

Injection

11850Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	1	..	*81420.63	42.50	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 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

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 be more than 12 treatment cycles under this restriction in a lifetime.

Injection

10171H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	..	*18707.07	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

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, **AND**
- Patient must have responded to PBS-subsidised treatment with this drug if previously used for initial treatment of CD30 positive peripheral T-cell lymphoma, non-cutaneous type.

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	..	*18707.07	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form; and

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

Injection

11073T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	3	..	*18707.07	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form; and

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

Injection

11079D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	3	..	*18707.07	42.50	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11087M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	..	*18707.07	42.50	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ BRENTUXIMAB VEDOTIN

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

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

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

Note Special Pricing Arrangements apply.

Authority required

Relapsed or Refractory Hodgkin lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

Injection

11096B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	..	*18707.07	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Authority required

CD30 positive cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

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

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

(a) a completed authority prescription form; and

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

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

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

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

Injection

11660Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
180 mg	3	..	*18707.07	42.50	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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Authority required

CD30 positive cutaneous T-cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

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

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

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

Injection

11664X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
180 mg	11	..	*18707.07	42.50	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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).
Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au
Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos
Or mailed to:
Services Australia
Complex Drugs
Reply Paid 9826
HOBART TAS 7001

Note This product is not PBS-subsidised for the treatment of previously untreated CD30 positive cutaneous T-cell lymphoma.

Authority required

CD30 positive peripheral T-cell lymphoma, non-cutaneous type

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have histological confirmation of CD30 expression in at least 3% of malignant cells, **AND**
- The treatment must be for first line therapy for this condition, **AND**
- The treatment must be for curative intent, **AND**
- The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone, **AND**
- The treatment must not be more than 6 treatment cycles under this restriction in a lifetime.

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

(a) a completed authority prescription form; and

(b) a completed Peripheral T-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 Peripheral T-cell lymphoma cell lymphoma.

Injection

12646N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	5	..	*18707.07	42.50	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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note This product is not PBS-subsidised for the treatment of previously untreated CD30 positive cutaneous T-cell lymphoma.

Authority required

CD30 positive peripheral T-cell lymphoma, non-cutaneous type

Treatment Phase: Continuing treatment

Clinical criteria:

- The treatment must be in combination with cyclophosphamide, doxorubicin and prednisone, **AND**
- Patient must have completed 6 initial cycles of PBS-subsidised treatment with this drug for this indication, **AND**
- Patient must have achieved at least a partial response to the 6 initial cycles of treatment with a combination of this drug and cyclophosphamide, doxorubicin and prednisone for this indication, **AND**
- The condition must not have progressed while receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be more than 2 treatment cycles under this restriction in a lifetime.

Partial response is defined using Lugano Response Criteria for Non-Hodgkin Lymphoma as:

(a) Positron emission tomography-based response: lymph nodes and extralymphatic sites - a score of 4 (uptake moderately > liver), or 5 (uptake markedly higher than liver and/or new lesions), with reduced uptake compared with baseline and residual mass(es) of any size; nonmeasured lesions - not applicable; organ enlargement - not applicable; new lesions - none; bone marrow - residual uptake higher than uptake in normal marrow but reduced compared with baseline (diffuse uptake compatible with reactive changes from chemotherapy allowed). If there are persistent focal changes in the marrow in the context of a nodal response, consideration should be given to further evaluation with MRI or biopsy or an interval scan; OR

(b) Computed tomography-based response: lymph nodes and extralymphatic sites - greater than or equal to 50% decrease in the sum of the product of the perpendicular diameters for multiple lesions, of up to six (6) target measurable nodes and extranodal sites; non-measured lesions - absent/normal, regressed but no increase; new lesions - none; bone marrow - not applicable.

Injection

12657E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	1	..	*18707.07	42.50	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

▪ ELOTUZUMAB

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

Note Special Pricing Arrangements apply.

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

Authority required

Relapsed and/or refractory 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 lenalidomide and dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

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

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

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

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

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

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12983H	1200 mg	5	..	*5037.10	42.50	Empliciti [BQ] (elotuzumab 300 mg injection, 1 vial) Empliciti [BQ] (elotuzumab 400 mg injection, 1 vial)

▪ ELOTUZUMAB

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

Note Special Pricing Arrangements apply.

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

Authority required

Relapsed and/or refractory 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 lenalidomide and 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.

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

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

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

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

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

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

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

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12989P	1200 mg	9	..	*5037.10	42.50	Empliciti [BQ] (elotuzumab 300 mg injection, 1 vial) Empliciti [BQ] (elotuzumab 400 mg injection, 1 vial)

▪ GEMTUZUMAB OZOGAMICIN

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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Induction treatment

Clinical criteria:

- Patient must have confirmed CD33-positive AML prior to initiation of treatment, **AND**
- The condition must be de novo, **AND**
- The condition must be previously untreated at the time of initiation (except for prior essential treatment with hydroxyurea or leukapheresis for patients with hyperleukocytic AML), **AND**
- Patient must have confirmed intermediate/favourable cytogenetic risk; OR
- Patient must have unknown cytogenetic risk due to inconclusive test results, **AND**

- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The condition must not be acute promyelocytic leukaemia, **AND**
- The treatment must be in combination with standard intensive remission induction chemotherapy for this condition, which must include cytarabine and an anthracycline, **AND**
- The treatment must not be used in combination with a tyrosine kinase inhibitor, **AND**
- The condition must not be internal tandem duplication (ITD) or tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3) mutation positive, **AND**
- Patient must not receive more than 1 induction cycle under this restriction in a lifetime.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12844B	5 mg	2	..	*9254.07	42.50	Mylotarg [PF] (gemtuzumab ozogamicin 5 mg injection, 1 vial)

▪ GEMTUZUMAB OZOGAMICIN

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 Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Authority required

Acute Myeloid Leukaemia

Treatment Phase: Consolidation treatment

Clinical criteria:

- Patient must have achieved a complete remission following induction treatment with this drug for this condition, **AND**
- The treatment must be in combination with standard intensive remission consolidation chemotherapy for this condition, which must include cytarabine and an anthracycline, **AND**
- Patient must not receive more than 2 consolidation cycles under this restriction in a lifetime.

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

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

Complete remission following induction is defined as fewer than 5% blasts in a normocellular marrow and an absolute neutrophil count of more than 1.0 x 10^9 cells/L with a platelet count of 100 x 10^9/L or more in the peripheral blood in the absence of transfusion.

Progressive disease is defined as the presence of any of the following:

a) Leukaemic cells in the CSF;

b) Re-appearance of circulating blast cells in the peripheral blood, not attributable to overshoot following recovery from myeloablative therapy;

c) Greater than 5 % blasts in the marrow not attributable to bone marrow regeneration or another cause;

d) Extramedullary leukaemia.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12861X	5 mg	1	..	*9254.07	42.50	Mylotarg [PF] (gemtuzumab ozogamicin 5 mg injection, 1 vial)

▪ IPILIMUMAB

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11478

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

Treatment Phase: Initial combination treatment (with nivolumab) as first-line drug therapy

Clinical criteria:

- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have previously been treated for this condition in the metastatic setting, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must be in combination with platinum-based chemotherapy for the first two cycles, **AND**
- The treatment must be in combination with nivolumab.

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

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

Authority required (STREAMLINED)

11391

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

Treatment Phase: Continuing combination treatment (with nivolumab) of first-line drug therapy

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 receiving PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with nivolumab.

Injection

12322M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	4	..	*16964.83	42.50	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

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

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

Note Special Pricing Arrangements apply.

Authority required (STREAMLINED)

11394

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

Treatment Phase: Grandfather treatment (treatment of a patient commenced on non-PBS-subsidised combination treatment as first-line drug therapy)

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this indication prior to 1 April 2021, **AND**
- The condition must be squamous type non-small cell lung cancer (NSCLC), **AND**
- Patient must not have been treated for this condition in the metastatic setting prior to initiating non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug 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 not have evidence of an activating epidermal growth factor receptor (EGFR) gene or an anaplastic lymphoma kinase (ALK) gene rearrangement or a c-ROS proto-oncogene 1 (ROS1) gene arrangement in tumour material, **AND**
- The treatment must not exceed 24 months in total, measured from the initial dose, or, must not extend beyond disease progression, whichever comes first, **AND**
- The treatment must be in combination with platinum-based chemotherapy for the first two cycles, **AND**
- The treatment must be in combination with nivolumab.

Injection

12324P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	4	..	*16964.83	42.50	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

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

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

Note Special Pricing Arrangements apply.

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

Authority required (STREAMLINED)

11930

Unresectable malignant mesothelioma

Clinical criteria:

- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with PBS-subsidised nivolumab for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a maximum total of 24 months in a lifetime for this condition.

Injection

12583G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	3	..	*16964.83	42.50	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ IPILIMUMAB

Caution Combination treatment with ipilimumab and nivolumab is associated with an increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note In the first few months after start of immunotherapy, some patients can have a transient tumour flare with subsequent disease response. When progression is suspected, this should be confirmed through a confirmatory scan, taken at least 4 weeks later.

Note A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: https://www.mdcalc.com/imdc-international-metastatic-rcc-database-consortium-risk-model-metastatic-renal-cell-carcinoma.
One point is assigned for each of:
(i) a time of diagnosis to systemic therapy of less than 1 year
(ii) a Karnofsky Performance Status of less than 80%
(iii) a haemaglobin less than the lower limit of normal
(iv) a corrected calcium level greater than the upper limit of normal
(v) a neutrophil count greater than the upper limit of normal
(vi) a platelet count greater than the upper limit of normal
Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.
Favourable IMDC risk is a score of 0.
Intermediate IMDC risk is a score of 1 to 2.
Poor IMDC risk is a score of 3 to 6.
Document any IMDC risk score assessment in the patient's medical records.

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	..	*16964.83	42.50	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 increased incidence and severity of immune-related adverse reactions compared with monotherapy with these agents. Monitoring at least prior to each dose is recommended.

Authority required (STREAMLINED)

10122

Unresectable Stage III or Stage IV malignant melanoma

Treatment Phase: Induction treatment

Clinical criteria:

- Patient must not have received prior treatment with ipilimumab or a PD-1 (programmed cell death-1) inhibitor for the treatment of unresectable Stage III or Stage IV malignant melanoma, **AND**
- Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be ocular or uveal melanoma, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab as induction therapy for this condition.

Induction treatment with nivolumab must not exceed a total of 4 doses at a maximum dose of 1 mg per kg every 3 weeks.

Induction treatment with ipilimumab must not exceed a total of 4 doses at a maximum dose of 3 mg per kg every 3 weeks.

The patient's body weight must be documented in the patient's medical records at the time treatment is initiated.

Injection

2641B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	3	..	*45094.43	42.50	Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial) Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)

▪ SACITUZUMAB GOVITECAN

Caution This medicine contains a cytotoxic component and causes chemotherapy-like toxicity, in particular, it can cause severe or life-threatening neutropenia and severe diarrhoea. For further information, refer to the Product Information.

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)

12656

Unresectable locally advanced or metastatic triple-negative breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have progressive disease following two or more prior systemic therapies, at least one of them in the locally advanced or metastatic setting, **AND**
- The condition must be inoperable, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation, **AND**
- The treatment must be the sole PBS-subsidised therapy for this PBS indication.

Injection

12966K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	7	..	*10479.20	42.50	Trodelvy [GI] (sacituzumab govitecan 180 mg injection, 1 vial)

▪ SACITUZUMAB GOVITECAN

Caution This medicine contains a cytotoxic component and causes chemotherapy-like toxicity, in particular, it can cause severe or life-threatening neutropenia and severe diarrhoea. For further information, refer to the Product Information.

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)

12669

Unresectable locally advanced or metastatic triple-negative breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this PBS indication.

Authority required (STREAMLINED)

12670

Unresectable locally advanced or metastatic triple-negative breast cancer

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather treatment

Clinical criteria:

- Patient must must have received treatment with this drug for this PBS indication prior to 1 May 2022, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 1 prior to treatment initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this PBS indication.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12945H	1200 mg	13	..	*10479.20	42.50	Trodelvy [GI] (sacituzumab govitecan 180 mg 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	..	*158.05	42.50	Carboplatin Accord [OC] (carboplatin 450 mg/45 mL injection, 45 mL vial) DBL Carboplatin [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	..	*136.04	42.50	Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial) Cisplatin Accord [OC] (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	..	*146.29	42.50	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)

Proteasome inhibitors

▪ BORTEZOMIB

Restricted benefit

Multiple myeloma

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12227M	3000 mcg	15	..	*605.79	42.50	Bortezom [CR] (bortezomib 3.5 mg injection, 1 vial) Bortezomib Accord [OC] (bortezomib 1 mg injection, 1 vial) Bortezomib Accord [OC] (bortezomib 3.5 mg injection, 1 vial) Bortezomib-Dr.Reddy's [RI] (bortezomib 3.5 mg injection, 1 vial) Bortezomib Ever Pharma [IT] (bortezomib 2.5 mg/mL injection, 1 mL vial) Bortezomib Ever Pharma [IT] (bortezomib 3.5 mg/1.4 mL injection, 1.4 mL vial)

Bortezomib Juno [JU] (bortezomib 1 mg injection, 1 vial)
Bortezomib Juno [JU] (bortezomib 2.5 mg injection, 1 vial)
Bortezomib Juno [JU] (bortezomib 3.5 mg injection, 1 vial)
Bortezomib Sandoz [SZ] (bortezomib 3.5 mg injection, 1 vial)
BORTEZOMIB-TEVA [TB] (bortezomib 3.5 mg injection, 1 vial)
DBL Bortezomib [PF] (bortezomib 1 mg injection, 1 vial)
DBL Bortezomib [PF] (bortezomib 2.5 mg injection, 1 vial)
DBL Bortezomib [PF] (bortezomib 3 mg injection, 1 vial)
DBL Bortezomib [PF] (bortezomib 3.5 mg injection, 1 vial)
Velcade [JC] (bortezomib 1 mg injection, 1 vial)
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 (STREAMLINED)

12934

Multiple myeloma

Treatment Phase: Initial treatment - twice weekly treatment regimen

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 receive more than three cycles of treatment under this restriction.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required (STREAMLINED)

12930

Multiple myeloma

Treatment Phase: Continuing treatment - twice weekly treatment regimen

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 receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11229B	120 mg	17	..	*2624.95	42.50	Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 60 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 (STREAMLINED)

12694

Multiple myeloma

Treatment Phase: Initial treatment - once weekly treatment regimen

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 receive more than three cycles of treatment under this restriction.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Authority required (STREAMLINED)

12849

Multiple myeloma

Treatment Phase: Continuing treatment - once weekly treatment regimen

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 receive more than 3 cycles of treatment per continuing treatment course authorised under this restriction.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12244K	160 mg	8	..	*3470.91	42.50	Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial) Kyprolis [AN] (carfilzomib 60 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	..	*335.39	42.50	Arsenic Trioxide Accord [OC] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) Arsenic Trioxide-AFT [AE] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL ampoules) Arsenic Trioxide Juno [JU] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) 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	..	*335.39	42.50	Arsenic Trioxide Accord [OC] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) Arsenic Trioxide-AFT [AE] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL ampoules) Arsenic Trioxide Juno [JU] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) Phenasen [FF] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

▪ 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	..	*771.07	42.50	Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

▪ ERIBULIN

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

7258

Advanced (unresectable and/or metastatic) liposarcoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have an ECOG performance status of 2 or less, **AND**
- The condition must be dedifferentiated, myxoid, round-cell or pleomorphic subtype, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline and ifosfamide (unless contraindicated) for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Authority required (STREAMLINED)

7280

Advanced (unresectable and/or metastatic) liposarcoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not develop progressive disease while being treated with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must be aged 18 years or older.

Injection

11212D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3 mg	7	..	*771.07	42.50	Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

Public

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	3.23	[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	17.89	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	42.50	Akynzeo [JZ]

▪ ONDANSETRON

Restricted benefit

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

ondansetron 4 mg/5 mL oral liquid, 50 mL

5848T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
‡1	..	..	80.78	42.50	Zofran syrup 50 mL [AS]

ondansetron 4 mg tablet, 4

5967C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	3.41	4.72	[a] APO-Ondansetron [TX]	[a] APX-Ondansetron [TY]
					[a] Ondansetron AN [EA]	[a] Ondansetron APOTEX [GX]
					[a] Ondansetron-DRLA [RZ]	[a] Ondansetron Mylan Tablets [AF]
					[a] Ondansetron SZ [HX]	[a] Zofran [AS]
					[a] Zotren 4 [RF]	

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	6.66	[a] APO-Ondansetron [TX]	[a] APX-Ondansetron [TY]
					[a] Ondansetron AN [EA]	[a] Ondansetron APOTEX [GX]
					[a] Ondansetron-DRLA [RZ]	[a] Ondansetron Mylan Tablets [AF]
					[a] Ondansetron SZ [HX]	[a] Zofran [AS]
					[a] Zotren 8 [RF]	

▪ ONDANSETRON

Note Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 4 mg and pharmaceutical benefits that have the form ondansetron 4 mg wafer are equivalent for the purposes of substitution.

Note Pharmaceutical benefits that have the form ondansetron tablet (orally disintegrating) 8 mg and pharmaceutical benefits that have the form ondansetron 8 mg wafer are equivalent for the purposes of substitution.

Restricted benefit

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

ondansetron 4 mg orally disintegrating tablet, 4

5857G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	3.41	4.72	[a] APO-Ondansetron ODT [TX]	[a] APX-Ondansetron ODT [TY]
					[a] Ondansetron AN ODT [EA]	[a] Ondansetron Mylan ODT [AF]
					[a] Ondansetron ODT-DRLA [RZ]	[a] Ondansetron ODT GH [GQ]
					[a] Ondansetron ODT Lupin [HQ]	[a] Ondansetron SZ ODT [HX]
					[a] Zotren ODT [RF]	

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	6.66	[a] APO-Ondansetron ODT [TX]	[a] APX-Ondansetron ODT [TY]
					[a] Ondansetron AN ODT [EA]	[a] Ondansetron Mylan ODT [AF]
					[a] Ondansetron ODT-DRLA [RZ]	[a] Ondansetron ODT GH [GQ]
					[a] Ondansetron ODT Lupin [HQ]	[a] Ondansetron SZ ODT [HX]
					[a] Zotren ODT [RF]	

ondansetron 4 mg wafer, 4

5969E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	..	[B]2.28	5.69	4.72	[a] Zofran Zydis [AS]

ondansetron 8 mg wafer, 4

5970F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	..	[B]2.28	7.63	6.66	[a] Zofran Zydis [AS]

▪ PALONOSETRON

Note No increase in the maximum quantity or number of units may be authorised.

Note This drug is not PBS-subsidised for administration with oral 5-HT3 antagonists.

Restricted benefit

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

palonosetron 250 microgram/5 mL injection, 5 mL vial

5853C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	..	..	22.04	23.35	[a] Aloxi [JZ]	[a] Palonosetron Dr.Reddy's [RZ]

▪ 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	5.88	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	Brand Name and Manufacturer
1	5	..	62.30	42.50	[a] Aprepitant APOTEX [TX]	[a] APREPITANT SCP [XC]

▪ 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11103J	1	5	..	97.16	42.50	Emend IV [MK]

ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

MONOCLONAL ANTIBODIES AND ANTIBODY DRUG CONJUGATES

CD38 (Clusters of Differentiation 38) inhibitors

DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy from week 25 until disease progression (administered every 4 weeks)

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 receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

daratumumab 1.8 g/15 mL injection, 15 mL vial

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12682L	1	5	..	7010.28	42.50	Darzalex SC [JC]

DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment of second-line drug therapy for weeks 10 to 24 (administered every 3 weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12745T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	4	..	7010.28	42.50	Darzalex SC [JC]

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment as second-line drug therapy for weeks 1 to 9 (administered once weekly)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- The treatment must be in combination with bortezomib and dexamethasone, **AND**
- Patient must have progressive disease after only one prior therapy (i.e. use must be as second-line drug therapy; use as third-line drug therapy or beyond is not PBS-subsidised).

Treatment criteria:

- Patient must be undergoing treatment with this drug in one of the following situations: (i) for the first time, (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and 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 documented 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.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12746W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	8	..	7010.28	42.50	Darzalex SC [JC]

▪ DARATUMUMAB

Note This drug is not PBS-subsidised for use in patients with multiple myeloma who have received two or more prior lines of therapy including a proteasome inhibitor (PI) and an immunomodulatory agent, or, who are refractory to both a PI and an immunomodulatory agent, as monotherapy.

Note Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 888 333.

Note No increase in the maximum number of repeats may be authorised.

Note Special Pricing Arrangements apply.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only. For continuing PBS-subsidised treatment, a 'Grandfathered' patient must qualify under the 'Continuing treatment' criteria.

Note This grandfather restriction will cease to operate from 3 months after the date specified in the clinical criteria.

Authority required

Relapsed and/or refractory multiple myeloma

Treatment Phase: Transitioning from non-PBS to PBS-subsidised supply - Grandfather arrangements

Clinical criteria:

- Patient must have been on treatment with this drug in the subcutaneous form for this condition prior to 1 November 2021, **AND**
- Patient must have met all initial treatment PBS-eligibility criteria applying to a non-grandfathered patient prior to having commenced treatment with this drug, which are: (i) the condition was confirmed by histological diagnosis, (ii) the treatment is/was being used as part of triple combination therapy with bortezomib and dexamethasone, (iii) the condition progressed (see definition of progressive disease below) after one prior therapy, but not after more than two prior lines of therapies (i.e. this drug was commenced as second-line treatment), (iv) the treatment was/is not to be used in combination with another PBS-subsidised drug indicated for this condition outside of the intended combination where stated, and (v) the patient had never been treated with this drug, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Progressive disease is defined as at least 1 of the following:

(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or

(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or

(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain; or

(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or

(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or

(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or

(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).

Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.

Details of: the histological diagnosis of multiple myeloma; prior treatments including name(s) of drug(s) and date of most recent treatment cycle; the basis of the diagnosis of progressive disease or failure to respond; and 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 documented 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.

A line of therapy is defined as 1 or more cycles of a planned treatment program. This may consist of 1 or more planned cycles of single-agent therapy or combination therapy, as well as a sequence of treatments administered in a planned manner.

A new line of therapy starts when a planned course of therapy is modified to include other treatment agents (alone or in combination) as a result of disease progression, relapse, or toxicity, with the exception to this being the need to attain a sufficient response for stem cell transplantation to proceed. A new line of therapy also starts when a planned period of observation off therapy is interrupted by a need for additional treatment for the disease.

daratumumab 1.8 g/15 mL injection, 15 mL vial

12673B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	7	..	7010.28	42.50	Darzalex SC [JC]

HER2 (Human Epidermal Growth Factor Receptor 2) inhibitors

▪ TRASTUZUMAB

Note Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Note No increase in the maximum number of repeats may be authorised.

Authority required (STREAMLINED)

10212

Early HER2 positive breast cancer

Treatment Phase: 3 weekly treatment regimen

Clinical criteria:

- Patient must have undergone surgery (adjuvant) or be preparing for surgery (neoadjuvant), **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 52 weeks of combined PBS-subsidised and non-PBS-subsidised therapy; OR
- Patient must not receive more than 52 weeks of combined trastuzumab and trastuzumab emtansine therapy if adjuvant trastuzumab emtansine therapy has been discontinued due to intolerance.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10743K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	3	..	1470.22	42.50	Herceptin SC [RO]

▪ 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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

9353

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) either in the primary tumour or a metastatic lesion, **AND**
- The treatment must not be in combination with nab-paclitaxel, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

Cardiac function must be tested by echocardiography (ECHO) or multigated acquisition (MUGA), prior to initiating treatment with this drug for this condition.

trastuzumab 600 mg/5 mL injection, 5 mL vial

10811B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	..	..	1470.22	42.50	Herceptin SC [RO]

▪ 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 Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Authority required (STREAMLINED)

9462

Metastatic (Stage IV) HER2 positive breast cancer

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure.

trastuzumab 600 mg/5 mL injection, 5 mL vial

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10817H	1	3	..	1470.22	42.50	Herceptin SC [RO]

▪ IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Other immunostimulants

▪ MYCOBACTERIUM BOVIS BCG DANISH STRAIN

Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12925G	‡3	1	..	*1317.00	42.50	BCG Culture SSI [LM]

▪ MYCOBACTERIUM BOVIS BCG TICE STRAIN

Restricted benefit

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis BCG Tice strain 500 million CFU injection, 3 vials

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5902P	1	1	..	399.49	42.50	OncoTICE [MK]

▪ VARIOUS

▪ ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Detoxifying agents for antineoplastic treatment

▪ FOLINIC ACID

folinic acid 100 mg/10 mL injection, 10 x 10 mL ampoules

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1904F	1	1	..	43.80	42.50	Leucovorin Calcium (Pfizer Australia Pty Ltd) [PF]

folinic acid 50 mg/5 mL injection, 10 x 5 mL ampoules

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1899Y	1	2	..	38.90	40.21	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5904R	1	..	..	76.00	42.50	Leucovorin Calcium (Hospira Pty Limited) [PF]

▪ MESNA

Restricted benefit

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

Clinical criteria:

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

mesna 1 g/10 mL injection, 15 x 10 mL ampoules

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5961R	1	5	..	150.63	42.50	Uromitexan [BX]

mesna 400 mg/4 mL injection, 15 x 4 mL ampoules

5960Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1	5	..	66.52	42.50	Uromitexan [BX]

Index of Manufacturers' Code

Code	Manufacturer
AE	AFT Pharmaceuticals (AU) Pty Ltd
AF	Alphapharm Pty Ltd
AN	Amgen Australia Pty Limited
AP	AstraZeneca Pty Ltd
AS	Aspen Pharmacare Australia Pty Limited
BQ	Bristol-Myers Squibb Australia Pty Ltd
BX	Baxter Healthcare Pty Limited
CR	Pharmacor Pty Limited
EA	Amneal Pharmaceuticals Pty Ltd
EI	Eisai Australia Pty Ltd
EW	Celltrion Healthcare Australia Pty Ltd
FB	Pierre Fabre Australia Pty Ltd
FF	Phebra Pty Ltd
GI	Gilead Sciences Pty Limited
GQ	Generic Health Pty Ltd
GX	Apotex Pty Ltd
HQ	Generic Health Pty Ltd
HX	Sandoz Pty Ltd
IT	InterPharma Pty Ltd
IX	Clinect Pty Ltd
JC	Janssen-Cilag Pty Ltd
JO	Juno Pharmaceuticals Pty Ltd
JU	Juno Pharmaceuticals Pty Ltd
JZ	Juniper Biologics Pty Ltd
LM	Link Medical Products Pty Ltd
LR	Cipla Australia Pty Ltd
MF	Mundipharma Pty Limited
MK	Merck Sharp & Dohme (Australia) Pty Ltd
OC	Accord Healthcare Pty. Ltd.
OD	Accord Healthcare Pty. Ltd.
OE	Omegapharm Pty Ltd
OQ	Organon Pharma Pty Ltd
PF	Pfizer Australia Pty Ltd
PK	Fresenius Kabi Australia Pty Limited
RA	Sun Pharma ANZ Pty Ltd
RF	Arrow Pharma Pty Ltd
RI	Dr Reddy's Laboratories (Australia) Pty Ltd
RO	Roche Products Pty Ltd
RQ	Reach Pharmaceuticals Pty Ltd
RZ	Dr Reddy's Laboratories (Australia) Pty Ltd
SG	Merck Healthcare Pty Ltd
SW	sanofi-aventis Australia Pty Ltd
SZ	Sandoz Pty Ltd
TB	Teva Pharma Australia Pty Ltd
TK	Takeda Pharmaceuticals Australia Pty. Ltd.
TS	Specialised Therapeutics Australia Pty Ltd
TX	Apotex Pty Ltd
TY	Apotex Pty Ltd
XC	Southern Cross Pharma Pty Ltd

Generic/Proprietary Index