Australian Government

Department of Health, Disability and Ageing

PBS

Schedule of Pharmaceutical Benefits

Efficient Funding of Chemotherapy

Effective 1 November 2026

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This Schedule provides information on the arrangements for the prescribing and supply of pharmaceutical benefits. These arrangements operate under the *National Health Act 1953*. However, at the time of printing, the relevant legislation giving authority for the changes included in this issue of the Schedule may still be subject to the usual Parliamentary scrutiny. This book is not a legal document, and, in cases of discrepancy, the legislation will be the source document for payment for the supply of pharmaceutical benefits. The legislation is available from the Federal Register of Legislation website at www.legislation.gov.au.

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Summary of Changes

These changes to the Schedule of Pharmaceutical Benefits – Efficient Funding of Chemotherapy are effective from 1 November 2026. The Schedule is updated on the first day of each month and is also available at www.pbs.gov.au.

Efficient Funding of Chemotherapy (Private Hospital)

Additions

Addition – Item

15603F **CYCLOPHOSPHAMIDE**,
cyclophosphamide 1 g injection, 1 vial *(Cyclophosphamide (Seacross Pharmaceuticals, UK))*;
cyclophosphamide 2 g injection, 1 vial *(Cyclophosphamide (Seacross Pharmaceuticals, UK))*

Alterations

Alteration – Note

15080Q **BRENTUXIMAB VEDOTIN**,
brentuximab vedotin 50 mg injection, 1 vial *(Adcetris)*

Alteration – Restriction

15080Q **BRENTUXIMAB VEDOTIN**,
brentuximab vedotin 50 mg injection, 1 vial *(Adcetris)*

14765D **TISLELIZUMAB**,
tislelizumab 100 mg/10 mL injection, 10 mL vial *(Tevimbra)*

Advance Notices

1 December 2026

Deletion – Item

12219D *DBL Bortezomib, PF* – **BORTEZOMIB**, bortezomib 3 mg injection, 1 vial

15093J *Darzalex, JC* – **DARATUMUMAB**, daratumumab 100 mg/5 mL injection, 5 mL vial

15093J *Darzalex, JC* – **DARATUMUMAB**, daratumumab 400 mg/20 mL injection, 20 mL vial

7233Q *Fludarabine Ebewe, SZ* – **FLUDARABINE**, fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials

7260D *Hycamtin, SZ* – **TOPOTECAN**, topotecan 4 mg injection, 5 vials

7264H *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

7265J *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

7266K *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

7267L *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

10383L *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

10402L *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

10589H *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

10597R *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

Efficient Funding of Chemotherapy (Public Hospital)

Additions

Addition – Item

15576T **CYCLOPHOSPHAMIDE**,
cyclophosphamide 1 g injection, 1 vial *(Cyclophosphamide (Seacross Pharmaceuticals, UK))*;
cyclophosphamide 2 g injection, 1 vial *(Cyclophosphamide (Seacross Pharmaceuticals, UK))*

Alterations

Alteration – Note

15098P **BRENTUXIMAB VEDOTIN**,
brentuximab vedotin 50 mg injection, 1 vial *(Adcetris)*

Alteration – Restriction

15098P **BRENTUXIMAB VEDOTIN**,
brentuximab vedotin 50 mg injection, 1 vial *(Adcetris)*

14756P **TISLELIZUMAB**,
tislelizumab 100 mg/10 mL injection, 10 mL vial *(Tevimbra)*

Advance Notices

1 December 2026

Deletion – Item

12227M *DBL Bortezomib, PF* – **BORTEZOMIB**, bortezomib 3 mg injection, 1 vial

15065X *Darzalex, JC* – **DARATUMUMAB**, daratumumab 100 mg/5 mL injection, 5 mL vial

15065X *Darzalex, JC* – **DARATUMUMAB**, daratumumab 400 mg/20 mL injection, 20 mL vial

4393F *Fludarabine Ebewe, SZ* – **FLUDARABINE**, fludarabine phosphate 50 mg/2 mL injection, 5 x 2 mL vials

4617B *Hycamtin, SZ* – **TOPOTECAN**, topotecan 4 mg injection, 5 vials

4632T *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

4639E *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

4650R *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

4703M *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

10391X *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

10401K *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

10581X *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

10588G *Kanjinti, XT* – **TRASTUZUMAB**, trastuzumab 420 mg injection, 1 vial

Related Pharmaceutical Benefits for Public Hospital use

Additions

Addition – Brand

5967C *Ondansetron VTRS, AF* – **ONDANSETRON**, ondansetron 4 mg tablet, 4

Advance Notices

1 December 2026

Deletion – Item

15092H *Darzalex SC, JC* – **DARATUMUMAB**, daratumumab 1.8 g/15 mL injection, 15 mL vial

1 January 2027

Deletion – Brand

2550F *Aprepitant APOTEX, TX* – **APREPITANT**, aprepitant 165 mg capsule, 1

About the Supplement

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

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

For information about the operational aspects of the Efficient Funding of Chemotherapy, such as, claiming, authority applications and stationery supplies contact Services Australia at www.servicesaustralia.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 ($9.24)
- Preparation fee ($92.56)
- Distribution fee ($31.51)
- Diluent fee ($6.24)

Section 94 Approved Public Hospital Authority

- Preparation fee ($92.56)

Section 94 Approved Private Hospital Authority

- Ready Prepared Dispensing Fee ($9.24)
- Preparation fee ($92.56)
- Distribution fee ($31.51) (not payable where the drug is trastuzumab)
- Diluent fee ($6.24)

Efficient Funding of Chemotherapy (Private Hospital)

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

ANTINEOPLASTIC AGENTS

ALKYLATING AGENTS

Nitrogen mustard analogues

BENDAMUSTINE

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.

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

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.

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

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.

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

Injection

10763L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	0.00	*226.11	25.00	BENDAMUSTINE EUGIA [YG] (bendamustine hydrochloride 25 mg injection, 1 vial)
					BENDAMUSTINE EUGIA [YG] (bendamustine hydrochloride 100 mg injection, 1 vial)
					BENDAMUSTINE HYDROCHLORIDE MEDSURGE [DZ] (bendamustine hydrochloride 25 mg injection, 1 vial)
					BENDAMUSTINE HYDROCHLORIDE MEDSURGE [DZ] (bendamustine hydrochloride 100 mg injection, 1 vial)
					Bendamustine Sandoz [SZ] (bendamustine hydrochloride 25 mg injection, 1 vial)
					Bendamustine Sandoz [SZ] (bendamustine hydrochloride 100 mg injection, 1 vial)

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10763L						Bendamustine Viatris [AF] (bendamustine hydrochloride 25 mg injection, 1 vial)
						Bendamustine Viatris [AF] (bendamustine hydrochloride 100 mg injection, 1 vial)

CYCLOPHOSPHAMIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7226H	2800 mg	17	0.00	* 190.04	25.00	CYCLOPHOSPHAMIDE-REACH [RQ] (cyclophosphamide 500 mg injection, 1 vial)
						CYCLOPHOSPHAMIDE-REACH [RQ] (cyclophosphamide 1 g injection, 1 vial)
						Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial)
						Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15407X	2800 mg	17	0.00	* 1,109.95	25.00	Cyclophosphamide (NorthStar, USA) [RQ] (cyclophosphamide 1 g injection, 1 vial)
						Cyclophosphamide (NorthStar, USA) [RQ] (cyclophosphamide 2 g injection, 1 vial)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15603F	2800 mg	17	0.00	* 1,031.87	25.00	Cyclophosphamide (Seacross Pharmaceuticals, UK) [RQ] (cyclophosphamide 1 g injection, 1 vial)
						Cyclophosphamide (Seacross Pharmaceuticals, UK) [RQ] (cyclophosphamide 2 g injection, 1 vial)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15505C	2800 mg	17	0.00	* 1,052.15	25.00	Cyclophosphamide (Sagent, USA) [RQ] (cyclophosphamide 2 g injection, 1 vial)

IFOSFAMIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7248L	4000 mg	19	0.00	*294.67	25.00	Holoxan [BX] (ifosfamide 1 g injection, 1 vial)
						Holoxan [BX] (ifosfamide 2 g injection, 1 vial)

ANTIMETABOLITES

Folic acid analogues

METHOTREXATE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7250N	250 mg	5	0.00	*165.40	25.00	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)
						DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)
						Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)
						Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)

METHOTREXATE

Restricted benefit

6276

Patients receiving treatment with a high dose regimen

Injection

7251P	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	20000 mg	0	0.00	*903.51	25.00	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)
						DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)
						Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)
						Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)

PEMETREXED

Injection

7255W	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1100 mg	5	0.00	*222.05	25.00	PEMETREXED EUGIA [YG] (pemetrexed 500 mg injection, 1 vial)
						Pemetrexed Accord [OD] (pemetrexed 100 mg injection, 1 vial)
						Pemetrexed Accord [OD] (pemetrexed 500 mg injection, 1 vial)
						Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial)
						Pemetrexed Ever Pharma [IT] (pemetrexed 100 mg/4 mL injection, 4 mL vial)
						Pemetrexed Ever Pharma [IT] (pemetrexed 500 mg/20 mL injection, 20 mL vial)
						Pemetrexed Ever Pharma [IT] (pemetrexed 1 g/40 mL injection, 40 mL vial)
						Pemetrexed SUN [RA] (pemetrexed 100 mg injection, 1 vial)
						Pemetrexed SUN [RA] (pemetrexed 500 mg injection, 1 vial)
						Pemetrexed SUN [RA] (pemetrexed 1 g injection, 1 vial)
						Pemetrexed-AFT [AE] (pemetrexed 100 mg injection, 1 vial)
						Pemetrexed-AFT [AE] (pemetrexed 500 mg injection, 1 vial)

PRALATREXATE

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.

Authority Required

18800

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, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Injection

11271F	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	80 mg	5	0.00	*4,339.55	25.00	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

PRALATREXATE

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.

Authority Required

18832

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, **AND**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Injection

11278N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
80 mg	11	0.00	*4,339.55	25.00	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

RALTITREXED

Injection

7256X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7 mg	8	0.00	*1,196.99	25.00	Tomudex [PF] (raltitrexed 2 mg injection, 1 vial)

Purine analogues

CLADRIBINE

Authority Required (STREAMLINED)

6265

Hairy cell leukaemia

Injection

7225G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
17 mg	6	0.00	*960.13	25.00	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 with the brand Fludarabine Juno and pharmaceutical benefits that have the form fludarabine phosphate 50 mg/2 mL injection with the brand Fludarabine Ebewe are equivalent for the purposes of substitution.

Injection

7233Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
55 mg	29	0.00	*261.59	25.00	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

7227J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7000 mg	15	0.00	*948.75	25.00	Pfizer Australia Pty Ltd [PF] (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)

FLUOROURACIL

Restricted benefit

6266

Patients requiring administration of fluorouracil by intravenous infusion

Injection

7234R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5500 mg	11	0.00	*162.71	25.00	Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 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

Restricted benefit

6297

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	0.00	*145.47	25.00	Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 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)

GEMCITABINE

Caution Pharmaceutical benefits containing gemcitabine may have different concentrations.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7246J	3000 mg	17	0.00	*203.48	25.00	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)
						GEMCITABINE EUGIA [YG] (gemcitabine 1 g/25 mL injection, 25 mL vial)
						GEMCITABINE EUGIA [YG] (gemcitabine 2 g/50 mL injection, 50 mL vial)
						Gemcitabine Irem [KS] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial)
						Gemcitabine Irem [KS] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

VINBLASTINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7261E	20 mg	17	0.00	*219.57	25.00	DBL Vinblastine [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)

VINCRISTINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7262F	2 mg	7	0.00	*176.53	25.00	DBL Vincristine Sulfate [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)

VINORELBINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7263G	70 mg	7	0.00	*202.31	25.00	Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial)
						Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial)

Podophyllotoxin derivatives

ETOPOSIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7237X	440 mg	14	0.00	*335.75	25.00	Etopophos [LM] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial)
						Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)

Taxanes

CABAZITAXEL

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

Authority Required (STREAMLINED)

13207

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must be in combination with prednisone or prednisolone, **AND**
- The condition must be resistant to treatment with docetaxel; **OR**
- Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel, **AND**
- The treatment must not be used in combination with a novel hormonal drug, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not receive PBS-subsidised cabazitaxel if progressive disease develops while on cabazitaxel.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7236W	55 mg	5	0.00	*211.54	25.00	Cabazitaxel Accord [OC] (cabazitaxel 60 mg/3 mL injection, 3 mL vial)
						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)
						MSN Cabazitaxel [RQ] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack)

DOCETAXEL

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10158P	250 mg	5	0.00	*207.19	25.00	Docetaxel Accord [OC] (docetaxel 80 mg/4 mL injection, 4 mL vial)
						Docetaxel Accord [OC] (docetaxel 160 mg/8 mL injection, 8 mL vial)

NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

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.

Note Not for use as neoadjuvant or adjuvant therapy.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10150F	275 mg	11	0.00	*663.53	25.00	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)
						nab-PACLITAXEL JUNO [JU] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)
						nab-Paclitaxel Accord [OC] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Authority Required (STREAMLINED)

6106

Metastatic breast cancer

Authority Required (STREAMLINED)

6119

HER2 positive breast cancer

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7270P	580 mg	5	0.00	*1,187.51	25.00	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)
						nab-PACLITAXEL JUNO [JU] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)
						nab-Paclitaxel Accord [OC] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

PACLITAXEL

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7254T	450 mg	3	0.00	*214.13	25.00	Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial)
						Paclitaxel Ebewe [SZ] (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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7249M	800 mg	11	0.00	*205.07	25.00	IRINOTECAN BAXTER [BX] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
						IRINOTECAN EUGIA [YG] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
						IRINOTECAN EUGIA [YG] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)
						Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
						Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)
						Irinotecan Irem [KS] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)

TOPOTECAN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7260D	3500 mcg	17	0.00	*172.08	25.00	Hycamtin [SZ] (topotecan 4 mg injection, 5 vials)
						Topotecan Accord [OC] (topotecan 4 mg/4 mL injection, 5 x 4 mL vials)

Other plant alkaloids and natural products

TRABECTEDIN

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

14197

Advanced (unresectable and/or metastatic) leiomyosarcoma or 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 have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

This drug 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
13344H	3250 mcg	7	0.00	*3,421.75	25.00	Yondelis [ZL] (trabectedin 1 mg injection, 1 vial)

TRABECTEDIN

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

14196

Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have an ECOG performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic.

This drug 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
13348M	3250 mcg	3	0.00	*3,421.75	25.00	Yondelis [ZL] (trabectedin 1 mg injection, 1 vial)

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN

Injection_intravesical

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7229L	135 mg	11	0.00	*198.83	25.00	Adriamycin [PF] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7229L						Doxorubicin ACC [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)

DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7230M	100 mg	5	0.00	*807.91	25.00	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	0.00	*319.95	25.00	Epirubicin Accord [OC] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)

IDARUBICIN

Restricted benefit
6247
Acute myelogenous leukaemia (AML)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7247K	30 mg	5	0.00	*321.53	25.00	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	0.00	*233.45	25.00	Mitozantrone Ebewe [SZ] (mitozantrone 20 mg/10 mL injection, 10 mL vial)

Other cytotoxic antibiotics

BLEOMYCIN

Restricted benefit
6275
Germ cell neoplasms
Restricted benefit
6224
Lymphoma

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7244G	30000 iu	11	0.00	*228.15	25.00	Bleomycin Accord [OC] (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
11787
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
11455X	1000 mg	5	0.00	*4,498.98	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

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

Authority Required

11815

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11456Y	1000 mg	9	0.00	*4,498.98	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

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

Authority Required

11755

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11460E	1000 mg	7	0.00	*4,498.98	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

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

Authority Required

11785

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
11473W	1000 mg	5	0.00	*4,498.98	25.00	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.

Authority Required (STREAMLINED)

18685

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, **AND**
- The treatment must not be in combination with acalabrutinib.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12193R	1000 mg	8	0.00	*4,498.98	25.00	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 amount or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority Required (STREAMLINED)

18618

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

Treatment Phase: For combination use with acalabrutinib from treatment cycles 2 to 7 inclusive in first-line therapy

Clinical criteria:

- The condition must be untreated, **AND**
- The treatment must be in combination with PBS-subsidised acalabrutinib (refer to Product Information for timing of obinutuzumab and acalabrutinib doses), **AND**
- The treatment must not be in combination with venetoclax.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13793Y	1000 mg	7	0.00	*4,498.98	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

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)

18082

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Pre-treatment prior to initiation of glofitamab

Clinical criteria:

- Patient must be eligible to receive treatment under the PBS listing criteria for glofitamab.

Patient is intended to receive a single dose of Obinutuzumab 1000 mg 7 days prior to initiating glofitamab treatment (Cycle 1, Day 1).

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15251Q	1000 mg	0	0.00	*4,498.98	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

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.

Authority Required (STREAMLINED)

14326

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**
- The treatment must be in combination with chlorambucil, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10418H	1000 mg	7	0.00	*4,498.98	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

RITUXIMAB

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13090Y	800 mg	11	0.00	*490.31	25.00	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.

Authority Required

18364

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) details of the proposed prescription(s);

(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.

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 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. Monday to Friday).

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

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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Injection

11673J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3384 mcg	2	0.00	*50,652.07	25.00	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 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

9601

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.

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 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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11668D	2820 mcg	4	0.00	*38,023.94	25.00	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

CD38 (Clusters of Differentiation 38) inhibitors

DARATUMUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

17413

Untreated multiple myeloma

Treatment Phase: Continuing treatment as first line drug therapy from week 25 onwards (administered once every four weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, and (iii) dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide, **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
15066Y	1920 mg	5	0.00	*11,394.55	25.00	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial)
						Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

DARATUMUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

17661

Untreated multiple myeloma

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2025, **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: (a) the condition was newly diagnosed, (b) the condition was confirmed by a histological diagnosis, (c) the patient was/is ineligible for a stem cell transplant, (d) the treatment is being given as triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, (iii) dexamethasone, (e) patient is not receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 24 weeks of treatment for the same PBS indication.

Details of the histological diagnosis of multiple myeloma, record of ineligibility for stem cell transplant and 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.

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.

Note Patients may qualify for PBS-subsidised treatment under this restriction to complete 24 weeks of treatment. For continuing PBS-subsidised treatment after week 24, 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

15093J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	15	0.00	*11,394.55	25.00	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial)
					Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

DARATUMUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

17660

Untreated multiple myeloma

Treatment Phase: Initial treatment as first-line drug therapy from week 0 to week 24

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, and (iii) dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide.

Treatment criteria:

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 24 weeks of treatment for the same PBS indication.

Details of the histological diagnosis of multiple myeloma, record of ineligibility for stem cell transplant and 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.

Injection

15094K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	15	0.00	*11,394.55	25.00	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

12845

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	0.00	*11,394.55	25.00	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

12691

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	0.00	*11,394.55	25.00	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

17491

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 PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), or irrespective of whether the disease staging has been changed (i.e. disease has changed from untreated multiple myeloma to relapsed or refractory multiple myeloma), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.

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	0.00	*11,394.55	25.00	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 Special Pricing Arrangements apply.

Authority Required

10414

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.

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.

Injection

10308M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
420 mg	3	0.00	*2,951.18	25.00	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 Special Pricing Arrangements apply.

Authority Required

13018

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.

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

10334X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
840 mg	0	0.00	*5,762.81	25.00	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

PERTUZUMAB

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 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

18829

Early 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 be used in combination with trastuzumab, **AND**
- The treatment must have been initiated in combination with chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- The treatment must not extend beyond the following when initial and continuing therapy are combined: (i) 18 weeks (6 cycles) in the neoadjuvant setting; or (ii) 12 months (18 cycles) in total.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15369X	420 mg	4	0.00	*2,951.18	25.00	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

PERTUZUMAB

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 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

18899

Early 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), **AND**
- Patient must have locally advanced, inflammatory or early stage, high risk (tumour greater than 2 cm in diameter or lymph node positive) breast cancer, **AND**
- The treatment must be used in combination with trastuzumab, **AND**
- The treatment must be initiated in combination with chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 1 treatment cycle under this restriction, **AND**
- The treatment must not extend beyond the following when initial and continuing therapy are combined: (i) 18 weeks (6 cycles) in the neoadjuvant setting; or (ii) 12 months (18 cycles) in total.

Details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15411D	840 mg	0	0.00	*5,762.81	25.00	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

TRASTUZUMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or 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)

15831

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.

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7264H	500 mg	0	0.00	*434.79	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7265J	250 mg	9	0.00	*316.15	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)

TRASTUZUMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Authority Required (STREAMLINED)

15820

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.

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

7266K	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1000 mg	0	0.00	*761.54	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 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	0.00	*641.29	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 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	0.00	*641.29	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 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

10402L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	0	0.00	*761.54	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
					Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 150 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

10589H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1000 mg	0	0.00	*761.54	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
					Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 150 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	0.00	*641.29	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)

TRASTUZUMAB DERUXTECAN

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

Note Special Pricing Arrangements apply.

Authority Required

15826

Metastatic (Stage IV) HER2 positive breast cancer

Clinical criteria:

- Patient must have evidence of human epidermal growth factor (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) in either the primary tumour/a metastatic lesion - establish this finding once only with the first PBS prescription, **AND**
- The condition must have progressed following treatment with at least one prior HER2 directed regimen for metastatic breast cancer; **OR**
- The condition must have, at the time of treatment initiation with this drug, progressed during/within 6 months following adjuvant treatment with a HER2 directed therapy, **AND**
- Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only.

Treatment criteria:

- Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; **OR**
- Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions.

Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription:

1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable).

2) Details of prior HER2 directed drug regimens prescribed for the patient.

3) Cardiac function test results (evidence obtained in relation to past PBS treatment is acceptable).

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13713R	675 mg	8	0.00	*17,835.27	25.00	Enhertu [AP] (trastuzumab deruxtecan 100 mg injection, 1 vial)

TRASTUZUMAB DERUXTECAN

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

Note Special Pricing Arrangements apply.

Authority Required

15832

Unresectable and/or metastatic HER2-low breast cancer

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2)-low disease, **AND**
- Patient must have received prior chemotherapy in the metastatic setting; **OR**
- Patient must have developed disease recurrence during or within 6 months of completing adjuvant chemotherapy, **AND**
- Patient must have received or be ineligible for endocrine therapy in the metastatic setting, if hormone receptor positive, **AND**
- Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only.

Treatment criteria:

- Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; **OR**
- Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions.

HER2-low is defined as an immunohistochemical (IHC) score of 1+ or an IHC score of 2+ and a negative result on in situ hybridization (ISH).

Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription:

1) Evidence of HER2-low status

2) Details of prior drug regimens prescribed for the patient

3) Cardiac function test results

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14577F	675 mg	8	0.00	*17,835.27	25.00	Enhertu [AP] (trastuzumab deruxtecan 100 mg injection, 1 vial)

TRASTUZUMAB EMTANSINE

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

Authority Required

15818

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 form upload or mail, it must include:

(i) details of the proposed prescription; 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).

Increased maximum amounts may only 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).

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

15819

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.

Increased maximum amounts may only be authorised 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).

Injection

11956G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
450 mg	6	0.00	*7,056.05	25.00	Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)
					Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)

TRASTUZUMAB EMTANSINE

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

Authority Required

15828

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.

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Authority Required

15827

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.

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

10281D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
450 mg	8	0.00	*7,056.05	25.00	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

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.

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.

Injection

7240C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
550 mg	5	0.00	*1,773.26	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
					Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

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.

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.

Injection

10265G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1100 mg	18	0.00	*3,134.68	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
					Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

Note Special Pricing Arrangements apply.

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.

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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7273T	1100 mg	11	0.00	*3,134.68	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

Note Special Pricing Arrangements apply.

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	1100 mg	11	0.00	*3,134.68	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

Note Special Pricing Arrangements apply.

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	1100 mg	0	0.00	*3,134.68	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

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.

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

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.

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

Injection

7223E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
880 mg	0	0.00	*2,590.13	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
					Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

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.

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)

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.

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.

Injection

7242E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1100 mg	0	0.00	*3,134.68	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
					Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

PANITUMUMAB

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.

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)

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 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.

Injection

10069Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
720 mg	5	0.00	*3,793.33	25.00	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)
					Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

PANITUMUMAB

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.

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)

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 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.

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	0.00	*3,793.33	25.00	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial) Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

PD-1/PD-L1 (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	0.00	*6,981.38	25.00	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	0.00	*6,981.38	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11957H	1680 mg	5	0.00	*9,718.09	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12098R	1680 mg	5	0.00	*9,718.09	25.00	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)

18242

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11309F	1200 mg	5	0.00	*6,981.38	25.00	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)

18257

Extensive-stage small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be previously untreated, **AND**
- Patient must not have previously received programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for any stage of small cell lung cancer, **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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11927R	1200 mg	3	0.00	*6,981.38	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11928T	1200 mg	4	0.00	*6,981.38	25.00	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)

18243

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11940K	1680 mg	3	0.00	*9,718.09	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12076N	1680 mg	3	0.00	*9,718.09	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12155R	1200 mg	8	0.00	*6,981.38	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12159Y	1680 mg	5	0.00	*9,718.09	25.00	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)

13451

Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)
Treatment Phase: 1,680 mg administered once every 4 weeks, or 840 mg every 2 weeks

Population criteria:

- Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; **OR**
- Patient must be continuing existing PBS-subsidised treatment with this drug; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.

Clinical criteria:

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy, **AND**
- The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement, **AND**
- The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13170E	1680 mg	5	0.00	*9,718.09	25.00	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)

13442

Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)
Treatment Phase: 1,200 mg administered once every 3 weeks

Population criteria:

- Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; **OR**
- Patient must be continuing existing PBS-subsidised treatment with this drug; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.

Clinical criteria:

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy, **AND**
- The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement, **AND**
- The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

Injection

13172G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	7	0.00	*6,981.38	25.00	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)

18326

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition, **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	0.00	*6,981.38	25.00	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 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	0.00	*6,981.38	25.00	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)

16053

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; **OR**
- The treatment must not exceed a dose of 800 mg 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	0.00	*7,984.79	25.00	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)

16085

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; **OR**
- The treatment must not exceed a dose of 800 mg every 2 weeks under this restriction.

Injection

11685B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	11	0.00	*7,984.79	25.00	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

AVELUMAB

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)
13290
Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer
Treatment Phase: Maintenance therapy - Continuing treatment
Clinical criteria:

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

Injection

13132E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	11	0.00	*5,369.71	25.00	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

AVELUMAB

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 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)
15485
Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer
Treatment Phase: Maintenance therapy - Initial treatment
Clinical criteria:

- Patient must have received first-line platinum-based chemotherapy, **AND**
- Patient must not have progressive disease following first-line platinum-based chemotherapy, **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**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition.

Injection

13123Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	7	0.00	*5,369.71	25.00	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

CEMIPLIMAB

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)
18455
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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition, **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.

Injection

13160P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
350 mg	6	0.00	*7,531.61	25.00	Libtayo [WM] (cemiplimab 350 mg/7 mL injection, 7 mL vial)

CEMIPLIMAB

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)

15063

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 both initial and continuing treatment restrictions, whichever comes first.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13162R	350 mg	6	0.00	*7,531.61	25.00	Libtayo [WM] (cemiplimab 350 mg/7 mL injection, 7 mL vial)

CEMIPLIMAB

Caution In the first few months after starting immunotherapy, a transient tumour flare may occur that may be mistaken as disease progression despite an overall positive response to treatment.

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 888 333.

Authority Required

13419

Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)

Treatment Phase: Initial treatment covering the first 3 treatment cycles

Clinical criteria:

- The condition must be unsuitable for each of: (i) curative surgical resection, (ii) curative radiotherapy, **AND**
- Patient must have had a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13135H	350 mg	2	0.00	*7,531.61	25.00	Libtayo [WM] (cemiplimab 350 mg/7 mL injection, 7 mL vial)

CEMIPLIMAB

Caution In the first few months after starting immunotherapy, a transient tumour flare may occur that may be mistaken as disease progression despite an overall positive response to treatment.

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 888 333.

Authority Required

13411

Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13153G	350 mg	7	0.00	*7,531.61	25.00	Libtayo [WM] (cemiplimab 350 mg/7 mL injection, 7 mL vial)

DOSTARLIMAB

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)

15205

Advanced, metastatic or recurrent endometrial carcinoma

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 receiving PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14109N	1000 mg	3	0.00	*15,648.69	25.00	Jemperli [GK] (dostarlimab 500 mg/10 mL injection, 10 mL vial)

DOSTARLIMAB

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)

15163

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Initial treatment covering the first 6 treatment cycles

Clinical criteria:

- Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test, **AND**
- The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy, **AND**
- The treatment must be initiated in combination with platinum-containing chemotherapy, **AND**
- The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy, **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**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14133W	500 mg	5	0.00	*7,894.12	25.00	Jemperli [GK] (dostarlimab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

15500

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 be untreated with immunotherapy at commencement of this drug, **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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11911X	1500 mg	4	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11911X						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)
14708
Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer)
Population criteria:

- Patient must have either of the following at treatment initiation: (i) locally advanced biliary tract cancer that is untreated with systemic anti-cancer therapy in the unresectable setting, (ii) metastatic biliary tract cancer that is untreated with systemic anti-cancer therapy in the metastatic setting.

Clinical criteria:

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information), **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13745K	1500 mg	5	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)
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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13766M	1500 mg	5	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)
18257
Extensive-stage small cell lung cancer
Treatment Phase: Initial treatment
Clinical criteria:

- The condition must be previously untreated, **AND**
- Patient must not have previously received programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for any stage of small cell lung cancer, **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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13779F	1500 mg	3	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)

16814

Advanced, metastatic or recurrent endometrial carcinoma

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 receiving PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.

Retain all pathology imaging and investigative test results in the patient's medical records.

Patients with a body weight of 30 kg or less during continuing treatment must receive weight-based dosing, equivalent to durvalumab 20 mg/kg, until weight is greater than 30 kg.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14889P	1500 mg	5	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)

16953

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Initial treatment covering the first 6 treatment cycles

Clinical criteria:

- Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test, **AND**
- The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy, **AND**
- The treatment must be initiated in combination with platinum-containing chemotherapy, **AND**
- The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy, **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**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

Retain all pathology imaging and investigative test results in the patient's medical records.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14932X	1120 mg	5	0.00	*8,287.91	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)

18481

Limited-stage small cell lung cancer

Clinical criteria:

- Patient must have received chemoradiation therapy (CRT), **AND**
- The condition must not have progressed following CRT, **AND**
- Patient must have had a WHO performance status of no greater than 1 at treatment initiation with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**

- The treatment must not exceed 24 months in total for this condition, measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

Injection

15330W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	5	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
					Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)

17505

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

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be undergoing combination treatment with tremelimumab for the first dose of treatment, **AND**
- 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 of a severity necessitating permanent treatment withdrawal, in the absence of disease progression to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI).

Authority Required (STREAMLINED)

17437

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

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.

Injection

15068C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	5	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
					Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)

18417

Urothelial carcinoma

Treatment Phase: Initial treatment - neoadjuvant setting

Clinical criteria:

- Patient must be initiating treatment with this drug for this condition; **OR**
- Patient must be transitioning from non-PBS to PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not have previously been treated with systemic therapy for muscle-invasive bladder cancer at the time this drug was initiated for this condition, **AND**
- The treatment must be once in a lifetime with this drug for this condition, **AND**
- The condition must be of muscle-invasive type disease with both: (i) clinical tumour stage of either T2, T3 or T4a, (ii) nodal status of up to stage N1, **AND**
- The treatment must be for neoadjuvant use in a patient preparing for radical cystectomy, **AND**
- Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- The treatment must be/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information).

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment where this prescription extends treatment beyond whichever comes first: (i) 4 cycles from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease progression recurrence despite treatment with this drug, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Authority Required (STREAMLINED)

18482

Urothelial carcinoma

Treatment Phase: Continuing treatment - adjuvant setting

Clinical criteria:

- Patient must have previously received PBS-subsidised neoadjuvant treatment with this drug in combination with gemcitabine plus cisplatin for this condition; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised treatment with this drug for this condition, (ii) previously treated in combination with cisplatin and gemcitabine as neoadjuvant treatment for this condition, **AND**
- Patient must have undergone radical cystectomy, **AND**
- The treatment must be for adjuvant therapy that is/was initiated within 6 months of radical cystectomy for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) maximum of 8 cycles for this condition from the first administered dose following radical cystectomy, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Treatment with this drug for this condition must not exceed 12 treatment cycles (neoadjuvant and adjuvant) in a lifetime.

Injection

15283J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	3	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
					Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

Note The recommended dose of durvalumab in the adjuvant setting is 1500 mg administered every 4 weeks for up to a maximum of 12 cycles (including 2 cycles of adjuvant durvalumab in combination with FLOT and 10 additional cycles of durvalumab 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 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

19159

Resected gastric and gastroesophageal junction adenocarcinoma

Treatment Phase: Adjuvant treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised neoadjuvant treatment with this drug for this condition; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) treated with combined therapy with durvalumab and FLOT as neoadjuvant treatment for this condition, **AND**
- The treatment must be for the purposes of adjuvant use following surgical resection, **AND**
- The treatment must be/have been initiated in combination with adjuvant FLOT for up to 2 cycles unless intolerant to FLOT requiring permanent discontinuation, **AND**
- The treatment must be sole PBS-subsidised systemic anti-cancer therapy from cycles 3-12 of adjuvant treatment, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) maximum of 12 cycles of adjuvant treatment for this condition from the first administered dose following surgery, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Where 'FLOT' is referenced in this restriction, it refers to the combination therapy of fluorouracil (5-FU) in combination with leucovorin (folinic acid), oxaliplatin and docetaxel.

Injection

15503Y

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	5	0.00	*11,052.53	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
					Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

Note The recommended dose of durvalumab in the neoadjuvant phase is 1500 mg administered every 4 weeks, for up to 2 cycles.

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 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

19222

Resectable gastric and gastroesophageal junction adenocarcinoma

Treatment Phase: Neoadjuvant treatment

Clinical criteria:

- Patient must be initiating treatment with this drug for this condition; **OR**
- Patient must be transitioning from existing non-PBS to PBS-subsidised supply of this drug, **AND**
- The condition must be Stage II or higher, **AND**
- The condition must be resectable, **AND**
- The treatment must be for the purpose of neoadjuvant use in a patient preparing for surgery, **AND**
- Patient must have a WHO performance status no greater than 1, **AND**
- The treatment must be initiated in combination with neoadjuvant FLOT, **AND**
- The condition must have been untreated with systemic therapy.

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment where this prescription extends treatment beyond whichever comes first: (i) 2 cycles of neoadjuvant treatment from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease progression/recurrence despite treatment with this drug, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Where 'FLOT' is referenced in this restriction, it refers to the combination therapy of fluorouracil (5-FU) in combination with leucovorin (folinic acid), oxaliplatin and docetaxel.

Injection

15514M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	1	0.00	*11,052.53	25.00	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.

Authority Required (STREAMLINED)

15471

Resectable non-small cell lung cancer (NSCLC)

Clinical criteria:

- The condition must be at least one of: (i) node positive, (ii) at least 4 cm in size, **AND**
- The treatment must be for neoadjuvant use in a patient preparing for surgical resection, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with platinum-based chemotherapy.

Treatment criteria:

- Patient must not be undergoing treatment with more than 3 PBS-subsidised doses of this drug per lifetime for this indication.

In non-squamous type NSCLC where any of the following is known to be present, this drug must not be a PBS benefit: (i) activating epidermal growth factor receptor (EGFR) gene mutation, (ii) anaplastic lymphoma kinase (ALK) gene rearrangement.

Injection

14232C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	2	0.00	*7,341.17	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
					Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)

NIVOLUMAB

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

18370

Urothelial carcinoma

Clinical criteria:

- The treatment must be for each of: (i) adjuvant therapy that is/was initiated within 6 months of radical surgical resection, (ii) muscle invasive type disease, (iii) disease considered to be at high risk of recurrence based on pathologic staging of radical surgery tissue (ypT2-ypT4a or ypN+), but yet to recur, (iv) use as the sole PBS-subsidised anti-cancer treatment for this condition, **AND**
- Patient must have received prior platinum containing neoadjuvant 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**
- Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1.

Treatment criteria:

- Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

An increase in repeat prescriptions, up to a value of 11, may only be sought where the prescribed dosing is 240 mg administered fortnightly.

Injection

14260M	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	480 mg	5	0.00	*9,741.71	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
						Opdivo [BQ] (nivolumab 100 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)

18070

Immunotherapy sensitive advanced or metastatic cancer

Clinical criteria:

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for the condition which treatment was commenced for.

Patients must only receive a maximum of 240 mg every two weeks, 360 mg every three weeks, or 480 mg every four weeks under a weight based or flat dosing regimen.

Injection

15224G	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	480 mg	13	0.00	*9,741.71	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
						Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)

NIVOLUMAB

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 Up to an additional 2 repeat prescriptions (7 in total) may be sought only where dosing is on a 2-weekly schedule in the first 16 weeks of treatment. This listing's stated number of repeat prescriptions is based on 4-weekly dosing.

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

Note Special Pricing Arrangements apply.

Authority Required

13900

Adjuvant treatment of stage II or III oesophageal cancer or gastro-oesophageal junction cancer

Clinical criteria:

- The condition must have histological evidence confirming a diagnosis of a least one of: (i) adenocarcinoma, (ii) squamous cell cancer; document this evidence in the patient's medical records, **AND**
- The condition must have been treated with neoadjuvant platinum-based chemoradiotherapy, **AND**
- The treatment must be for the purposes of adjuvant use following complete surgical resection that occurred within 16 weeks prior to initiating this drug, **AND**
- The condition must have evidence, through resected specimen, that residual disease meets the Tumour Nodes Metastases (TNM) staging system (as published by the Union for International Cancer Control) of either: (i) at least ypT1, (ii) at least ypN1; document this evidence in the patient's medical records, **AND**
- Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment with a dosing regimen as set out in the drug's approved Australian Product Information, **AND**
- Patient must not be undergoing PBS-subsidised treatment with this drug where this prescription extends treatment beyond whichever comes first: (i) 12 months from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease recurrence despite treatment with this drug; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Injection

13246E	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	480 mg	5	0.00	*9,741.71	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
						Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 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
16935
Stage IIIB, IIIC, IIID or Stage IV malignant melanoma
Treatment Phase: Initial treatment
Clinical criteria:

- The treatment must be in addition to complete surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **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.

When nivolumab is initially prescribed as a 3-weekly dosing regimen, patients must only receive a maximum of 240 mg every 3 weeks for 2 cycles (i.e., 1 repeat). When prescribed as a weight based or flat dose adjuvant regimen, patients must only receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment.

Authority Required
16962
Stage IIIB, IIIC, IIID or Stage IV malignant melanoma
Treatment Phase: Continuing treatment
Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have undergone 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.

When prescribed as a weight based or flat dose adjuvant regimen, patients must receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11906P	480 mg	5	0.00	*9,741.71	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
						Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 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.

Authority Required (STREAMLINED)
14727
Stage II or Stage III triple negative breast cancer
Clinical criteria:

- The treatment must be initiated in combination with neoadjuvant chemotherapy, **AND**
- The condition must not have progressed/recurred whilst on treatment with this drug.

Treatment criteria:

- Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction, **AND**
- Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; **OR**
- Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 4 repeat prescriptions.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13739D	400 mg	7	0.00	*14,873.23	25.00	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.

Authority Required (STREAMLINED)
17992
Intermediate or high risk of recurrence clear cell variant renal cell carcinoma (RCC)
Clinical criteria:

- Patient must have: (i) pT2 with Grade 4 or sarcomatoid features; or (ii) pT3, with any grade without nodal involvement (N0) or distant metastases (M0); or (iii) pT4, any grade N0 and M0; or (iv) any pT, any grade with nodal involvement and M0; or (v) metastatic disease and has undergone complete resection of primary and metastatic lesions, **AND**
- The treatment must be in addition to complete surgical resection, **AND**
- The treatment must commence within 12 weeks of complete resection, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must not have previously been treated with systemic therapy for this condition, prior to commencing treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised anti-cancer therapy for this condition, **AND**
- Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy.

Treatment criteria:

- Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; **OR**
- Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.

Injection

15210M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	7	0.00	*14,873.23	25.00	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.

Authority Required (STREAMLINED)

18413

Resectable locally advanced squamous cell carcinoma of the oral cavity, pharynx or larynx

Clinical criteria:

- Patient must have stage III-IVB squamous cell carcinoma of the oral cavity, pharynx or larynx, **AND**
- Patient must have tumour(s) that are resectable as assessed by the treating clinician; **OR**
- Patient must have undergone surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must not have experienced disease recurrence or progression while being treated with this drug for this condition, **AND**
- The treatment must be commenced as neoadjuvant therapy and continued in combination with radiation therapy with or without chemotherapy after surgical resection; **OR**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The treatment must not exceed a total of 12 cumulative months, either as: (i) 17 doses (based on a 3-weekly dose regimen), (ii) 8 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless of if it was PBS/non-PBS subsidised.

Treatment criteria:

- Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; **OR**
- Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.

Injection

15335D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	7	0.00	*14,873.23	25.00	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.

Authority Required (STREAMLINED)

19192

Immunotherapy sensitive advanced or metastatic cancer

Clinical criteria:

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for the condition which treatment was commenced for.

Treatment criteria:

- Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; **OR**
- Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.

Injection

15523B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	7	0.00	*14,873.23	25.00	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

10688

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

10676

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	0.00	*14,873.23	25.00	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

PEMBROLIZUMAB

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

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

14770

Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

- The treatment must be in addition 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 have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).

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 Commencing treatment within 12 weeks of complete resection means either 12 weeks after resection or 12 weeks prior to resection.

Where non-PBS-subsidised supply has occurred, the total amount of PBS-subsidised supply is intended to be the balance of 18 doses less the number of non-PBS-subsidised doses.

Authority Required

14786

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Treatment criteria:

- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing.

Clinical criteria:

- Patient must not have experienced disease recurrence, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).

Injection

12120X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	7	0.00	*7,506.39	25.00	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

TISLELIZUMAB

Caution In the first few months after starting immunotherapy, a transient tumour flare may occur that may be mistaken as disease progression despite an overall positive response to treatment.

Caution When administering tislelizumab in combination with chemotherapy, administer tislelizumab before chemotherapy when both are given on the same day.

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)

19495

Advanced or metastatic gastro-oesophageal cancer

Clinical criteria:

- Patient must be untreated (up until initiating this drug) with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer, **AND**
- Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- Patient must not have developed disease progression while receiving treatment for this condition.

Injection

14765D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	7	0.00	*6,621.29	25.00	Tevimbra [IE] (tislelizumab 100 mg/10 mL injection, 10 mL vial)

TORIPALIMAB

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

17616

Recurrent or metastatic nasopharyngeal carcinoma

Clinical criteria:

- Patient must have a WHO performance status of no higher than 2, **AND**
- The condition must not be amenable to salvage surgery or radiotherapy, **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 commenced in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting (i.e. used in combination with PBC for 6 cycles in the first line setting unless intolerance/contraindication is confirmed); **OR**
- The treatment must be the sole PBS-subsidised therapy at the time of treatment initiation where the condition has progressed following treatment with PBC (i.e. used as monotherapy in the second line setting).

Treatment criteria:

- Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 cumulative months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

An increase above the listed maximum amount may only be requested when a dose of 3 mg/kg every 2 weeks is prescribed in the second line setting.

Injection

15126D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
240 mg	7	0.00	*9,728.98	25.00	Zytorvi [RZ] (Toripalimab 240 mg/6 mL injection, 6 mL vial)

VEGF/VEGFR (Vascular Endothelial Growth Factor / -Receptor) inhibitors

BEVACIZUMAB

Injection

12508H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1800 mg	7	0.00	*900.77	25.00	Abevmy [SZ] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
					Abevmy [SZ] (bevacizumab 400 mg/16 mL injection, 16 mL vial)
					Mvasi [AN] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
					Mvasi [AN] (bevacizumab 400 mg/16 mL injection, 16 mL vial)
					Vegzelma [EW] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
					Vegzelma [EW] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

Other monoclonal antibodies and antibody drug conjugates

AMIVANTAMAB

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 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

16472

Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation, **AND**
- Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition, **AND**
- Patient must not have previously received this drug for this condition; **OR**
- Patient must be each of: (i) currently receiving non-PBS-subsidised supply for this drug for this PBS indication, (ii) free of disease progression since commencing non-PBS-subsidised supply, **AND**
- The treatment must be/have been in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting, (i.e. used in combination with PBC in the first line setting); **OR**
- The treatment must be the sole PBS-subsidised therapy where the condition has progressed following treatment with platinum-based chemotherapy, (i.e. used as monotherapy in the second line setting).

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

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

Injection

14802C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2100 mg	5	0.00	*9,168.23	25.00	Rybrevant [JC] (amivantamab 350 mg/7 mL injection, 7 mL vial)

AMIVANTAMAB

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 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

16402

Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

14807H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2100 mg	7	0.00	*9,168.23	25.00	Rybrevant [JC] (amivantamab 350 mg/7 mL injection, 7 mL vial)

BLINATUMOMAB

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

Note 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 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

18579

Acute lymphoblastic leukaemia

Treatment Phase: Consolidation treatment of relapsed or refractory B-precursor cell ALL

Clinical criteria:

- Patient must have previously received PBS-subsidised induction treatment with this drug for relapsed or refractory B-precursor cell ALL, **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.

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 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.

Injection

11115B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	2	0.00	*78,488.03	25.00	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 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 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

18651

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment - balance of supply - relapsed or refractory B-precursor cell ALL

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 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.

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.

Injection

11119F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	0	0.00	*78,488.03	25.00	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 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 authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No increase in the maximum 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

18871

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment of relapsed or refractory B-precursor cell ALL

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 not have received more than 1 line of salvage therapy, **AND**
- The condition must be one of the following: (i) untreated with this drug for Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL), (ii) treated with this drug for Pre-B-cell ALL, but the condition has not relapsed within 6 months of completing that course of treatment, **AND**
- The condition must have more than 5% blasts in bone marrow; **OR**
- The condition must have measurable residual disease based on measurement in bone marrow following complete remission, **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) details of the proposed prescription; and

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

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

(4) for Philadelphia chromosome positive patients:

(i) the date of the most recent treatment with a TKI (in combination with chemotherapy); OR

(ii) if applicable the date of initial combined treatment with TKI and corticosteroids (if unable to tolerate chemotherapy).

(5) if applicable, the date of completion of blinatumomab treatment for Pre-B-cell ALL in CR and the date of the patient's subsequent relapse; and

(6) the percentage blasts in bone marrow count measured 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	0	0.00	*67,295.39	25.00	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 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 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

18650

Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)

Treatment Phase: Initial treatment of newly-diagnosed Pre-B-cell ALL in the consolidation phase

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 acute lymphoblastic leukaemia (ALL); **OR**
- Patient must have Philadelphia chromosome positive ALL, and both (i) have achieved complete remission following combination therapy with a tyrosine kinase inhibitor and corticosteroids (ii) be unable to tolerate chemotherapy, **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.

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.

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

(1) details of the proposed prescription; and

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

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

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

(5) the date of the course of combination therapy with a tyrosine kinase inhibitor and corticosteroid for Philadelphia chromosome positive patients.

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 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

18688

Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)

Treatment Phase: Continuing treatment of Pre-B-cell ALL in complete haematological remission (CR)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission, **AND**
- Patient must not have developed disease progression while receiving 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 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
11867N	784 mcg	1	0.00	*78,488.03	25.00	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

18300

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 in a lifetime, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

The authority application 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 histopathology report from an Approved Pathology Authority demonstrating the patient has a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and

(b) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample or of a flow cytometric analysis of lymphoma cells of the blood showing CD30 positivity of at least 3% of malignant cells; and

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

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

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

(i) details of the proposed prescription; 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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11651F	180 mg	3	0.00	*18,076.19	25.00	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

BRENTUXIMAB VEDOTIN

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

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

18503

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, **AND**
- The treatment must not exceed 4 cycles under this restriction.

Applications for authorisation of 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 or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and

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

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

(d) 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.

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

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

(i) details of the proposed prescription; 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).

Injection

10172J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	3	0.00	*18,076.19	25.00	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. Monday to Friday).

Authority Required

13261

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not have developed disease progression while 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, **AND**
- The treatment must not exceed 12 cycles under this restriction in a lifetime.

Injection

10180T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	0.00	*18,076.19	25.00	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. Monday to Friday).

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

17507

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 developed disease progression 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 for this condition in a lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11067L	200 mg	11	0.00	*18,076.19	25.00	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. Monday to Friday).

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

17508

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, **AND**
- Patient must not have received prior treatment with this drug for this condition; **OR**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11080E	200 mg	3	0.00	*18,076.19	25.00	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. Monday to Friday).

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

17440

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 developed disease progression 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 for this condition in a lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11086L	200 mg	11	0.00	*18,076.19	25.00	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. Monday to Friday).

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
17438
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, **AND**
- Patient must not have received prior treatment with this drug for this condition; **OR**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11089P	200 mg	3	0.00	*18,076.19	25.00	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. Monday to Friday).

Authority Required
13181
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 in a lifetime.

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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11661R	180 mg	11	0.00	*18,076.19	25.00	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. Monday to Friday).
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
19460
Advanced Stage CD30 positive Hodgkin lymphoma
Clinical criteria:

- 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 a multi-drug chemotherapy regimen, **AND**
- The treatment must not be more than 6 treatment cycles under this restriction in a lifetime.

At the time of the authority application, medical practitioners must request the appropriate maximum amount and number of repeats to complete up to 6 cycles of treatment based on the following:

- Up to a maximum of 180 mg and 5 repeats may be requested where dosing is administered as part of the BrECADD regimen (i.e. in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone); or
- Up to a maximum of 120 mg and 11 repeats may be requested where dosing is administered as part of the A+AVD regimen (i.e. in combination with doxorubicin, vinblastine and dacarbazine)

Injection

15080Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
180 mg	11	0.00	*18,076.19	25.00	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. Monday to Friday).

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

Authority Required

13212

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**
- Patient must not have developed 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.

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

12632W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	1	0.00	*18,076.19	25.00	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

BRENTUXIMAB VEDOTIN

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

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

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

18301

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 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 a histology report on the tumour sample from an Approved Pathology Authority showing CD30 positivity of at least 3% malignant cells; and

(b) The date of initial diagnosis of Peripheral T-cell lymphoma.

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

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

(i) details of the proposed prescription; 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).

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12656D	200 mg	5	0.00	*18,076.19	25.00	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

ELOTUZUMAB

Note Continuing treatment with elotuzumab is only available through the Pharmaceutical Benefits Scheme (PBS) for existing eligible patients from 1 December 2024.

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

Note Special Pricing Arrangements apply.

Authority Required

12847

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.

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
12995Y	1200 mg	5	0.00	*5,158.88	25.00	Empliciti [BQ] (elotuzumab 300 mg injection, 1 vial)
						Empliciti [BQ] (elotuzumab 400 mg injection, 1 vial)

ENFORTUMAB VEDOTIN

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)

19059

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

Clinical criteria:

- The condition must have progressed on/following both: (i) platinum-based chemotherapy, (ii) programmed cell death 1/ligand 1 (PD-1/PD-L1) inhibitor therapy; **OR**
- The condition must have progressed on/following platinum-based chemotherapy, whilst PD-1/PD-L1 inhibitor therapy resulted in an intolerance that required treatment cessation, **AND**

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this indication in any prior line of treatment, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must be undergoing treatment with this drug for the first time; **OR**
- Patient must be undergoing continuing treatment with this drug, with each of the following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13634N	125 mg	8	0.00	*6,348.66	25.00	Padcev [LL] (enfortumab vedotin 20 mg injection, 1 vial)
						Padcev [LL] (enfortumab vedotin 30 mg injection, 1 vial)

ENFORTUMAB VEDOTIN

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)

19195

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

Clinical criteria:

- Patient must not have received prior systemic therapy for this condition at the initiation of treatment with this drug, with the exception of neoadjuvant/adjuvant chemotherapy, **AND**
- Patient must have/have had a WHO performance status score of no greater than 2 at treatment initiation with this drug.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of no more than 24 months of: (i) enfortumab vedotin, (ii) pembrolizumab; **OR**
- Patient must be undergoing monotherapy with this drug after exceeding a lifetime total of 24 cumulative months of combination therapy consisting of: (i) enfortumab vedotin, (ii) pembrolizumab, from the first administered dose; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to pembrolizumab, requiring temporary/permanent discontinuation; document the details in the patient's medical records, **AND**
- Patient must be undergoing treatment with this drug for the first time; **OR**
- Patient must be undergoing continuing treatment with this drug, with each of the following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.

Authority Required (STREAMLINED)

19060

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

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

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2026, **AND**
- Patient must have/have had a WHO performance status score of no greater than 2 prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of no more than 24 months of: (i) enfortumab vedotin, (ii) pembrolizumab; **OR**
- Patient must be undergoing monotherapy with this drug after exceeding a lifetime total of 24 cumulative months of combination therapy consisting of: (i) enfortumab vedotin, (ii) pembrolizumab, from the first administered dose; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to pembrolizumab, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only.
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
15522Y	125 mg	7	0.00	*6,348.66	25.00	Padcev [LL] (enfortumab vedotin 20 mg injection, 1 vial)
						Padcev [LL] (enfortumab vedotin 30 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

12559

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	0.00	*9,434.89	25.00	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

12566

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
12904E	5 mg	1	0.00	*9,434.89	25.00	Mylotarg [PF] (gemtuzumab ozogamicin 5 mg injection, 1 vial)

GLOFITAMAB

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 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

18124

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Initial treatment (Cycle 1, Day 15)

Clinical criteria:

- Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition, **AND**
- Patient must be unsuitable for stem cell transplant, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received or intend to receive a Cycle 1, Day 8 dose of glofitamab for this indication, **AND**
- The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components.

Glofitamab should be administered as an intravenous infusion according to the dose step-up schedule in Cycle 1 (2.5 mg on Day 8 and 10 mg on Day 15) leading to the recommended dosage of 30 mg on Day 1 of Cycles 2-12. Refer to the TGA approved Product Information.

Injection

15266L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10000 mcg	0	0.00	*5,479.38	25.00	Columvi [RO] (Glofitamab 10 mg/10 mL injection, 10 mL vial)

GLOFITAMAB

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 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

18107

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Initial treatment (Cycle 1, Day 8)

Clinical criteria:

- Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition, **AND**
- Patient must be unsuitable for stem cell transplant, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received or intend to receive a single pre-treatment dose of obinutuzumab for this indication, **AND**
- The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components.

Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.

Glofitamab should be administered as an intravenous infusion according to the dose step-up schedule in Cycle 1 (2.5 mg on Day 8 and 10 mg on Day 15) leading to the recommended dosage of 30 mg on Day 1 of Cycles 2-12. Refer to the TGA approved Product Information.

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

Injection

15269P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2500 mcg	0	0.00	*1,474.51	25.00	Columvi [RO] (Glofitamab 2.5 mg/2.5 mL injection, 2.5 mL vial)

GLOFITAMAB

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 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

18105

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Continuing treatment (Cycles 2-12)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a total of 12 cycles of this drug for this indication, regardless of whether treatment was non-PBS or PBS-subsidised.

Authority Required

18061

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS condition prior to 1 March 2026, **AND**
- Patient must have been unable to receive treatment with CAR-T cell therapy prior to commencing treatment with this drug for this condition, **AND**
- Patient must have been unsuitable for stem cell transplant prior to commencing treatment with this drug for this condition, **AND**
- Patient must have had a WHO performance status of 2 or less prior to commencing 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 given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components, **AND**
- The treatment must not exceed a total of 12 cycles of this drug for this indication, regardless of whether treatment was non-PBS or PBS-subsidised.

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
15227K	30000 mcg	10	0.00	*16,159.04	25.00	Columvi [RO] (Glofitamab 10 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)

18071

Immunotherapy sensitive advanced or metastatic cancer

Clinical criteria:

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for the condition which treatment was commenced for.

The stated maximum amount in this listing is 360 mg however alternative dosing schedules may be prescribed in a quantity up to this amount, but need not be this amount for every cancer type.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15237Y	360 mg	4	0.00	*43,495.07	25.00	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)
						Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial)

IPILIMUMAB

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)

18069

Stage III melanoma

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must be in addition to complete surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab.

Prescribed amounts must be consistent with the treatment protocol used for an individual patient.

When ipilimumab is initially prescribed as a 3-weekly dosing regimen, patients must only receive a maximum of 80 mg every 3 weeks for 2 cycles (i.e., 1 repeat), in combination with nivolumab.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2638W	80 mg	1	0.00	*10,978.43	25.00	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)
						Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial)

MOGAMULIZUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

13246

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 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 therapy for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15277C	120 mg	7	0.00	*13,420.91	25.00	POTELIGEO [KO] (mogamulizumab 20 mg/5 mL injection, 5 mL vial)

MOGAMULIZUMAB

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 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

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

Note Special Pricing Arrangements apply.

Authority Required

18425

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
- Patient must be ineligible for stem cell transplant, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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

(i) details of the proposed prescription; 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).

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15306N	120 mg	3	0.00	*13,420.91	25.00	POTELIGEO [KO] (mogamulizumab 20 mg/5 mL injection, 5 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12944G	1200 mg	7	0.00	*10,677.14	25.00	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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12965J	1200 mg	13	0.00	*10,677.14	25.00	Trodelvy [GI] (sacituzumab govitecan 180 mg injection, 1 vial)

TAFASITAMAB

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

Note Special Pricing Arrangements apply.

Authority Required

18931

Relapsed or refractory follicular lymphoma

Treatment Phase: Initial treatment (Cycles 1 - 5 inclusive)

Clinical criteria:

- The treatment must be/have been initiated in combination with rituximab and lenalidomide, **AND**
- The condition must have relapsed or been refractory to at least one prior therapy prior to initiating treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 5 cycles of treatment under this restriction.

The treatment must not exceed a total of 12 cycles in a lifetime for this indication measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15438M	1400 mg	15	0.00	*8,514.84	25.00	MINJUVI [XB] (Tafasitamab 200 mg injection, 1 vial)

TAFASITAMAB

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

Note Special Pricing Arrangements apply.

Authority Required

18976

Relapsed or refractory follicular lymphoma

Treatment Phase: Continuing treatment (Cycles 6 - 12 inclusive)

Clinical criteria:

- The treatment must be in combination with lenalidomide, **AND**
- Patient must have previously received treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 7 cycles of treatment under this restriction, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

The treatment must not exceed a total of 12 cycles in a lifetime for this indication measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15496N	1400 mg	13	0.00	*8,514.84	25.00	MINJUVI [XB] (Tafasitamab 200 mg injection, 1 vial)

TREMELIMUMAB

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)

17477

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

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be undergoing combination treatment with PBS-subsidised durvalumab, **AND**
- 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 of a severity necessitating permanent treatment withdrawal, in the absence of disease progression to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI).

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment with this drug for this indication more than once per lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15108E	300 mg	0	0.00	*16,931.57	25.00	Imjudo [AP] (tremelimumab 300 mg/15 mL injection, 15 mL vial)

Combinations of monoclonal antibodies and antibody drug conjugates

NIVOLUMAB + RELATLIMAB

Caution Combination treatment with nivolumab and relatlimab is associated with an increased incidence and severity of immune-related adverse reactions compared with nivolumab monotherapy. Monitoring at least prior to each dose is recommended.
Note Only one prescribed amount can be used for dispensing and claiming purposes. For nivolumab with relatlimab (Opdualag), nivolumab has been selected as the primary ingredient and the maximum amount reflects the maximum amount of nivolumab only. The prescribed amount of nivolumab will be used to determine the number of vials needed.
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)

16151

Unresectable Stage III or Stage IV malignant melanoma

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 not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.

The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.

The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14677L	480 mg	11	0.00	*18,590.09	25.00	Opdualag [BQ] (nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial)

NIVOLUMAB + RELATLIMAB

Caution Combination treatment with nivolumab and relatlimab is associated with an increased incidence and severity of immune-related adverse reactions compared with nivolumab monotherapy. Monitoring at least prior to each dose is recommended.
Note Only one prescribed amount can be used for dispensing and claiming purposes. For nivolumab with relatlimab (Opdualag), nivolumab has been selected as the primary ingredient and the maximum amount reflects the maximum amount of nivolumab only. The prescribed amount of nivolumab will be used to determine the number of vials needed.

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)

16881

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 either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; **OR**
- Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be uveal melanoma, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must weigh 40 kg or more
- Patient must be at least 12 years of age.

Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.

The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.

The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14664T	480 mg	8	0.00	*18,590.09	25.00	Opdualag [BQ] (nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial)

OTHER ANTINEOPLASTIC AGENTS

Platinum compounds

CARBOPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7222D	900 mg	5	0.00	*210.53	25.00	Carboplatin Accord [OC] (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	0.00	*189.21	25.00	Cisplatin Accord [OC] (cisplatin 50 mg/50 mL injection, 50 mL vial)
						Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial)

OXALIPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7253R	300 mg	11	0.00	*200.66	25.00	OXALIPLATIN BAXTER [BX] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)
						Oxaliplatin Accord [OC] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)

Proteasome inhibitors

BORTEZOMIB

Restricted benefit

11099

Multiple myeloma

Restricted benefit

13745

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Administration on Days 1, 8, 15 and 22 of six treatment cycles (28 days per cycle) in total

Treatment criteria:

- Patient must be undergoing concurrent treatment with PBS-subsidised daratumumab for this PBS indication.

Injection

12219D	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	3000 mcg	15	0.00	*160.31	25.00	BORTEZOMIB EUGIA [YG] (bortezomib 3.5 mg injection, 1 vial)
						BORTEZOMIB MEDSURGE [DZ] (bortezomib 3.5 mg injection, 1 vial)
						BORTRACZO [JM] (bortezomib 2.5 mg/mL injection, 1 mL vial)
						BORTRACZO [JM] (bortezomib 3.5 mg/1.4 mL injection, 1.4 mL vial)
						Bortezom [CR] (bortezomib 3.5 mg injection, 1 vial)
						Bortezomib Accord [OC] (bortezomib 1 mg injection, 1 vial)
						Bortezomib Accord [OC] (bortezomib 2.5 mg/mL injection, 1 mL vial)
						Bortezomib Accord [OC] (bortezomib 3.5 mg injection, 1 vial)
						Bortezomib Accord [OC] (bortezomib 3.5 mg/1.4 mL injection, 1.4 mL 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 2.5 mg injection, 1 vial)
						Bortezomib Juno [JU] (bortezomib 3.5 mg injection, 1 vial)
						DBL Bortezomib [PF] (bortezomib 3 mg injection, 1 vial)
						DBL Bortezomib [PF] (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	0.00	*2,584.29	25.00	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	0.00	*3,399.21	25.00	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 Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

14389

Relapsed and/or refractory multiple myeloma

Treatment Phase: Initial treatment for Cycles 1 to 3

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 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.

Provide details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of the 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 once only through the Authority application for lenalidomide.

Authority Required (STREAMLINED)

14363

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment for Cycles 3 to 12

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 progressive disease 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.

Authority Required (STREAMLINED)

14364

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment for Cycles 13 onwards

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 progressive disease 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

13637R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
60 mg	17	0.00	*1,361.92	25.00	Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial)
					Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial)
					Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial)

Histone deacetylase (HDAC) inhibitors

ROMIDEPSIN

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 amount or number of units may be authorised.

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

Authority Required

18800

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, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Injection

15379K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
40 mg	5	0.00	*5,101.15	25.00	ROMIDEPSIN-REACH [RQ] (romidepsin 10 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack)

ROMIDEPSIN

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 amount or number of units may be authorised.

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

Authority Required

18832

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, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Authority Required

18736

Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma

Treatment Phase: Grandfather arrangement - Transitioning from non-PBS-subsidised treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2026, **AND**
- The condition must be relapsed or chemotherapy refractory, **AND**
- Patient must have undergone appropriate prior front-line curative intent chemotherapy prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed progressive disease while receiving treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

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

15405T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
40 mg	8	0.00	*5,101.15	25.00	ROMIDEPSIN-REACH [RQ] (romidepsin 10 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack)

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	0.00	*235.55	25.00	Arsenic Trioxide Accord [OC] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) 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	0.00	*235.55	25.00	Arsenic Trioxide Accord [OC] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

7241D

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

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.

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

Injection

10140Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3 mg	13	0.00	*633.71	25.00	Eribulin Dr.Reddy's [RZ] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)
					Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

ERIBULIN

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.

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

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.

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

Injection

11199K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3 mg	7	0.00	*633.71	25.00	Eribulin Dr.Reddy's [RZ] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)
					Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

TEBENTAFUSP

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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)

15085

Advanced (unresectable or metastatic) uveal melanoma

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; **OR**
- Patient must have previously received inpatient treatment with this drug for this condition in the public hospital setting, **AND**
- Patient must not receive PBS-subsidised treatment with this drug for this condition if it is no longer determined to be clinically beneficial by the treating clinician.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13824N	136 mcg	7	0.00	*35,799.01	25.00	Kimmtrak [WM] (tebentafusp 100 microgram/0.5 mL injection, 0.5 mL vial)

TEBENTAFUSP

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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 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

14813

Advanced (unresectable or metastatic) uveal melanoma

Treatment Phase: Initial treatment - day 1

Clinical criteria:

- Patient must have HLA-A*02: 01-positive disease, **AND**
- Patient must have uveal melanoma that has been confirmed either (i) histologically, (ii) cytologically, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior systemic therapy for metastatic disease.

Population criteria:

- Patient must be at least 18 years of age.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.

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

Positive HLA-A*02: 01 assessment must be documented in the patient's medical records.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13818G	20 mcg	0	0.00	*17,969.28	25.00	Kimmtrak [WM] (tebentafusp 100 microgram/0.5 mL injection, 0.5 mL vial)

TEBENTAFUSP

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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 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)

14825

Advanced (unresectable or metastatic) uveal melanoma

Treatment Phase: Initial treatment - day 15

Clinical criteria:

- Patient must have HLA-A*02: 01-positive disease, **AND**
- Patient must have previously received PBS-subsidised initial day 8 treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an

appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.

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

Positive HLA-A*02: 01 assessment must be documented in the patient's medical records.

Injection

13822L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
68 mcg	0	0.00	*17,969.28	25.00	Kimmtrak [WM] (tebentafusp 100 microgram/0.5 mL injection, 0.5 mL vial)

TEBENTAFUSP

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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 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)

14821

Advanced (unresectable or metastatic) uveal melanoma

Treatment Phase: Initial treatment - day 8

Clinical criteria:

- Patient must have HLA-A*02: 01-positive disease, **AND**
- Patient must have previously received PBS-subsidised initial day 1 treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.

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

Positive HLA-A*02: 01 assessment must be documented in the patient's medical records.

Injection

13833C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
30 mcg	0	0.00	*17,969.28	25.00	Kimmtrak [WM] (tebentafusp 100 microgram/0.5 mL injection, 0.5 mL vial)

Combinations of antineoplastic agents

DAUNORUBICIN + CYTARABINE

Caution Liposomal daunorubicin and cytarabine (Vyxeos) must not be substituted or interchanged with other daunorubicin and/or cytarabine containing products. Due to substantial differences in the pharmacokinetic parameters, the dose and schedule recommendations for Vyxeos are different from other medications that contain daunorubicin and/or cytarabine in other forms.

Note Only one prescribed amount can be used for dispensing and claiming purposes. For daunorubicin with cytarabine (Vyxeos), daunorubicin has been selected as the primary ingredient and the maximum amount reflects the maximum amount of daunorubicin only. The prescribed amount of daunorubicin will be used to determine the number of vials needed.

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 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

16187

Acute Myeloid Leukaemia

Treatment Phase: Induction therapy

Clinical criteria:

- Patient must not have received prior chemotherapy as induction therapy for this condition, **AND**
- The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality), **AND**
- The condition must not be either: (i) internal tandem duplication (ITD); (ii) tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3), mutation positive, **AND**
- Patient must not have favourable cytogenetic risk acute myeloid leukaemia (AML), **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**

- The treatment must not exceed two cycles of induction therapy under this restriction.

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

The prescriber must confirm whether the patient has newly diagnosed therapy-related AML or AML-MRC. The test result and date of testing must be provided at the time of application and documented in the patient's file.

The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.

Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14663R	97 mg	4	0.00	*25,129.58	25.00	Vyxeos [JA] (daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial)

DAUNORUBICIN + CYTARABINE

Caution Liposomal daunorubicin and cytarabine (Vyxeos) must not be substituted or interchanged with other daunorubicin and/or cytarabine containing products. Due to substantial differences in the pharmacokinetic parameters, the dose and schedule recommendations for Vyxeos are different from other medications that contain daunorubicin and/or cytarabine in other forms.

Note Only one prescribed amount can be used for dispensing and claiming purposes. For daunorubicin with cytarabine (Vyxeos), daunorubicin has been selected as the primary ingredient and the maximum amount reflects the maximum amount of daunorubicin only. The prescribed amount of daunorubicin will be used to determine the number of vials needed.

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 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

16197

Acute Myeloid Leukaemia

Treatment Phase: Consolidation therapy

Clinical criteria:

- The treatment must be for consolidation treatment following induction treatment with this product, **AND**
- The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality), **AND**
- The treatment must not exceed two cycles of consolidation therapy under this restriction.

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

The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.

Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14672F	64 mg	3	0.00	*16,799.57	25.00	Vyxeos [JA] (daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial)

Efficient Funding of Chemotherapy (Public Hospital)

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ANTINEOPLASTIC AND IMMUNOMODULATING AGENTS

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ALKYLATING AGENTS

Nitrogen mustard analogues

BENDAMUSTINE

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.

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

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.

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

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.

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

Injection

10760H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	0.00	*177.92	25.00	BENDAMUSTINE EUGIA [YG] (bendamustine hydrochloride 25 mg injection, 1 vial)
					BENDAMUSTINE EUGIA [YG] (bendamustine hydrochloride 100 mg injection, 1 vial)
					BENDAMUSTINE HYDROCHLORIDE MEDSURGE [DZ] (bendamustine hydrochloride 25 mg injection, 1 vial)
					BENDAMUSTINE HYDROCHLORIDE MEDSURGE [DZ] (bendamustine hydrochloride 100 mg injection, 1 vial)
					Bendamustine Sandoz [SZ] (bendamustine hydrochloride 25 mg injection, 1 vial)
					Bendamustine Sandoz [SZ] (bendamustine hydrochloride 100 mg injection, 1 vial)

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10760H						Bendamustine Viatris [AF] (bendamustine hydrochloride 25 mg injection, 1 vial)
						Bendamustine Viatris [AF] (bendamustine hydrochloride 100 mg injection, 1 vial)

CYCLOPHOSPHAMIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4327R	2800 mg	17	0.00	* 142.35	25.00	CYCLOPHOSPHAMIDE-REACH [RQ] (cyclophosphamide 500 mg injection, 1 vial)
						CYCLOPHOSPHAMIDE-REACH [RQ] (cyclophosphamide 1 g injection, 1 vial)
						Endoxan [BX] (cyclophosphamide 1 g injection, 1 vial)
						Endoxan [BX] (cyclophosphamide 2 g injection, 1 vial)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15395G	2800 mg	17	0.00	* 1,049.56	25.00	Cyclophosphamide (NorthStar, USA) [RQ] (cyclophosphamide 1 g injection, 1 vial)
						Cyclophosphamide (NorthStar, USA) [RQ] (cyclophosphamide 2 g injection, 1 vial)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15576T	2800 mg	17	0.00	* 972.56	25.00	Cyclophosphamide (Seacross Pharmaceuticals, UK) [RQ] (cyclophosphamide 1 g injection, 1 vial)
						Cyclophosphamide (Seacross Pharmaceuticals, UK) [RQ] (cyclophosphamide 2 g injection, 1 vial)

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15520W	2800 mg	17	0.00	* 992.56	25.00	Cyclophosphamide (Sagent, USA) [RQ] (cyclophosphamide 2 g injection, 1 vial)

IFOSFAMIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4448D	4000 mg	19	0.00	*245.52	25.00	Holoxan [BX] (ifosfamide 1 g injection, 1 vial)
						Holoxan [BX] (ifosfamide 2 g injection, 1 vial)

ANTIMETABOLITES

Folic acid analogues

METHOTREXATE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4502Y	250 mg	5	0.00	*118.06	25.00	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)
						DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)
						Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)
						Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)

METHOTREXATE

Restricted benefit

6276

Patients receiving treatment with a high dose regimen

Injection

4512L	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	20000 mg	0	0.00	*845.96	25.00	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)
						DBL Methotrexate [PF] (methotrexate 1 g/10 mL injection, 10 mL vial)
						Methotrexate Accord [OD] (methotrexate 1 g/10 mL injection, 10 mL vial)
						Methotrexate Ebewe [SZ] (methotrexate 5 g/50 mL injection, 50 mL vial)

PEMETREXED

Injection

4600D	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1100 mg	5	0.00	*173.94	25.00	PEMETREXED EUGIA [YG] (pemetrexed 500 mg injection, 1 vial)
						Pemetrexed Accord [OD] (pemetrexed 100 mg injection, 1 vial)
						Pemetrexed Accord [OD] (pemetrexed 500 mg injection, 1 vial)
						Pemetrexed Accord [OD] (pemetrexed 1 g injection, 1 vial)
						Pemetrexed Ever Pharma [IT] (pemetrexed 100 mg/4 mL injection, 4 mL vial)
						Pemetrexed Ever Pharma [IT] (pemetrexed 500 mg/20 mL injection, 20 mL vial)
						Pemetrexed Ever Pharma [IT] (pemetrexed 1 g/40 mL injection, 40 mL vial)
						Pemetrexed SUN [RA] (pemetrexed 100 mg injection, 1 vial)
						Pemetrexed SUN [RA] (pemetrexed 500 mg injection, 1 vial)
						Pemetrexed SUN [RA] (pemetrexed 1 g injection, 1 vial)
						Pemetrexed-AFT [AE] (pemetrexed 100 mg injection, 1 vial)
						Pemetrexed-AFT [AE] (pemetrexed 500 mg injection, 1 vial)

PRALATREXATE

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.

Authority Required

18832

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, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Injection

11272G	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	80 mg	11	0.00	*4,234.56	25.00	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

PRALATREXATE

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.

Authority Required

18800

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, **AND**

- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Injection

11293J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
80 mg	5	0.00	*4,234.56	25.00	Folotyn [MF] (pralatrexate 20 mg/mL injection, 1 mL vial)

RALTITREXED

Injection

4610P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7 mg	8	0.00	*1,135.40	25.00	Tomudex [PF] (raltitrexed 2 mg injection, 1 vial)

Purine analogues

CLADRIBINE

Authority Required (STREAMLINED)

6265

Hairy cell leukaemia

Injection

4326Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
17 mg	6	0.00	*901.82	25.00	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 with the brand Fludarabine Juno and pharmaceutical benefits that have the form fludarabine phosphate 50 mg/2 mL injection with the brand Fludarabine Ebewe are equivalent for the purposes of substitution.

Injection

4393F

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
55 mg	29	0.00	*212.92	25.00	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

4357H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
7000 mg	15	0.00	*890.56	25.00	Pfizer Australia Pty Ltd [PF] (cytarabine 100 mg/5 mL injection, 5 x 5 mL vials)

FLUOROURACIL

Restricted benefit

6266

Patients requiring administration of fluorouracil by intravenous infusion

Injection

4394G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5500 mg	11	0.00	*115.40	25.00	Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 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

Restricted benefit

6297

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	0.00	*98.40	25.00	Fluorouracil Accord [OC] (fluorouracil 500 mg/10 mL injection, 10 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)

GEMCITABINE

Caution Pharmaceutical benefits containing gemcitabine may have different concentrations.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4439P	3000 mg	17	0.00	*155.61	25.00	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)
						GEMCITABINE EUGIA [YG] (gemcitabine 1 g/25 mL injection, 25 mL vial)
						GEMCITABINE EUGIA [YG] (gemcitabine 2 g/50 mL injection, 50 mL vial)
						Gemcitabine Irem [KS] (gemcitabine 1 g/26.3 mL injection, 26.3 mL vial)
						Gemcitabine Irem [KS] (gemcitabine 2 g/52.6 mL injection, 52.6 mL vial)

PLANT ALKALOIDS AND OTHER NATURAL PRODUCTS

Vinca alkaloids and analogues

VINBLASTINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4618C	20 mg	17	0.00	*171.48	25.00	DBL Vinblastine [PF] (vinblastine sulfate 10 mg/10 mL injection, 5 x 10 mL vials)

VINCRISTINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4619D	2 mg	7	0.00	*129.02	25.00	DBL Vincristine Sulfate [PF] (vincristine sulfate 1 mg/mL injection, 5 x 1 mL vials)

VINORELBINE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4620E	70 mg	7	0.00	*154.46	25.00	Vinorelbine Ebewe [SZ] (vinorelbine 10 mg/mL injection, 1 mL vial)
						Vinorelbine Ebewe [SZ] (vinorelbine 50 mg/5 mL injection, 5 mL vial)

Podophyllotoxin derivatives

ETOPOSIDE

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4428C	440 mg	14	0.00	*286.06	25.00	Etopophos [LM] (etoposide phosphate 1.136 g (etoposide 1 g) injection, 1 vial)
						Etoposide Ebewe [SZ] (etoposide 100 mg/5 mL injection, 5 x 5 mL vials)

Taxanes

CABAZITAXEL

Note Where the term 'novel hormonal drug' appears in this restriction, it refers to: (i) abiraterone, (ii) abiraterone and methylprednisolone, (iii) abiraterone and prednisolone, (iv) apalutamide, (v) darolutamide, (vi) enzalutamide.

Authority Required (STREAMLINED)

13207

Castration resistant metastatic carcinoma of the prostate

Clinical criteria:

- The treatment must be in combination with prednisone or prednisolone, **AND**
- The condition must be resistant to treatment with docetaxel; **OR**
- Patient must have a documented intolerance necessitating permanent treatment withdrawal or a contraindication to docetaxel, **AND**
- The treatment must not be used in combination with a novel hormonal drug, **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	0.00	*163.56	25.00	Cabazitaxel Accord [OC] (cabazitaxel 60 mg/3 mL injection, 3 mL vial)
					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)
					MSN Cabazitaxel [RQ] (cabazitaxel 60 mg/1.5 mL injection [1.5 mL vial] (&) inert substance diluent [4.5 mL vial], 1 pack)

DOCETAXEL

Injection

10148D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
250 mg	5	0.00	*159.26	25.00	Docetaxel Accord [OC] (docetaxel 80 mg/4 mL injection, 4 mL vial)
					Docetaxel Accord [OC] (docetaxel 160 mg/8 mL injection, 8 mL vial)

NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

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.

Note Not for use as neoadjuvant or adjuvant therapy.

Injection

10165B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
275 mg	11	0.00	*609.31	25.00	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)
					nab-PACLITAXEL JUNO [JU] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)
					nab-Paclitaxel Accord [OC] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)

NANOPARTICLE ALBUMIN-BOUND PACLITAXEL

Authority Required (STREAMLINED)

6106

Metastatic breast cancer

Authority Required (STREAMLINED)

6119

HER2 positive breast cancer

Injection

4531L

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
580 mg	5	0.00	*1,126.06	25.00	Abraxane [TS] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)
					nab-PACLITAXEL JUNO [JU] (paclitaxel (as nanoparticle albumin-bound) 100 mg injection, 1 vial)
					nab-Paclitaxel Accord [OC] (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	0.00	*166.12	25.00	Paclitaxel Accord [OC] (paclitaxel 300 mg/50 mL injection, 50 mL vial)
					Paclitaxel Ebewe [SZ] (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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4451G	800 mg	11	0.00	*157.20	25.00	IRINOTECAN BAXTER [BX] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
						IRINOTECAN EUGIA [YG] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
						IRINOTECAN EUGIA [YG] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)
						Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 100 mg/5 mL injection, 5 mL vial)
						Irinotecan Accord [OC] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)
						Irinotecan Irem [KS] (irinotecan hydrochloride trihydrate 500 mg/25 mL injection, 25 mL vial)

TOPOTECAN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4617B	3500 mcg	17	0.00	*124.64	25.00	Hycamtin [SZ] (topotecan 4 mg injection, 5 vials)
						Topotecan Accord [OC] (topotecan 4 mg/4 mL injection, 5 x 4 mL vials)

Other plant alkaloids and natural products

TRABECTEDIN

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

14197

Advanced (unresectable and/or metastatic) leiomyosarcoma or 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 have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

This drug 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
13340D	3250 mcg	7	0.00	*3,329.44	25.00	Yondelis [ZL] (trabectedin 1 mg injection, 1 vial)

TRABECTEDIN

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

14196

Advanced (unresectable and/or metastatic) leiomyosarcoma or liposarcoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have an ECOG performance status of 2 or less, **AND**
- Patient must have received prior chemotherapy treatment including an anthracycline, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The condition must be one of the following subtypes for patients with liposarcoma: (i) dedifferentiated, (ii) myxoid, (iii) round-cell, (iv) pleomorphic.

This drug 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
13346K	3250 mcg	3	0.00	*3,329.44	25.00	Yondelis [ZL] (trabectedin 1 mg injection, 1 vial)

CYTOTOXIC ANTIBIOTICS AND RELATED SUBSTANCES

Anthracyclines and related substances

DOXORUBICIN

Injection_intravesical

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4361M	135 mg	11	0.00	*151.03	25.00	Adriamycin [PF] (doxorubicin hydrochloride 50 mg/25 mL injection, 25 mL vial)

4361M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
					Doxorubicin ACC [OC] (doxorubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)

DOXORUBICIN HYDROCHLORIDE (AS PEGYLATED LIPOSOMAL)

Injection

4364Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
100 mg	5	0.00	*751.70	25.00	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

4375G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
220 mg	5	0.00	*270.46	25.00	Epirubicin Accord [OC] (epirubicin hydrochloride 200 mg/100 mL injection, 100 mL vial)

IDARUBICIN

Restricted benefit

6247

Acute myelogenous leukaemia (AML)

Injection

4440Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
30 mg	5	0.00	*272.02	25.00	Zavedos Solution [PF] (idarubicin hydrochloride 5 mg/5 mL injection, 5 mL vial)

MITOZANTRONE

Injection

4514N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
30 mg	5	0.00	*185.16	25.00	Mitozantrone Ebewe [SZ] (mitozantrone 20 mg/10 mL injection, 10 mL vial)

Other cytotoxic antibiotics

BLEOMYCIN

Restricted benefit

6275

Germ cell neoplasms

Restricted benefit

6224

Lymphoma

Injection

4433H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
30000 iu	11	0.00	*179.94	25.00	Bleomycin Accord [OC] (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

11755

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11457B	1000 mg	7	0.00	*4,391.80	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

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

Authority Required

11815

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11458C	1000 mg	9	0.00	*4,391.80	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

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

Authority Required

11787

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	0.00	*4,391.80	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

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

Authority Required

11785

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	0.00	*4,391.80	25.00	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.

Authority Required (STREAMLINED)

18685

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, **AND**
- The treatment must not be in combination with acalabrutinib.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12204H	1000 mg	8	0.00	*4,391.80	25.00	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 amount or number of units may be authorised.
Note No increase in the maximum number of repeats may be authorised.

Authority Required (STREAMLINED)

18618

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

Treatment Phase: For combination use with acalabrutinib from treatment cycles 2 to 7 inclusive in first-line therapy

Clinical criteria:

- The condition must be untreated, **AND**
- The treatment must be in combination with PBS-subsidised acalabrutinib (refer to Product Information for timing of obinutuzumab and acalabrutinib doses), **AND**
- The treatment must not be in combination with venetoclax.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13787P	1000 mg	7	0.00	*4,391.80	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

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)

18082

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Pre-treatment prior to initiation of glofitamab

Clinical criteria:

- Patient must be eligible to receive treatment under the PBS listing criteria for glofitamab.

Patient is intended to receive a single dose of Obinutuzumab 1000 mg 7 days prior to initiating glofitamab treatment (Cycle 1, Day 1).

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15265K	1000 mg	0	0.00	*4,391.80	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

OBINUTUZUMAB

Note The latest International Workshop on CLL (iwCLL) provides guidance on various aspects of management of CLL/SLL. Notably, two of these are:

(1) when to treat versus when to monitor the patient without therapy - see 'Indications for treatment' section; and

(2) recognising progressive disease - see 'Definition of response, relapse, and refractory disease' section.

See the following literature reference for details:

Hallek, M et al. iwCLL guidelines for diagnosis, indications for treatment, response assessment, and supportive management of CLL. *Blood* vol. 131, 25 (2018): 2745-2760.

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.

Authority Required (STREAMLINED)

14326

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**
- The treatment must be in combination with chlorambucil, **AND**
- The treatment must only be prescribed for a patient with active disease in accordance with the International Workshop on CLL (iwCLL) guidance (latest version) in relation to when to prescribe drug treatment for this condition.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10407R	1000 mg	7	0.00	*4,391.80	25.00	Gazyva [RO] (obinutuzumab 1 g/40 mL injection, 40 mL vial)

RITUXIMAB

Note Prescribing/pharmacy claiming: prescribe/claim this benefit through the Section 100 Highly Specialised Drugs Program PBS item code(s) when administered for non-oncology indications. Prescribe/claim this benefit through the Efficient Funding of Chemotherapy PBS item code(s) when administered for oncology indications.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13102N	800 mg	11	0.00	*438.46	25.00	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.

Authority Required

18364

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) details of the proposed prescription(s);

(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.

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 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. Monday to Friday).

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

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

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Injection

11696N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3384 mcg	2	0.00	*49,907.68	25.00	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 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

9601

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.

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 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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11680R	2820 mcg	4	0.00	*37,453.90	25.00	Besponsa [PF] (inotuzumab ozogamicin 1 mg injection, 1 vial)

CD38 (Clusters of Differentiation 38) inhibitors

DARATUMUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

17661

Untreated multiple myeloma

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2025, **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: (a) the condition was newly diagnosed, (b) the condition was confirmed by a histological diagnosis, (c) the patient was/is ineligible for a stem cell transplant, (d) the treatment is being given as triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, (iii) dexamethasone, (e) patient is not receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 24 weeks of treatment for the same PBS indication.

Details of the histological diagnosis of multiple myeloma, record of ineligibility for stem cell transplant and 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.

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.

Note Patients may qualify for PBS-subsidised treatment under this restriction to complete 24 weeks of treatment. For continuing PBS-subsidised treatment after week 24, 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

15065X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	15	0.00	*11,192.16	25.00	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial)
					Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

DARATUMUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

17413

Untreated multiple myeloma

Treatment Phase: Continuing treatment as first line drug therapy from week 25 onwards (administered once every four weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, and (iii) dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide, **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

15072G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	5	0.00	*11,192.16	25.00	Darzalex [JC] (daratumumab 100 mg/5 mL injection, 5 mL vial)
					Darzalex [JC] (daratumumab 400 mg/20 mL injection, 20 mL vial)

DARATUMUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

17660

Untreated multiple myeloma

Treatment Phase: Initial treatment as first-line drug therapy from week 0 to week 24

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, and (iii) dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide.

Treatment criteria:

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 24 weeks of treatment for the same PBS indication.

Details of the histological diagnosis of multiple myeloma, record of ineligibility for stem cell transplant and 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.

Injection

15077M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1920 mg	15	0.00	*11,192.16	25.00	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

12845

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	0.00	*11,192.16	25.00	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

17491

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 PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), or irrespective of whether the disease staging has been changed (i.e. disease has changed from untreated multiple myeloma to relapsed or refractory multiple myeloma), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12228N	1920 mg	8	0.00	*11,192.16	25.00	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

12691

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	0.00	*11,192.16	25.00	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 Special Pricing Arrangements apply.

Authority Required

13018

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.

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

10267J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
840 mg	0	0.00	*5,638.18	25.00	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 Special Pricing Arrangements apply.

Authority Required

10414

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.

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.

Injection

10333W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
420 mg	3	0.00	*2,865.37	25.00	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

PERTUZUMAB

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 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

18899

Early 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), **AND**
- Patient must have locally advanced, inflammatory or early stage, high risk (tumour greater than 2 cm in diameter or lymph node positive) breast cancer, **AND**
- The treatment must be used in combination with trastuzumab, **AND**
- The treatment must be initiated in combination with chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- Patient must not receive more than 1 treatment cycle under this restriction, **AND**
- The treatment must not extend beyond the following when initial and continuing therapy are combined: (i) 18 weeks (6 cycles) in the neoadjuvant setting; or (ii) 12 months (18 cycles) in total.

Details (date, unique identifying number/code, or provider number) of the pathology report from an Approved Pathology Authority confirming evidence of HER2 gene amplification 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15386T	840 mg	0	0.00	*5,638.18	25.00	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

PERTUZUMAB

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 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

18829

Early 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 be used in combination with trastuzumab, **AND**
- The treatment must have been initiated in combination with chemotherapy, **AND**
- The treatment must not be used in a patient with a left ventricular ejection fraction (LVEF) of less than 45% and/or with symptomatic heart failure, **AND**
- The treatment must not extend beyond the following when initial and continuing therapy are combined: (i) 18 weeks (6 cycles) in the neoadjuvant setting; or (ii) 12 months (18 cycles) in total.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15402P	420 mg	4	0.00	*2,865.37	25.00	Perjeta [RO] (pertuzumab 420 mg/14 mL injection, 14 mL vial)

TRASTUZUMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or 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)

15831

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.

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

4632T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
500 mg	0	0.00	*414.80	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
					Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 150 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	0.00	*297.80	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
					Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)

TRASTUZUMAB

Note Authority applications for increased quantities/repeats (where relevant) may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

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

Authority Required (STREAMLINED)

15820

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.

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

4650R	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
	1000 mg	0	0.00	*737.04	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 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	0.00	*618.46	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 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	0	0.00	*737.04	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 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	0.00	*618.46	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
					Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 150 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	0	0.00	*737.04	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
					Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
					Trazimera [PF] (trastuzumab 150 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	0.00	*618.46	25.00	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 [XT] (trastuzumab 420 mg injection, 1 vial)
						Ogivri [SZ] (trastuzumab 150 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 60 mg injection, 1 vial)
						Trazimera [PF] (trastuzumab 150 mg injection, 1 vial)

TRASTUZUMAB DERUXTECAN

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

Note Special Pricing Arrangements apply.

Authority Required

15826

Metastatic (Stage IV) HER2 positive breast cancer

Clinical criteria:

- Patient must have evidence of human epidermal growth factor (HER2) gene amplification as demonstrated by in situ hybridisation (ISH) in either the primary tumour/a metastatic lesion - establish this finding once only with the first PBS prescription, **AND**
- The condition must have progressed following treatment with at least one prior HER2 directed regimen for metastatic breast cancer; **OR**
- The condition must have, at the time of treatment initiation with this drug, progressed during/within 6 months following adjuvant treatment with a HER2 directed therapy, **AND**
- Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only.

Treatment criteria:

- Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; **OR**
- Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions.

Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription:

1) Evidence of HER2 gene amplification (evidence obtained in relation to past PBS treatment is acceptable).

2) Details of prior HER2 directed drug regimens prescribed for the patient.

3) Cardiac function test results (evidence obtained in relation to past PBS treatment is acceptable).

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13718B	675 mg	8	0.00	*17,543.98	25.00	Enhertu [AP] (trastuzumab deruxtecan 100 mg injection, 1 vial)

TRASTUZUMAB DERUXTECAN

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

Authority Required

15832

Unresectable and/or metastatic HER2-low breast cancer

Clinical criteria:

- Patient must have evidence of human epidermal growth factor receptor 2 (HER2)-low disease, **AND**
- Patient must have received prior chemotherapy in the metastatic setting; **OR**
- Patient must have developed disease recurrence during or within 6 months of completing adjuvant chemotherapy, **AND**
- Patient must have received or be ineligible for endocrine therapy in the metastatic setting, if hormone receptor positive, **AND**
- Patient must have, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The treatment must not be prescribed where any of the following is present: (i) left ventricular ejection fraction of less than 50%, (ii) symptomatic heart failure; confirm cardiac function testing for the first PBS prescription only.

Treatment criteria:

- Patient must be undergoing initial treatment with this drug - the following are true: (i) this is the first prescription for this drug, (ii) this prescription seeks no more than 3 repeat prescriptions; **OR**
- Patient must be undergoing continuing treatment with drug - the following are true: (i) there has been an absence of further disease progression whilst on active treatment with this drug, (ii) this prescription does not seek to re-treat after disease progression, (iii) this prescription seeks no more than 8 repeat prescriptions.

HER2-low is defined as an immunohistochemical (IHC) score of 1+ or an IHC score of 2+ and a negative result on in situ hybridization (ISH).

Confirm that the following information is documented/retained in the patient's medical records once only with the first PBS prescription:

1) Evidence of HER2-low status

2) Details of prior drug regimens prescribed for the patient

3) Cardiac function test results

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14578G	675 mg	8	0.00	*17,543.98	25.00	Enhertu [AP] (trastuzumab deruxtecan 100 mg injection, 1 vial)

TRASTUZUMAB EMTANSINE

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

Authority Required

15818

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 form upload or mail, it must include:

(i) details of the proposed prescription; 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).

Increased maximum amounts may only 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).

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

15819

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.

Increased maximum amounts may only be authorised 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).

Injection

11951B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
450 mg	6	0.00	*6,913.56	25.00	Kadcyla [RO] (trastuzumab emtansine 100 mg injection, 1 vial)
					Kadcyla [RO] (trastuzumab emtansine 160 mg injection, 1 vial)

TRASTUZUMAB EMTANSINE

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

Authority Required

15828

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.

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Authority Required

15827

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.

Increased maximum amounts may only be authorised where a patient's weight is greater than 125 kg.

Injection

10282E

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
450 mg	8	0.00	*6,913.56	25.00	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

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.

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.

Injection

4435K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
550 mg	5	0.00	*1,703.71	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
					Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

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.

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.

Injection

10262D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1100 mg	18	0.00	*3,046.33	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
					Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

Note Special Pricing Arrangements apply.

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.

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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4731B	1100 mg	11	0.00	*3,046.33	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
						Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

Note Special Pricing Arrangements apply.

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
12816M	1100 mg	11	0.00	*3,046.33	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
						Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

Note Special Pricing Arrangements apply.

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
12820R	1100 mg	0	0.00	*3,046.33	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial)
						Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

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.

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

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.

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4312Y	880 mg	0	0.00	*2,509.30	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

CETUXIMAB

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.

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)

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.

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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4436L	1100 mg	0	0.00	*3,046.33	25.00	Erbitux [SG] (cetuximab 100 mg/20 mL injection, 20 mL vial) Erbitux [SG] (cetuximab 500 mg/100 mL injection, 100 mL vial)

PANITUMUMAB

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.

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)

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 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.

Injection

10082P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
720 mg	5	0.00	*3,695.90	25.00	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)
					Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

PANITUMUMAB

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.

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)

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 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.

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
10513H	720 mg	9	0.00	*3,695.90	25.00	Vectibix [AN] (panitumumab 100 mg/5 mL injection, 5 mL vial)
						Vectibix [AN] (panitumumab 400 mg/20 mL injection, 20 mL vial)

PD-1/PD-L1 (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
11277M	1200 mg	7	0.00	*6,839.93	25.00	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
11802E	1200 mg	7	0.00	*6,839.93	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11930X	1680 mg	5	0.00	*9,538.86	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12097Q	1680 mg	5	0.00	*9,538.86	25.00	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)

18242

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11284X	1200 mg	5	0.00	*6,839.93	25.00	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)

18257

Extensive-stage small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be previously untreated, **AND**
- Patient must not have previously received programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for any stage of small cell lung cancer, **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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11926Q	1200 mg	3	0.00	*6,839.93	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11929W	1200 mg	4	0.00	*6,839.93	25.00	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)

18243

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11931Y	1680 mg	3	0.00	*9,538.86	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12078Q	1680 mg	3	0.00	*9,538.86	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12168K	1200 mg	8	0.00	*6,839.93	25.00	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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12174R	1680 mg	5	0.00	*9,538.86	25.00	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)

13451

Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)

Treatment Phase: 1,680 mg administered once every 4 weeks, or 840 mg every 2 weeks

Population criteria:

- Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; **OR**
- Patient must be continuing existing PBS-subsidised treatment with this drug; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.

Clinical criteria:

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy, **AND**
- The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement, **AND**
- The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13173H	1680 mg	5	0.00	*9,538.86	25.00	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)

13442

Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)

Treatment Phase: 1,200 mg administered once every 3 weeks

Population criteria:

- Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; **OR**
- Patient must be continuing existing PBS-subsidised treatment with this drug; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.

Clinical criteria:

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy, **AND**
- The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement, **AND**
- The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

Injection

13174J

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	7	0.00	*6,839.93	25.00	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)

18326

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition, **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	0.00	*6,839.93	25.00	Tecentriq [RO] (atezolizumab 1.2 g/20 mL injection, 20 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	0.00	*6,839.93	25.00	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)

16085

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; **OR**
- The treatment must not exceed a dose of 800 mg every 2 weeks under this restriction.

Injection

11671G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1200 mg	11	0.00	*7,829.50	25.00	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)

16053

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; **OR**
- The treatment must not exceed a dose of 800 mg 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	0.00	*7,829.50	25.00	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

AVELUMAB

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)

13290

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

Treatment Phase: Maintenance therapy - Continuing treatment

Clinical criteria:

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

Injection

13126W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	11	0.00	*5,250.52	25.00	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

AVELUMAB

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 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)

15485

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

Treatment Phase: Maintenance therapy - Initial treatment

Clinical criteria:

- Patient must have received first-line platinum-based chemotherapy, **AND**
- Patient must not have progressive disease following first-line platinum-based chemotherapy, **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**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for this condition.

Injection

13122P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
800 mg	7	0.00	*5,250.52	25.00	Bavencio [SG] (avelumab 200 mg/10 mL injection, 10 mL vial)

CEMIPLIMAB

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)

15063

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 both initial and continuing treatment restrictions, whichever comes first.

Injection

13161Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
350 mg	6	0.00	*7,382.56	25.00	Libtayo [WM] (cemiplimab 350 mg/7 mL injection, 7 mL vial)

CEMIPLIMAB

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)

18455

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition, **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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13169D	350 mg	6	0.00	*7,382.56	25.00	Libtayo [WM] (cemiplimab 350 mg/7 mL injection, 7 mL vial)

CEMIPLIMAB

Caution In the first few months after starting immunotherapy, a transient tumour flare may occur that may be mistaken as disease progression despite an overall positive response to treatment.

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 888 333.

Authority Required

13419

Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)

Treatment Phase: Initial treatment covering the first 3 treatment cycles

Clinical criteria:

- The condition must be unsuitable for each of: (i) curative surgical resection, (ii) curative radiotherapy, **AND**
- Patient must have had a WHO performance status of 0 or 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13152F	350 mg	2	0.00	*7,382.56	25.00	Libtayo [WM] (cemiplimab 350 mg/7 mL injection, 7 mL vial)

CEMIPLIMAB

Caution In the first few months after starting immunotherapy, a transient tumour flare may occur that may be mistaken as disease progression despite an overall positive response to treatment.

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 888 333.

Authority Required

13411

Metastatic or locally advanced cutaneous squamous cell carcinoma (CSCC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Treatment criteria:

- Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13159N	350 mg	7	0.00	*7,382.56	25.00	Libtayo [WM] (cemiplimab 350 mg/7 mL injection, 7 mL vial)

DOSTARLIMAB

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)

15163

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Initial treatment covering the first 6 treatment cycles

Clinical criteria:

- Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test, **AND**

- The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy, **AND**
- The treatment must be initiated in combination with platinum-containing chemotherapy, **AND**
- The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy, **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**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14122G	500 mg	5	0.00	*7,740.06	25.00	Jemperli [GK] (dostarlimab 500 mg/10 mL injection, 10 mL vial)

DOSTARLIMAB

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)

15205

Advanced, metastatic or recurrent endometrial carcinoma

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 receiving PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14130Q	1000 mg	3	0.00	*15,387.56	25.00	Jemperli [GK] (dostarlimab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

15500

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 be untreated with immunotherapy at commencement of this drug, **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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11915D	1500 mg	4	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial) Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)
14708
Locally advanced, metastatic or recurrent biliary tract cancer (intrahepatic cholangiocarcinoma, extrahepatic cholangiocarcinoma, and gallbladder cancer)
Population criteria:

- Patient must have either of the following at treatment initiation: (i) locally advanced biliary tract cancer that is untreated with systemic anti-cancer therapy in the unresectable setting, (ii) metastatic biliary tract cancer that is untreated with systemic anti-cancer therapy in the metastatic setting.

Clinical criteria:

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information), **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13767N	1500 mg	5	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)
18257
Extensive-stage small cell lung cancer
Treatment Phase: Initial treatment
Clinical criteria:

- The condition must be previously untreated, **AND**
- Patient must not have previously received programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for any stage of small cell lung cancer, **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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13775B	1500 mg	3	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)
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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13780G	1500 mg	5	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
						Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)

16814

Advanced, metastatic or recurrent endometrial carcinoma

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 receiving PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 36 cumulative months from the first administered dose, once in a lifetime.

Retain all pathology imaging and investigative test results in the patient's medical records.

Patients with a body weight of 30 kg or less during continuing treatment must receive weight-based dosing, equivalent to durvalumab 20 mg/kg, until weight is greater than 30 kg.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14925M	1500 mg	5	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial) Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)

16953

Advanced, metastatic or recurrent endometrial carcinoma

Treatment Phase: Initial treatment covering the first 6 treatment cycles

Clinical criteria:

- Patient must have deficient mismatch repair (dMMR) endometrial cancer, as determined by immunohistochemistry test, **AND**
- The condition must be unsuitable for at least one of the following: (i) curative surgical resection, (ii) curative radiotherapy, **AND**
- The treatment must be initiated in combination with platinum-containing chemotherapy, **AND**
- The condition must be, at treatment initiation with this drug, either: (i) untreated with systemic therapy, (ii) treated with neoadjuvant/adjuvant systemic therapy, but the cancer has recurred or progressed after more than 6 months from the last dose of systemic therapy, **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**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score no higher than 1 prior to treatment initiation.

Retain all pathology imaging and investigative test results in the patient's medical records.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14942K	1120 mg	5	0.00	*8,128.43	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial) Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)

18481

Limited-stage small cell lung cancer

Clinical criteria:

- Patient must have received chemoradiation therapy (CRT), **AND**
- The condition must not have progressed following CRT, **AND**
- Patient must have had a WHO performance status of no greater than 1 at treatment initiation with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication, **AND**
- The treatment must not exceed 24 months in total for this condition, measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

Injection

15324M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	5	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
					Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)
17505
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
Treatment Phase: Initial treatment
Clinical criteria:

- Patient must be undergoing combination treatment with tremelimumab for the first dose of treatment, **AND**
- 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 of a severity necessitating permanent treatment withdrawal, in the absence of disease progression to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI).

Authority Required (STREAMLINED)
17437
Advanced (unresectable) Barcelona Clinic Liver Cancer Stage B or Stage C hepatocellular carcinoma
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.

Injection

15091G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	5	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
					Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

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)
18417
Urothelial carcinoma
Treatment Phase: Initial treatment - neoadjuvant setting
Clinical criteria:

- Patient must be initiating treatment with this drug for this condition; **OR**
- Patient must be transitioning from non-PBS to PBS-subsidised treatment with this drug for this condition, **AND**
- The condition must not have previously been treated with systemic therapy for muscle-invasive bladder cancer at the time this drug was initiated for this condition, **AND**
- The treatment must be once in a lifetime with this drug for this condition, **AND**
- The condition must be of muscle-invasive type disease with both: (i) clinical tumour stage of either T2, T3 or T4a, (ii) nodal status of up to stage N1, **AND**
- The treatment must be for neoadjuvant use in a patient preparing for radical cystectomy, **AND**
- Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- The treatment must be/have been initiated with both: (i) gemcitabine, (ii) cisplatin (refer to Product Information of gemcitabine and cisplatin for dosing information).

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment where this prescription extends treatment beyond whichever comes first: (i) 4 cycles from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease progression recurrence despite treatment with this drug, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Authority Required (STREAMLINED)
18482
Urothelial carcinoma
Treatment Phase: Continuing treatment - adjuvant setting

Clinical criteria:

- Patient must have previously received PBS-subsidised neoadjuvant treatment with this drug in combination with gemcitabine plus cisplatin for this condition; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised treatment with this drug for this condition, (ii) previously treated in combination with cisplatin and gemcitabine as neoadjuvant treatment for this condition, **AND**
- Patient must have undergone radical cystectomy, **AND**
- The treatment must be for adjuvant therapy that is/was initiated within 6 months of radical cystectomy for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) maximum of 8 cycles for this condition from the first administered dose following radical cystectomy, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Treatment with this drug for this condition must not exceed 12 treatment cycles (neoadjuvant and adjuvant) in a lifetime.

Injection

15292W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	3	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
					Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

Note The recommended dose of durvalumab in the adjuvant setting is 1500 mg administered every 4 weeks for up to a maximum of 12 cycles (including 2 cycles of adjuvant durvalumab in combination with FLOT and 10 additional cycles of durvalumab 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 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

19159

Resected gastric and gastroesophageal junction adenocarcinoma

Treatment Phase: Adjuvant treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised neoadjuvant treatment with this drug for this condition; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS-subsidised supply of this drug, (ii) treated with combined therapy with durvalumab and FLOT as neoadjuvant treatment for this condition, **AND**
- The treatment must be for the purposes of adjuvant use following surgical resection, **AND**
- The treatment must be/have been initiated in combination with adjuvant FLOT for up to 2 cycles unless intolerant to FLOT requiring permanent discontinuation, **AND**
- The treatment must be sole PBS-subsidised systemic anti-cancer therapy from cycles 3-12 of adjuvant treatment, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) maximum of 12 cycles of adjuvant treatment for this condition from the first administered dose following surgery, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Where 'FLOT' is referenced in this restriction, it refers to the combination therapy of fluorouracil (5-FU) in combination with leucovorin (folinic acid), oxaliplatin and docetaxel.

Injection

15504B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	5	0.00	*10,854.88	25.00	Imfinzi [AP] (durvalumab 120 mg/2.4 mL injection, 2.4 mL vial)
					Imfinzi [AP] (durvalumab 500 mg/10 mL injection, 10 mL vial)

DURVALUMAB

Note The recommended dose of durvalumab in the neoadjuvant phase is 1500 mg administered every 4 weeks, for up to 2 cycles.

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 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

19222

Resectable gastric and gastroesophageal junction adenocarcinoma
Treatment Phase: Neoadjuvant treatment

Clinical criteria:

- Patient must be initiating treatment with this drug for this condition; **OR**
- Patient must be transitioning from existing non-PBS to PBS-subsidised supply of this drug, **AND**
- The condition must be Stage II or higher, **AND**
- The condition must be resectable, **AND**
- The treatment must be for the purpose of neoadjuvant use in a patient preparing for surgery, **AND**
- Patient must have a WHO performance status no greater than 1, **AND**
- The treatment must be initiated in combination with neoadjuvant FLOT, **AND**
- The condition must have been untreated with systemic therapy.

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment where this prescription extends treatment beyond whichever comes first: (i) 2 cycles of neoadjuvant treatment from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease progression/recurrence despite treatment with this drug, (iii) unacceptable toxicity; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Where 'FLOT' is referenced in this restriction, it refers to the combination therapy of fluorouracil (5-FU) in combination with leucovorin (folinic acid), oxaliplatin and docetaxel.

Injection

15518R

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
1500 mg	1	0.00	*10,854.88	25.00	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 Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

18370

Urothelial carcinoma

Clinical criteria:

- The treatment must be for each of: (i) adjuvant therapy that is/was initiated within 6 months of radical surgical resection, (ii) muscle invasive type disease, (iii) disease considered to be at high risk of recurrence based on pathologic staging of radical surgery tissue (ypT2-ypT4a or ypN+), but yet to recur, (iv) use as the sole PBS-subsidised anti-cancer treatment for this condition, **AND**
- Patient must have received prior platinum containing neoadjuvant 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**
- Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1.

Treatment criteria:

- Patient must be undergoing treatment with a dosing regimen as set out in the drug's Therapeutic Goods Administration (TGA) approved Product Information, **AND**
- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

An increase in repeat prescriptions, up to a value of 11, may only be sought where the prescribed dosing is 240 mg administered fortnightly.

Injection

14231B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	5	0.00	*9,562.12	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
					Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)

NIVOLUMAB

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

Authority Required (STREAMLINED)

15471

Resectable non-small cell lung cancer (NSCLC)

Clinical criteria:

- The condition must be at least one of: (i) node positive, (ii) at least 4 cm in size, **AND**
- The treatment must be for neoadjuvant use in a patient preparing for surgical resection, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The treatment must be in combination with platinum-based chemotherapy.

Treatment criteria:

- Patient must not be undergoing treatment with more than 3 PBS-subsidised doses of this drug per lifetime for this indication.

In non-squamous type NSCLC where any of the following is known to be present, this drug must not be a PBS benefit: (i) activating epidermal growth factor receptor (EGFR) gene mutation, (ii) anaplastic lymphoma kinase (ALK) gene rearrangement.

Injection

14233D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
360 mg	2	0.00	*7,194.73	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
					Opdivo [BQ] (nivolumab 100 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)

18070

Immunotherapy sensitive advanced or metastatic cancer

Clinical criteria:

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for the condition which treatment was commenced for.

Patients must only receive a maximum of 240 mg every two weeks, 360 mg every three weeks, or 480 mg every four weeks under a weight based or flat dosing regimen.

Injection

15238B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	13	0.00	*9,562.12	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
					Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 mL vial)

NIVOLUMAB

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 Up to an additional 2 repeat prescriptions (7 in total) may be sought only where dosing is on a 2-weekly schedule in the first 16 weeks of treatment. This listing's stated number of repeat prescriptions is based on 4-weekly dosing.

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

Note Special Pricing Arrangements apply.

Authority Required

13900

Adjuvant treatment of stage II or III oesophageal cancer or gastro-oesophageal junction cancer

Clinical criteria:

- The condition must have histological evidence confirming a diagnosis of a least one of: (i) adenocarcinoma, (ii) squamous cell cancer; document this evidence in the patient's medical records, **AND**
- The condition must have been treated with neoadjuvant platinum-based chemoradiotherapy, **AND**
- The treatment must be for the purposes of adjuvant use following complete surgical resection that occurred within 16 weeks prior to initiating this drug, **AND**
- The condition must have evidence, through resected specimen, that residual disease meets the Tumour Nodes Metastases (TNM) staging system (as published by the Union for International Cancer Control) of either: (i) at least ypT1, (ii) at least ypN1; document this evidence in the patient's medical records, **AND**
- Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment with a dosing regimen as set out in the drug's approved Australian Product Information, **AND**
- Patient must not be undergoing PBS-subsidised treatment with this drug where this prescription extends treatment beyond whichever comes first: (i) 12 months from treatment initiation, irrespective of whether initial treatment was PBS-subsidised/non-PBS-subsidised, (ii) disease recurrence despite treatment with this drug; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

Injection

13240W

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	5	0.00	*9,562.12	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
					Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 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

16935

Stage IIIB, IIIC, IIID or Stage IV malignant melanoma

Treatment Phase: Initial treatment

Clinical criteria:

- The treatment must be in addition to complete surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **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.

When nivolumab is initially prescribed as a 3-weekly dosing regimen, patients must only receive a maximum of 240 mg every 3 weeks for 2 cycles (i.e., 1 repeat). When prescribed as a weight based or flat dose adjuvant regimen, patients must only receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment.

Authority Required

16962

Stage IIIB, IIIC, IIID or Stage IV malignant melanoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have undergone 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.

When prescribed as a weight based or flat dose adjuvant regimen, patients must receive a maximum of 240 mg every 2 weeks or 480 mg every 4 weeks for a maximum of 12 months of adjuvant treatment.

Injection

11900H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
480 mg	5	0.00	*9,562.12	25.00	Opdivo [BQ] (nivolumab 40 mg/4 mL injection, 4 mL vial)
					Opdivo [BQ] (nivolumab 100 mg/10 mL injection, 10 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.

Authority Required (STREAMLINED)

14727

Stage II or Stage III triple negative breast cancer

Clinical criteria:

- The treatment must be initiated in combination with neoadjuvant chemotherapy, **AND**
- The condition must not have progressed/recurred whilst on treatment with this drug.

Treatment criteria:

- Patient must not be undergoing treatment with this drug beyond 52 cumulative weeks under this restriction, **AND**
- Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; **OR**
- Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 4 repeat prescriptions.

Injection

13752T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	7	0.00	*14,622.80	25.00	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.

Authority Required (STREAMLINED)

17992

Intermediate or high risk of recurrence clear cell variant renal cell carcinoma (RCC)

Clinical criteria:

- Patient must have: (i) pT2 with Grade 4 or sarcomatoid features; or (ii) pT3, with any grade without nodal involvement (N0) or distant metastases (M0); or (iii) pT4, any grade N0 and M0; or (iv) any pT, any grade with nodal involvement and M0; or (v) metastatic disease and has undergone complete resection of primary and metastatic lesions, **AND**
- The treatment must be in addition to complete surgical resection, **AND**

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

Treatment criteria:

- Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; **OR**
- Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.

Injection

15208K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	7	0.00	*14,622.80	25.00	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.

Authority Required (STREAMLINED)

18413

Resectable locally advanced squamous cell carcinoma of the oral cavity, pharynx or larynx

Clinical criteria:

- Patient must have stage III-IVB squamous cell carcinoma of the oral cavity, pharynx or larynx, **AND**
- Patient must have tumour(s) that are resectable as assessed by the treating clinician; **OR**
- Patient must have undergone surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- Patient must not have experienced disease recurrence or progression while being treated with this drug for this condition, **AND**
- The treatment must be commenced as neoadjuvant therapy and continued in combination with radiation therapy with or without chemotherapy after surgical resection; **OR**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition, **AND**
- The treatment must not exceed a total of 12 cumulative months, either as: (i) 17 doses (based on a 3-weekly dose regimen), (ii) 8 doses (based on a 6-weekly dose regimen) whichever comes first from the first dose of this drug regardless of if it was PBS/non-PBS subsidised.

Treatment criteria:

- Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; **OR**
- Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.

Injection

15329T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	7	0.00	*14,622.80	25.00	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.

Authority Required (STREAMLINED)

19192

Immunotherapy sensitive advanced or metastatic cancer

Clinical criteria:

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for the condition which treatment was commenced for.

Treatment criteria:

- Patient must be undergoing treatment with this drug administered once every 3 weeks - prescribe up to 7 repeat prescriptions; **OR**
- Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions.

Injection

15519T

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
400 mg	7	0.00	*14,622.80	25.00	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

10688

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

10676

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12127G	400 mg	3	0.00	*14,622.80	25.00	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

PEMBROLIZUMAB

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

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

14770

Stage IIIB, Stage IIIC or Stage IIID malignant melanoma

Treatment Phase: Initial treatment - 3 weekly treatment regimen

Clinical criteria:

- The treatment must be in addition 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 have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).

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 Commencing treatment within 12 weeks of complete resection means either 12 weeks after resection or 12 weeks prior to resection.

Where non-PBS-subsidised supply has occurred, the total amount of PBS-subsidised supply is intended to be the balance of 18 doses less the number of non-PBS-subsidised doses.

Authority Required

14786

Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
Treatment Phase: Continuing treatment - 3 weekly treatment regimen

Treatment criteria:

- Patient must be undergoing continuing PBS-subsidised treatment commenced through an 'Initial treatment' listing.

Clinical criteria:

- Patient must not have experienced disease recurrence, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received more than 12 months of therapy (irrespective of whether therapy has been partly PBS-subsidised/non-PBS-subsidised).

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12130K	200 mg	7	0.00	*7,357.68	25.00	Keytruda [MK] (pembrolizumab 100 mg/4 mL injection, 4 mL vial)

TISLELIZUMAB

Caution In the first few months after starting immunotherapy, a transient tumour flare may occur that may be mistaken as disease progression despite an overall positive response to treatment.

Caution When administering tislelizumab in combination with chemotherapy, administer tislelizumab before chemotherapy when both are given on the same day.

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)

19495

Advanced or metastatic gastro-oesophageal cancer

Clinical criteria:

- Patient must be untreated (up until initiating this drug) with programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for gastro-oesophageal cancer, **AND**
- Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1, **AND**
- Patient must not have developed disease progression while receiving treatment for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14756P	200 mg	7	0.00	*6,484.80	25.00	Tevimbra [IE] (tislelizumab 100 mg/10 mL injection, 10 mL vial)

TORIPALIMAB

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

17616

Recurrent or metastatic nasopharyngeal carcinoma

Clinical criteria:

- Patient must have a WHO performance status of no higher than 2, **AND**
- The condition must not be amenable to salvage surgery or radiotherapy, **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 commenced in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting (i.e. used in combination with PBC for 6 cycles in the first line setting unless intolerance/contraindication is confirmed); **OR**
- The treatment must be the sole PBS-subsidised therapy at the time of treatment initiation where the condition has progressed following treatment with PBC (i.e. used as monotherapy in the second line setting).

Treatment criteria:

- Patient must not be undergoing treatment with this drug as a PBS benefit where the treatment duration extends beyond the following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 cumulative months from treatment initiation; annotate any remaining repeat prescriptions with the word 'cancelled' where this occurs.

An increase above the listed maximum amount may only be requested when a dose of 3 mg/kg every 2 weeks is prescribed in the second line setting.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15125C	240 mg	7	0.00	*9,549.59	25.00	Zytorvi [RZ] (Toripalimab 240 mg/6 mL injection, 6 mL vial)

VEGF/VEGFR (Vascular Endothelial Growth Factor / -Receptor) inhibitors

BEVACIZUMAB

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12479T	1800 mg	7	0.00	*843.34	25.00	Abevmy [SZ] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
						Abevmy [SZ] (bevacizumab 400 mg/16 mL injection, 16 mL vial)
						Mvasi [AN] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
						Mvasi [AN] (bevacizumab 400 mg/16 mL injection, 16 mL vial)
						Vegzelma [EW] (bevacizumab 100 mg/4 mL injection, 4 mL vial)
						Vegzelma [EW] (bevacizumab 400 mg/16 mL injection, 16 mL vial)

Other monoclonal antibodies and antibody drug conjugates

AMIVANTAMAB

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 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

16472

Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have evidence in tumour material of an activating epidermal growth factor receptor (EGFR) exon 20 insertion mutation, **AND**
- Patient must have/have had a WHO performance status of no greater than 2 at treatment initiation with this drug for this condition, **AND**
- Patient must not have previously received this drug for this condition; **OR**
- Patient must be each of: (i) currently receiving non-PBS-subsidised supply for this drug for this PBS indication, (ii) free of disease progression since commencing non-PBS-subsidised supply, **AND**
- The treatment must be/have been in combination with platinum-based chemotherapy (PBC) where the patient has not previously received systemic therapy for this condition in the metastatic setting, (i.e. used in combination with PBC in the first line setting); **OR**
- The treatment must be the sole PBS-subsidised therapy where the condition has progressed following treatment with platinum-based chemotherapy, (i.e. used as monotherapy in the second line setting).

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

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14800Y	2100 mg	5	0.00	*8,996.56	25.00	Rybrevant [JC] (amivantamab 350 mg/7 mL injection, 7 mL vial)

AMIVANTAMAB

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 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

16402

Stage IIIB/ IIIC (locally advanced) or Stage IV (metastatic) non-small cell lung cancer (NSCLC)

Treatment Phase: Continuing treatment

Clinical criteria:

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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14801B	2100 mg	7	0.00	*8,996.56	25.00	Rybrevant [JC] (amivantamab 350 mg/7 mL injection, 7 mL vial)

BLINATUMOMAB

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

Note 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 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

18579

Acute lymphoblastic leukaemia

Treatment Phase: Consolidation treatment of relapsed or refractory B-precursor cell ALL

Clinical criteria:

- Patient must have previously received PBS-subsidised induction treatment with this drug for relapsed or refractory B-precursor cell ALL, **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.

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 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.

Injection

11117D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	2	0.00	*77,359.40	25.00	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 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 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

18651

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment - balance of supply - relapsed or refractory B-precursor cell ALL

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 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.

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.

Injection

11120G

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	0	0.00	*77,359.40	25.00	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 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 authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Note No increase in the maximum 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

18871

Acute lymphoblastic leukaemia

Treatment Phase: Induction treatment of relapsed or refractory B-precursor cell ALL

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 not have received more than 1 line of salvage therapy, **AND**
- The condition must be one of the following: (i) untreated with this drug for Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL), (ii) treated with this drug for Pre-B-cell ALL, but the condition has not relapsed within 6 months of completing that course of treatment, **AND**
- The condition must have more than 5% blasts in bone marrow; **OR**
- The condition must have measurable residual disease based on measurement in bone marrow following complete remission, **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) details of the proposed prescription; and

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

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

(4) for Philadelphia chromosome positive patients:

(i) the date of the most recent treatment with a TKI (in combination with chemotherapy); OR

(ii) if applicable the date of initial combined treatment with TKI and corticosteroids (if unable to tolerate chemotherapy).

(5) if applicable, the date of completion of blinatumomab treatment for Pre-B-cell ALL in CR and the date of the patient's subsequent relapse; and

(6) the percentage blasts in bone marrow count measured 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	0	0.00	*66,321.28	25.00	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 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 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

18650

Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)

Treatment Phase: Initial treatment of newly-diagnosed Pre-B-cell ALL in the consolidation phase

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 acute lymphoblastic leukaemia (ALL); **OR**
- Patient must have Philadelphia chromosome positive ALL, and both (i) have achieved complete remission following combination therapy with a tyrosine kinase inhibitor and corticosteroids (ii) be unable to tolerate chemotherapy, **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.

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.

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

(1) details of the proposed prescription; and

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

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

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

(5) the date of the course of combination therapy with a tyrosine kinase inhibitor and corticosteroid for Philadelphia chromosome positive patients.

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 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

18688

Precursor B-cell acute lymphoblastic leukaemia (Pre-B-cell ALL)

Treatment Phase: Continuing treatment of Pre-B-cell ALL in complete haematological remission (CR)

Treatment criteria:

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

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must have achieved a complete remission, **AND**
- Patient must not have developed disease progression while receiving 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 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

11850Q

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
784 mcg	1	0.00	*77,359.40	25.00	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

18300

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 in a lifetime, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

The authority application 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 histopathology report from an Approved Pathology Authority demonstrating the patient has a diagnosis of either mycosis fungoides, Sezary syndrome or primary cutaneous anaplastic large cell lymphoma; and

(b) details (date, unique identifying number/code or provider number) of a histology report on the tumour sample or of a flow cytometric analysis of lymphoma cells of the blood showing CD30 positivity of at least 3% of malignant cells; and

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

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

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

(i) details of the proposed prescription; 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

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11660Q	180 mg	3	0.00	*17,781.56	25.00	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

BRENTUXIMAB VEDOTIN

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

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

18503

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, **AND**
- The treatment must not exceed 4 cycles under this restriction.

Applications for authorisation of 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 or provider number) of a histology report showing evidence of the tumour's CD30 positivity; and

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

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

(d) 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.

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

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

(i) details of the proposed prescription; 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).

Injection

10166C

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	3	0.00	*17,781.56	25.00	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. Monday to Friday).

Authority Required

13261

CD30 positive systemic anaplastic large cell lymphoma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must not have developed disease progression while 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, **AND**
- The treatment must not exceed 12 cycles under this restriction in a lifetime.

Injection

10171H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	11	0.00	*17,781.56	25.00	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. Monday to Friday).

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

17438

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, **AND**
- Patient must not have received prior treatment with this drug for this condition; **OR**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11073T	200 mg	3	0.00	*17,781.56	25.00	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. Monday to Friday).

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

17508

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, **AND**
- Patient must not have received prior treatment with this drug for this condition; **OR**
- Patient must not have failed PBS-subsidised treatment with this drug for this condition in the first-line setting.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11079D	200 mg	3	0.00	*17,781.56	25.00	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. Monday to Friday).

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

17440

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 developed disease progression 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 for this condition in a lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11087M	200 mg	11	0.00	*17,781.56	25.00	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. Monday to Friday).

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

17507

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 developed disease progression 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 for this condition in a lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11096B	200 mg	11	0.00	*17,781.56	25.00	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. Monday to Friday).

Authority Required

13181

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 in a lifetime.

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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
11664X	180 mg	11	0.00	*17,781.56	25.00	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. Monday to Friday).

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

19460

Advanced Stage CD30 positive Hodgkin lymphoma

Clinical criteria:

- 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 a multi-drug chemotherapy regimen, **AND**
- The treatment must not be more than 6 treatment cycles under this restriction in a lifetime.

At the time of the authority application, medical practitioners must request the appropriate maximum amount and number of repeats to complete up to 6 cycles of treatment based on the following:

- Up to a maximum of 180 mg and 5 repeats may be requested where dosing is administered as part of the BrECADD regimen (i.e. in combination with etoposide, cyclophosphamide, doxorubicin, dacarbazine, dexamethasone); or
- Up to a maximum of 120 mg and 11 repeats may be requested where dosing is administered as part of the A+AVD regimen (i.e. in combination with doxorubicin, vinblastine and dacarbazine)

Injection

15098P

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
180 mg	11	0.00	*17,781.56	25.00	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

BRENTUXIMAB VEDOTIN

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

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

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

18301

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 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 a histology report on the tumour sample from an Approved Pathology Authority showing CD30 positivity of at least 3% malignant cells; and

(b) The date of initial diagnosis of Peripheral T-cell lymphoma.

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

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

(i) details of the proposed prescription; 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).

Injection

12646N

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
200 mg	5	0.00	*17,781.56	25.00	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. Monday to Friday).

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

Authority Required

13212

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**

- Patient must not have developed 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.

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
12657E	200 mg	1	0.00	*17,781.56	25.00	Adcetris [TK] (brentuximab vedotin 50 mg injection, 1 vial)

ELOTUZUMAB

Note Continuing treatment with elotuzumab is only available through the Pharmaceutical Benefits Scheme (PBS) for existing eligible patients from 1 December 2024.

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

Note Special Pricing Arrangements apply.

Authority Required

12847

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.

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
12983H	1200 mg	5	0.00	*5,042.59	25.00	Empliciti [BQ] (elotuzumab 300 mg injection, 1 vial)
						Empliciti [BQ] (elotuzumab 400 mg injection, 1 vial)

ENFORTUMAB VEDOTIN

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)

19059

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

Clinical criteria:

- The condition must have progressed on/following both: (i) platinum-based chemotherapy, (ii) programmed cell death 1/ligand 1 (PD-1/PD-L1) inhibitor therapy; **OR**

- The condition must have progressed on/following platinum-based chemotherapy, whilst PD-1/PD-L1 inhibitor therapy resulted in an intolerance that required treatment cessation, **AND**
- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- Patient must not have previously received PBS-subsidised treatment with this drug for this indication in any prior line of treatment, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Treatment criteria:

- Patient must be undergoing treatment with this drug for the first time; **OR**
- Patient must be undergoing continuing treatment with this drug, with each of the following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13648H	125 mg	8	0.00	*6,215.95	25.00	Padcev [LL] (enfortumab vedotin 20 mg injection, 1 vial)
						Padcev [LL] (enfortumab vedotin 30 mg injection, 1 vial)

ENFORTUMAB VEDOTIN

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)

19195

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

Clinical criteria:

- Patient must not have received prior systemic therapy for this condition at the initiation of treatment with this drug, with the exception of neoadjuvant/adjuvant chemotherapy, **AND**
- Patient must have/have had a WHO performance status score of no greater than 2 at treatment initiation with this drug.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of no more than 24 months of: (i) enfortumab vedotin, (ii) pembrolizumab; **OR**
- Patient must be undergoing monotherapy with this drug after exceeding a lifetime total of 24 cumulative months of combination therapy consisting of: (i) enfortumab vedotin, (ii) pembrolizumab, from the first administered dose; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to pembrolizumab, requiring temporary/permanent discontinuation; document the details in the patient's medical records, **AND**
- Patient must be undergoing treatment with this drug for the first time; **OR**
- Patient must be undergoing continuing treatment with this drug, with each of the following being true: (i) all other PBS eligibility criteria in this restriction are met, (ii) disease progression is absent.

Authority Required (STREAMLINED)

19060

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

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

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 September 2026, **AND**
- Patient must have/have had a WHO performance status score of no greater than 2 prior to initiation of non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition.

Treatment criteria:

- Patient must be undergoing combination therapy consisting of no more than 24 months of: (i) enfortumab vedotin, (ii) pembrolizumab; **OR**
- Patient must be undergoing monotherapy with this drug after exceeding a lifetime total of 24 cumulative months of combination therapy consisting of: (i) enfortumab vedotin, (ii) pembrolizumab, from the first administered dose; **OR**
- Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to pembrolizumab, requiring temporary/permanent discontinuation; document the details in the patient's medical records.

Note Patients may qualify for PBS-subsidised treatment under this restriction once only.
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
15513L	125 mg	7	0.00	*6,215.95	25.00	Padcev [LL] (enfortumab vedotin 20 mg injection, 1 vial)
						Padcev [LL] (enfortumab vedotin 30 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

12559

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

12844B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5 mg	2	0.00	*9,259.56	25.00	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

12566

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

12861X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
5 mg	1	0.00	*9,259.56	25.00	Mylotarg [PF] (gemtuzumab ozogamicin 5 mg injection, 1 vial)

GLOFITAMAB

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 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

18124

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Initial treatment (Cycle 1, Day 15)

Clinical criteria:

- Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition, **AND**
- Patient must be unsuitable for stem cell transplant, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received or intend to receive a Cycle 1, Day 8 dose of glofitamab for this indication, **AND**
- The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components.

Glofitamab should be administered as an intravenous infusion according to the dose step-up schedule in Cycle 1 (2.5 mg on Day 8 and 10 mg on Day 15) leading to the recommended dosage of 30 mg on Day 1 of Cycles 2-12. Refer to the TGA approved Product Information.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15228L	10000 mcg	0	0.00	*5,358.66	25.00	Columvi [RO] (Glofitamab 10 mg/10 mL injection, 10 mL vial)

GLOFITAMAB

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 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

18107

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Initial treatment (Cycle 1, Day 8)

Clinical criteria:

- Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition, **AND**
- Patient must be unsuitable for stem cell transplant, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must have received or intend to receive a single pre-treatment dose of obinutuzumab for this indication, **AND**
- The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components.

Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.

Glofitamab should be administered as an intravenous infusion according to the dose step-up schedule in Cycle 1 (2.5 mg on Day 8 and 10 mg on Day 15) leading to the recommended dosage of 30 mg on Day 1 of Cycles 2-12. Refer to the TGA approved Product Information.

This drug 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
15250P	2500 mcg	0	0.00	*1,409.09	25.00	Columvi [RO] (Glofitamab 2.5 mg/2.5 mL injection, 2.5 mL vial)

GLOFITAMAB

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 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

18105

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

Treatment Phase: Continuing treatment (Cycles 2-12)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must be given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components, **AND**
- Patient must not have developed disease progression while being treated with this drug for this condition, **AND**
- The treatment must not exceed a total of 12 cycles of this drug for this indication, regardless of whether treatment was non-PBS or PBS-subsidised.

Authority Required

18061

Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this PBS condition prior to 1 March 2026, **AND**
- Patient must have been unable to receive treatment with CAR-T cell therapy prior to commencing treatment with this drug for this condition, **AND**
- Patient must have been unsuitable for stem cell transplant prior to commencing treatment with this drug for this condition, **AND**
- Patient must have had a WHO performance status of 2 or less prior to commencing 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 given in combination with gemcitabine and oxaliplatin for the first 8 cycles unless the patient has a contraindication/toxicity necessitating discontinuation of one or both chemotherapy components, **AND**
- The treatment must not exceed a total of 12 cycles of this drug for this indication, regardless of whether treatment was non-PBS or PBS-subsidised.

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
15249N	30000 mcg	10	0.00	*15,890.86	25.00	Columvi [RO] (Glofitamab 10 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)

18071

Immunotherapy sensitive advanced or metastatic cancer

Clinical criteria:

- Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for the condition which treatment was commenced for.

The stated maximum amount in this listing is 360 mg however alternative dosing schedules may be prescribed in a quantity up to this amount, but need not be this amount for every cancer type.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15230N	360 mg	4	0.00	*42,849.52	25.00	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)
						Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial)

IPILIMUMAB

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)

18069

Stage III melanoma

Clinical criteria:

- Patient must not have received prior PBS-subsidised treatment for this condition, **AND**
- The treatment must be in addition to complete surgical resection, **AND**
- Patient must have a WHO performance status of 1 or less, **AND**
- The treatment must be in combination with PBS-subsidised treatment with nivolumab.

Prescribed amounts must be consistent with the treatment protocol used for an individual patient.

When ipilimumab is initially prescribed as a 3-weekly dosing regimen, patients must only receive a maximum of 80 mg every 3 weeks for 2 cycles (i.e., 1 repeat), in combination with nivolumab.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
2641B	80 mg	1	0.00	*10,781.80	25.00	Yervoy [BQ] (ipilimumab 50 mg/10 mL injection, 10 mL vial)
						Yervoy [BQ] (ipilimumab 200 mg/40 mL injection, 40 mL vial)

MOGAMULIZUMAB

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

Note Special Pricing Arrangements apply.

Authority Required

13246

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 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 therapy for this condition.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15271R	120 mg	7	0.00	*13,190.56	25.00	POTELIGEO [KO] (mogamulizumab 20 mg/5 mL injection, 5 mL vial)

MOGAMULIZUMAB

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 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

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

Note Special Pricing Arrangements apply.

Authority Required

18425

Cutaneous T-cell lymphoma

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must have received systemic treatment with chemotherapy, **AND**
- Patient must demonstrate relapsed or chemotherapy-refractory disease, **AND**
- Patient must be ineligible for stem cell transplant, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

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

(i) details of the proposed prescription; 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).

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15318F	120 mg	3	0.00	*13,190.56	25.00	POTELIGEO [KO] (mogamulizumab 20 mg/5 mL injection, 5 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)

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.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12945H	1200 mg	13	0.00	*10,484.69	25.00	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)

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
12966K	1200 mg	7	0.00	*10,484.69	25.00	Trodelvy [GI] (sacituzumab govitecan 180 mg injection, 1 vial)

TAFASITAMAB

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

Note Special Pricing Arrangements apply.

Authority Required

18931

Relapsed or refractory follicular lymphoma

Treatment Phase: Initial treatment (Cycles 1 - 5 inclusive)

Clinical criteria:

- The treatment must be/have been initiated in combination with rituximab and lenalidomide, **AND**
- The condition must have relapsed or been refractory to at least one prior therapy prior to initiating treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 5 cycles of treatment under this restriction.

The treatment must not exceed a total of 12 cycles in a lifetime for this indication measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15427Y	1400 mg	15	0.00	*8,352.21	25.00	MINJUVI [XB] (Tafasitamab 200 mg injection, 1 vial)

TAFASITAMAB

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

Note Special Pricing Arrangements apply.

Authority Required

18976

Relapsed or refractory follicular lymphoma

Treatment Phase: Continuing treatment (Cycles 6 - 12 inclusive)

Clinical criteria:

- The treatment must be in combination with lenalidomide, **AND**
- Patient must have previously received treatment with this drug for this condition, **AND**
- The treatment must not exceed a total of 7 cycles of treatment under this restriction, **AND**

- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

The treatment must not exceed a total of 12 cycles in a lifetime for this indication measured from the initial dose, or must not extend beyond disease progression, whichever comes first.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15484Y	1400 mg	13	0.00	*8,352.21	25.00	MINJUVI [XB] (Tafasitamab 200 mg injection, 1 vial)

TREMELIMUMAB

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)

17477

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

Treatment Phase: Initial treatment

Clinical criteria:

- Patient must be undergoing combination treatment with PBS-subsidised durvalumab, **AND**
- 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 of a severity necessitating permanent treatment withdrawal, in the absence of disease progression to a vascular endothelial growth factor (VEGF) tyrosine kinase inhibitor (TKI).

Treatment criteria:

- Patient must not be undergoing PBS-subsidised treatment with this drug for this indication more than once per lifetime.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15090F	300 mg	0	0.00	*16,652.74	25.00	Imjudo [AP] (tremelimumab 300 mg/15 mL injection, 15 mL vial)

Combinations of monoclonal antibodies and antibody drug conjugates

NIVOLUMAB + RELATLIMAB

Caution Combination treatment with nivolumab and relatlimab is associated with an increased incidence and severity of immune-related adverse reactions compared with nivolumab monotherapy. Monitoring at least prior to each dose is recommended.
Note Only one prescribed amount can be used for dispensing and claiming purposes. For nivolumab with relatlimab (Opdualag), nivolumab has been selected as the primary ingredient and the maximum amount reflects the maximum amount of nivolumab only. The prescribed amount of nivolumab will be used to determine the number of vials needed.
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)

16151

Unresectable Stage III or Stage IV malignant melanoma

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 not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.

Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.

The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.

The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14676K	480 mg	11	0.00	*18,288.36	25.00	Opdualag [BQ] (nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial)

NIVOLUMAB + RELATLIMAB

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

Note Only one prescribed amount can be used for dispensing and claiming purposes. For nivolumab with relatlimab (Opdualag), nivolumab has been selected as the primary ingredient and the maximum amount reflects the maximum amount of nivolumab only. The prescribed amount of nivolumab will be used to determine the number of vials needed.

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)

16881

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 either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma; **OR**
- Patient must not have experienced disease recurrence within 6 months of completing either: (i) PD-1 inhibitor treatment, (ii) CTLA-4 inhibitor treatment, if previously treated for resected or resectable melanoma, **AND**
- Patient must have an Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1, **AND**
- The condition must not be uveal melanoma, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

Population criteria:

- Patient must weigh 40 kg or more
- Patient must be at least 12 years of age.

Patients must only receive a maximum of 480 mg nivolumab and 160 mg relatlimab every four weeks under a flat dosing regimen.

The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.

The prescription must include the amount of nivolumab with relatlimab (Opdualag) that is appropriate to be prescribed for the patient. For the purposes of PBS subsidy, the maximum amount requested is based on the nivolumab dose only. The prescribed amount of nivolumab must be expressed in milligrams.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14678M	480 mg	8	0.00	*18,288.36	25.00	Opdualag [BQ] (nivolumab 240 mg/20 mL + relatlimab 80 mg/20 mL injection, 20 mL vial)

OTHER ANTINEOPLASTIC AGENTS

Platinum compounds

CARBOPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4309T	900 mg	5	0.00	*162.56	25.00	Carboplatin Accord [OC] (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	0.00	*141.53	25.00	Cisplatin Accord [OC] (cisplatin 50 mg/50 mL injection, 50 mL vial)
						Cisplatin Accord [OC] (cisplatin 100 mg/100 mL injection, 100 mL vial)

OXALIPLATIN

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4542C	300 mg	11	0.00	*152.83	25.00	OXALIPLATIN BAXTER [BX] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)
						Oxaliplatin Accord [OC] (oxaliplatin 100 mg/20 mL injection, 20 mL vial)

Proteasome inhibitors

BORTEZOMIB

Restricted benefit

11099

Multiple myeloma

Restricted benefit

13745

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Administration on Days 1, 8, 15 and 22 of six treatment cycles (28 days per cycle) in total

Treatment criteria:

- Patient must be undergoing concurrent treatment with PBS-subsidised daratumumab for this PBS indication.

Injection

12227M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3000 mcg	15	0.00	*113.03	25.00	BORTEZOMIB EUGIA [YG] (bortezomib 3.5 mg injection, 1 vial)
					BORTEZOMIB MEDSURGE [DZ] (bortezomib 3.5 mg injection, 1 vial)
					BORTRACZO [JM] (bortezomib 2.5 mg/mL injection, 1 mL vial)
					BORTRACZO [JM] (bortezomib 3.5 mg/1.4 mL injection, 1.4 mL vial)
					Bortezom [CR] (bortezomib 3.5 mg injection, 1 vial)
					Bortezomib Accord [OC] (bortezomib 1 mg injection, 1 vial)
					Bortezomib Accord [OC] (bortezomib 2.5 mg/mL injection, 1 mL vial)
					Bortezomib Accord [OC] (bortezomib 3.5 mg injection, 1 vial)
					Bortezomib Accord [OC] (bortezomib 3.5 mg/1.4 mL injection, 1.4 mL 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 2.5 mg injection, 1 vial)
					Bortezomib Juno [JU] (bortezomib 3.5 mg injection, 1 vial)
					DBL Bortezomib [PF] (bortezomib 3 mg injection, 1 vial)
					DBL Bortezomib [PF] (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

11229B

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
120 mg	17	0.00	*2,503.54	25.00	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

12244K

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
160 mg	8	0.00	*3,307.21	25.00	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 Special Pricing Arrangements apply.

Authority Required (STREAMLINED)
14389
Relapsed and/or refractory multiple myeloma
Treatment Phase: Initial treatment for Cycles 1 to 3
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 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.
Provide details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of the 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 once only through the Authority application for lenalidomide.

Authority Required (STREAMLINED)
14363
Relapsed and/or refractory multiple myeloma
Treatment Phase: Continuing treatment for Cycles 3 to 12
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 progressive disease 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.

Authority Required (STREAMLINED)

14364

Relapsed and/or refractory multiple myeloma

Treatment Phase: Continuing treatment for Cycles 13 onwards

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 progressive disease 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
13638T	60 mg	17	0.00	*1,298.05	25.00	Kyprolis [AN] (carfilzomib 10 mg injection, 1 vial)
						Kyprolis [AN] (carfilzomib 30 mg injection, 1 vial)
						Kyprolis [AN] (carfilzomib 60 mg injection, 1 vial)

Histone deacetylase (HDAC) inhibitors

ROMIDEPSIN

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 amount or number of units may be authorised.

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

Authority Required

18800

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, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
15387W	40 mg	5	0.00	*4,985.64	25.00	ROMIDEPSIN-REACH [RQ] (romidepsin 10 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack)

ROMIDEPSIN

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 amount or number of units may be authorised.

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

Authority Required

18832

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, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

Authority Required

18736

Relapsed or chemotherapy refractory Peripheral T-cell Lymphoma

Treatment Phase: Grandfather arrangement - Transitioning from non-PBS-subsidised treatment

Clinical criteria:

- Patient must have previously received non-PBS-subsidised treatment with this drug for this condition prior to 1 July 2026, **AND**
- The condition must be relapsed or chemotherapy refractory, **AND**
- Patient must have undergone appropriate prior front-line curative intent chemotherapy prior to commencing non-PBS-subsidised treatment with this drug for this condition, **AND**
- Patient must not have developed progressive disease while receiving treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this PBS indication.

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
15370Y	40 mg	8	0.00	*4,985.64	25.00	ROMIDEPSIN-REACH [RQ] (romidepsin 10 mg injection [1 vial] (&) inert substance diluent [2 mL vial], 1 pack)

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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
10691Q	18 mg	140	0.00	*187.24	25.00	Arsenic Trioxide Accord [OC] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials) 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

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
4371C	18 mg	89	0.00	*187.24	25.00	Arsenic Trioxide Accord [OC] (arsenic trioxide 10 mg/10 mL injection, 10 x 10 mL vials)

4371C

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

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.

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

Injection

10144X

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3 mg	13	0.00	*579.91	25.00	Eribulin Dr.Reddy's [RZ] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)
					Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

ERIBULIN

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.

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

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.

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

Injection

11212D

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
3 mg	7	0.00	*579.91	25.00	Eribulin Dr.Reddy's [RZ] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)
					Halaven [EI] (eribulin mesilate 1 mg/2 mL injection, 2 mL vial)

TEBENTAFUSP

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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)

15085

Advanced (unresectable or metastatic) uveal melanoma

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; **OR**
- Patient must have previously received inpatient treatment with this drug for this condition in the public hospital setting, **AND**
- Patient must not receive PBS-subsidised treatment with this drug for this condition if it is no longer determined to be clinically beneficial by the treating clinician.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.

Injection

13823M

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
136 mcg	7	0.00	*35,259.68	25.00	Kimmtrak [WM] (tebentafusp 100 microgram/0.5 mL injection, 0.5 mL vial)

TEBENTAFUSP

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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 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)

14821

Advanced (unresectable or metastatic) uveal melanoma

Treatment Phase: Initial treatment - day 8

Clinical criteria:

- Patient must have HLA-A*02: 01-positive disease, **AND**
- Patient must have previously received PBS-subsidised initial day 1 treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.

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

Positive HLA-A*02: 01 assessment must be documented in the patient's medical records.

Injection

13819H

Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
30 mcg	0	0.00	*17,676.12	25.00	Kimmtrak [WM] (tebentafusp 100 microgram/0.5 mL injection, 0.5 mL vial)

TEBENTAFUSP

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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 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)

14825

Advanced (unresectable or metastatic) uveal melanoma

Treatment Phase: Initial treatment - day 15

Clinical criteria:

- Patient must have HLA-A*02: 01-positive disease, **AND**
- Patient must have previously received PBS-subsidised initial day 8 treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.

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

Positive HLA-A*02: 01 assessment must be documented in the patient's medical records.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13831Y	68 mcg	0	0.00	*17,676.12	25.00	Kimmtrak [WM] (tebentafusp 100 microgram/0.5 mL injection, 0.5 mL vial)

TEBENTAFUSP

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).

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 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

14813

Advanced (unresectable or metastatic) uveal melanoma

Treatment Phase: Initial treatment - day 1

Clinical criteria:

- Patient must have HLA-A*02: 01-positive disease, **AND**
- Patient must have uveal melanoma that has been confirmed either (i) histologically, (ii) cytologically, **AND**
- The treatment must be the sole PBS-subsidised therapy for this condition, **AND**
- Patient must not have received prior systemic therapy for metastatic disease.

Population criteria:

- Patient must be at least 18 years of age.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for the first 3 doses (on Days 1, 8 and 15) and for at least 16 hours after each infusion is completed. If the patient does not experience hypotension that is Grade 2 or worse (requiring medical intervention) with the third dose, subsequent doses can be administered in an appropriate outpatient/ambulatory care setting. Supervision by a health care professional is recommended for a minimum of 30 minutes following each infusion.

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

Positive HLA-A*02: 01 assessment must be documented in the patient's medical records.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
13832B	20 mcg	0	0.00	*17,676.12	25.00	Kimmtrak [WM] (tebentafusp 100 microgram/0.5 mL injection, 0.5 mL vial)

Combinations of antineoplastic agents

DAUNORUBICIN + CYTARABINE

Caution Liposomal daunorubicin and cytarabine (Vyxeos) must not be substituted or interchanged with other daunorubicin and/or cytarabine containing products. Due to substantial differences in the pharmacokinetic parameters, the dose and schedule recommendations for Vyxeos are different from other medications that contain daunorubicin and/or cytarabine in other forms.

Note Only one prescribed amount can be used for dispensing and claiming purposes. For daunorubicin with cytarabine (Vyxeos), daunorubicin has been selected as the primary ingredient and the maximum amount reflects the maximum amount of daunorubicin only. The prescribed amount of daunorubicin will be used to determine the number of vials needed.

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 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

16197

Acute Myeloid Leukaemia

Treatment Phase: Consolidation therapy

Clinical criteria:

- The treatment must be for consolidation treatment following induction treatment with this product, **AND**
- The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality), **AND**
- The treatment must not exceed two cycles of consolidation therapy under this restriction.

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

The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.

Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14661P	64 mg	3	0.00	*16,522.56	25.00	Vyxeos [JA] (daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial)

DAUNORUBICIN + CYTARABINE

Caution Liposomal daunorubicin and cytarabine (Vyxeos) must not be substituted or interchanged with other daunorubicin and/or cytarabine containing products. Due to substantial differences in the pharmacokinetic parameters, the dose and schedule recommendations for Vyxeos are different from other medications that contain daunorubicin and/or cytarabine in other forms.

Note Only one prescribed amount can be used for dispensing and claiming purposes. For daunorubicin with cytarabine (Vyxeos), daunorubicin has been selected as the primary ingredient and the maximum amount reflects the maximum amount of daunorubicin only. The prescribed amount of daunorubicin will be used to determine the number of vials needed.

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 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

16187

Acute Myeloid Leukaemia

Treatment Phase: Induction therapy

Clinical criteria:

- Patient must not have received prior chemotherapy as induction therapy for this condition, **AND**
- The condition must be either: (i) newly diagnosed therapy-related acute myeloid leukaemia (AML), (ii) newly diagnosed AML with myelodysplasia-related changes (MRC) (prior myelodysplastic syndromes (MDS) or MDS-related cytogenetic or molecular abnormality), **AND**
- The condition must not be either: (i) internal tandem duplication (ITD); (ii) tyrosine kinase domain (TKD) FMS tyrosine kinase 3 (FLT3), mutation positive, **AND**
- Patient must not have favourable cytogenetic risk acute myeloid leukaemia (AML), **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of 2 or less, **AND**
- The treatment must not exceed two cycles of induction therapy under this restriction.

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

The prescriber must confirm whether the patient has newly diagnosed therapy-related AML or AML-MRC. The test result and date of testing must be provided at the time of application and documented in the patient's file.

The prescribed dose must be according to the Therapeutic Goods Administration (TGA) Product Information.

Each prescription must include the amount of daunorubicin with cytarabine (Vyxeos) that is appropriate to be prescribed for the patient. For the purposes of the authority application, the maximum amount requested is based on the daunorubicin dose only. The prescribed amount of daunorubicin must be expressed in milligrams.

Injection

	Max. Amount	No. of Rpts	Premium $	DPMA $	MRVSN $	Brand Name and Manufacturer
14669C	97 mg	4	0.00	*24,737.56	25.00	Vyxeos [JA] (daunorubicin hydrochloride 44 mg + cytarabine 100 mg injection, 1 vial)

Related Pharmaceutical Benefits for Public Hospital use

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ALIMENTARY TRACT AND METABOLISM

ANTIEMETICS AND ANTINAUSEANTS

ANTIEMETICS AND ANTINAUSEANTS

Serotonin (5HT3) antagonists

FOSNETUPITANT + PALONOSETRON

Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Note Various sources of information outline the emetic risk associated with cancer treatment. Examples include the National Comprehensive Cancer Network guidelines (USA), eviQ guidelines and approved Product Information of individual drugs. These examples are not a comprehensive list of which anti-cancer drugs that have moderate to high emesis risk.

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.

Authority Required

14387

Nausea and vomiting

Clinical criteria:

- The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy, **AND**
- The treatment must be in combination with dexamethasone, unless contraindicated, **AND**
- Patient must be unable to swallow; **OR**
- Patient must be contraindicated to oral anti-emetics.

fosnetupitant 235 mg + palonosetron 250 microgram injection, 1 vial

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
13650K	1	5	0.00	91.27	25.00	Akynzeo IV [XT]

GRANISETRON

Restricted benefit

4139

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

granisetron 2 mg tablet, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
5898K	2	0	0.00	*16.58	18.12	Kytril [IX]

NETUPITANT + PALONOSETRON

Note This medicine is not PBS-subsidised for nausea and vomiting associated with radiotherapy being used to treat malignancy.

Note Various sources of information outline the emetic risk associated with cancer treatment. Examples include the National Comprehensive Cancer Network guidelines (USA), eviQ guidelines and approved Product Information of individual drugs. These examples are not a comprehensive list of which anti-cancer drugs that have moderate to high emesis risk.

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

Authority Required (STREAMLINED)

14443

Nausea and vomiting

Clinical criteria:

- The treatment must be in combination with dexamethasone, unless contraindicated, **AND**
- The treatment must be for prevention of nausea and vomiting associated with moderate to highly emetogenic anti-cancer therapy.

netupitant 300 mg + palonosetron 500 microgram capsule, 1

	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
10714X	‡1	5	0.00	81.66	25.00	Akynzeo [XT]

ONDANSETRON

Restricted benefit

5778

Nausea and vomiting

Clinical criteria:

- The condition must be associated with cytotoxic chemotherapy being used to treat malignancy which occurs within 48 hours of chemotherapy administration.

Increased maximum quantities will be limited to a maximum of 7 days per chemotherapy cycle.

ondansetron 4 mg tablet, 4

5967C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	3.50	5.04	[a] APX-Ondansetron [TY]	[a] Ondansetron-DRLA [RZ]
					[a] Ondansetron SZ [HX]	[a] Ondansetron Tablets Viatris [AL]
					[a] Ondansetron VTRS [AF]	[a] ONDANSETRON-WGR [WG]
					[a] Zofran [AS]	[a] Zotren 4 [RF]

ondansetron 4 mg/5 mL oral liquid, 50 mL

5848T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
‡1	0	0.00	80.78	25.00	[a] ONDANSETRON-AFT [AE]	[a] Zofran syrup 50 mL [AS]

ondansetron 8 mg tablet, 4

5968D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	4.33	5.87	[a] APX-Ondansetron [TY]	[a] Ondansetron-DRLA [RZ]
					[a] Ondansetron SZ [HX]	[a] Ondansetron Tablets Viatris [AL]
					[a] Ondansetron VTRS [AF]	[a] ONDANSETRON-WGR [WG]
					[a] Zofran [AS]	[a] Zotren 8 [RF]

ONDANSETRON

Restricted benefit

5743

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.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	3.50	5.04	[a] APX-Ondansetron ODT [TY]	[a] Ondansetron ODT-DRLA [RZ]
					[a] Ondansetron ODT Viatris [AL]	[a] ONDANSETRON ODT-WGR [WG]
					[a] Ondansetron SZ ODT [HX]	[a] Zotren ODT [RF]

ondansetron 8 mg orally disintegrating tablet, 4

5858H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	4.33	5.87	[a] APX-Ondansetron ODT [TY]	[a] Ondansetron ODT-DRLA [RZ]
					[a] Ondansetron ODT Viatris [AL]	[a] Ondansetron ODT VTRS [MQ]
					[a] ONDANSETRON ODT-WGR [WG]	[a] Ondansetron SZ ODT [HX]
					[a] Zotren ODT [RF]	

PALONOSETRON

Restricted benefit

5805

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.

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.

palonosetron 250 microgram/5 mL injection, 5 mL vial

5853C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	0	0.00	9.91	11.45	[a] Palonosetron Dr.Reddy's [RZ]	[a] Palonosetron JN [XT]
					[a] PALONOSETRON Medsurge [DZ]	

Other antiemetics

APREPITANT

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.

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)

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.

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)

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.

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)

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.

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.

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aprepitant 165 mg capsule, 1

2550F

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	49.52	25.00	[a] Aprepitant APOTEX [TX]	[a] APREPITANT SCP [XC]

FOSAPREPITANT

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.

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)

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.

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)

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.

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)

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.

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.

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fosaprepitant 150 mg injection, 1 vial

11103J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
1	5	0.00	47.63	25.00	[a] FOSAPREPITANT-AFT [AE]	[a] FOSAPREPITANT MEDSURGE [DZ]
					[a] FOSAPREPITANT MSN [RQ]	

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

12691

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

12682L

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	6,659.77	25.00	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

12845

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.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	0.00	6,659.77	25.00	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

17491

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 PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), or irrespective of whether the disease staging has been changed (i.e. disease has changed from untreated multiple myeloma to relapsed or refractory multiple myeloma), (ii) changing the drug's form (intravenous/subcutaneous) within the first 9 weeks of treatment for the same PBS indication.

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.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	8	0.00	6,659.77	25.00	Darzalex SC [JC]

DARATUMUMAB

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 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

17413

Untreated multiple myeloma

Treatment Phase: Continuing treatment as first line drug therapy from week 25 onwards (administered once every four weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition, **AND**
- The treatment must form part of triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, and (iii) dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide, **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

15083W	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	5	0.00	6,659.77	25.00	Darzalex SC [JC]

DARATUMUMAB

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 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

17661

Untreated multiple myeloma

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

Clinical criteria:

- Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 November 2025, **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: (a) the condition was newly diagnosed, (b) the condition was confirmed by a histological diagnosis, (c) the patient was/is ineligible for a stem cell transplant, (d) the treatment is being given as triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, (iii) dexamethasone, (e) patient is not receiving

concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide, **AND**

- Patient must not have developed disease progression while receiving treatment with this drug for this condition.

Treatment criteria:

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 24 weeks of treatment for the same PBS indication.

Details of the histological diagnosis of multiple myeloma, record of ineligibility for stem cell transplant and 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.

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.

Note Patients may qualify for PBS-subsidised treatment under this restriction to complete 24 weeks of treatment. For continuing PBS-subsidised treatment after week 24, 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.

daratumumab 1.8 g/15 mL injection, 15 mL vial

15092H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	15	0.00	6,659.77	25.00	Darzalex SC [JC]

DARATUMUMAB

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 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

17660

Untreated multiple myeloma

Treatment Phase: Initial treatment as first-line drug therapy from week 0 to week 24

Clinical criteria:

- The condition must be newly diagnosed, **AND**
- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must be ineligible for a primary stem cell transplantation, **AND**
- The treatment must form part of triple combination therapy limited only to: (i) this drug, (ii) lenalidomide, and (iii) dexamethasone, **AND**
- Patient must not be receiving concomitant PBS-subsidised treatment with bortezomib, carfilzomib, elotuzumab, pomalidomide, selinexor or thalidomide.

Treatment criteria:

- Patient must be undergoing PBS-subsidised treatment with this drug once per lifetime. Meaning, patient must access this drug in one of the following situations: (i) for the first time, irrespective of whether the diagnosis has been re-classified (i.e. the diagnosis has changed between multiple myeloma/amyloidosis), (ii) changing the drug's form (intravenous/subcutaneous) within the first 24 weeks of treatment for the same PBS indication.

Details of the histological diagnosis of multiple myeloma, record of ineligibility for stem cell transplant and 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.

daratumumab 1.8 g/15 mL injection, 15 mL vial

15102W

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	15	0.00	6,659.77	25.00	Darzalex SC [JC]

DARATUMUMAB

Note The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

Note Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 888 333.

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

PBS Authorities

GPO Box 9826

[Your capital city]

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

18406

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Initial treatment from week 0 to week 24

Clinical criteria:

- The condition must have histological evidence consistent with a diagnosis of systemic light-chain amyloidosis, **AND**
- The condition must be untreated with drug therapy, including this drug, irrespective of whether the diagnosis has been reclassified (i.e. the diagnosis changes between multiple myeloma/amyloidosis), **AND**
- Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 2 at treatment initiation.

Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing concomitant treatment limited to each of: (i) bortezomib, (ii) cyclophosphamide, (iii) dexamethasone, at certain weeks of treatment as outlined in the drug's approved Product Information.

The authority application must be made via the Online PBS Authorities System (real time assessment), or in writing via HPOS form upload or mail, and must include:

Details of the histological evidence supporting the diagnosis of systemic light chain amyloidosis, limited to: (i) the name of pathologist/pathology provider, (ii) the site of biopsy

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

(i) details of the proposed prescription; 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).

daratumumab 1.8 g/15 mL injection, 15 mL vial

13201T

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	15	0.00	6,659.77	25.00	Darzalex SC [JC]

DARATUMUMAB

Note The intravenously administered presentation of this drug is not PBS listed for this indication at the request of the sponsor.

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

13774

Newly diagnosed systemic light chain amyloidosis

Treatment Phase: Continuing treatment from week 25 onwards (administered once every four weeks)

Clinical criteria:

- Patient must have previously received PBS-subsidised treatment with this drug for this condition.

Treatment criteria:

- Must be treated by a haematologist (this does not exclude treatment via a multidisciplinary team, but the PBS authority application must be sought by the treating haematologist), **AND**
- Patient must be undergoing continuing treatment that does not extend treatment duration beyond whichever comes first: (i) disease progression, (ii) 96 cumulative weeks from the first administered dose, once in a lifetime.

daratumumab 1.8 g/15 mL injection, 15 mL vial

13203X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	6,659.77	25.00	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.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	0.00	1,470.22	25.00	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.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	0	0.00	1,470.22	25.00	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

10817H	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	3	0.00	1,470.22	25.00	Herceptin SC [RO]

PD-1/PD-L1 (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.

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14249Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	7	0.00	6,747.37	25.00	Tecentriq SC [RO]

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.

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14268Y	Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
	1	7	0.00	6,747.37	25.00	Tecentriq SC [RO]

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.

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14226R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	4	0.00	6,747.37	25.00	Tecentriq SC [RO]

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)

18242

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition.

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14250B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	6,747.37	25.00	Tecentriq SC [RO]

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)

15455

Resected early stage (Stage II to IIIA) non-small cell lung cancer (NSCLC)

Treatment Phase: 1,875 mg administered once every 3 weeks

Population criteria:

- Patient must be both: (i) initiating treatment, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy; **OR**
- Patient must be continuing existing PBS-subsidised treatment with this drug; **OR**
- Patient must be both: (i) transitioning from existing non-PBS to PBS subsidised supply of this drug, (ii) untreated with programmed cell death-1/ligand 1 (PD-1/PD-L1) inhibitor therapy at the time this drug was initiated.

Clinical criteria:

- Patient must have/have had a WHO performance status score of no greater than 1 at treatment initiation with this drug, **AND**
- The treatment must be for the purpose of adjuvant therapy following all of: (i) surgical resection, (ii) platinum-based chemotherapy, **AND**
- The condition must have/have had, at treatment commencement, an absence of each of the following gene abnormalities confirmed via tumour material sampling: (i) an activating epidermal growth factor receptor (EGFR) gene mutation, (ii) an anaplastic lymphoma kinase (ALK) gene rearrangement, **AND**
- The condition must have/have had, at treatment commencement, confirmation of programmed cell death ligand 1 (PD-L1) expression on at least 50% of tumour cells, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

Treatment criteria:

- Patient must be undergoing treatment that does not occur beyond the following, whichever comes first: (i) the first instance of disease progression/recurrence, (ii) 12 months in total for this condition from the first administered dose; mark any remaining repeat prescriptions with the words 'cancelled' where (i)/(ii) has occurred.

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14255G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	7	0.00	6,747.37	25.00	Tecentriq SC [RO]

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)

18257

Extensive-stage small cell lung cancer

Treatment Phase: Initial treatment

Clinical criteria:

- The condition must be previously untreated, **AND**
- Patient must not have previously received programmed cell death-1/ligand-1 (PD-1/PD-L1) inhibitor therapy for any stage of small cell lung cancer, **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.

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14289C

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	0.00	6,747.37	25.00	Tecentriq SC [RO]

ATEZOLIZUMAB

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

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

Note Special Pricing Arrangements apply.

Authority Required (STREAMLINED)

10917

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

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

Treatment criteria:

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

Clinical criteria:

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

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

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14575D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	8	0.00	6,747.37	25.00	Tecentriq SC [RO]

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)

18326

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; **OR**
- The condition must have progressed after treatment with a prior targeted therapy PBS-listed for this condition, **AND**
- Patient must not have received prior treatment with a programmed cell death-1 (PD-1) inhibitor or a programmed cell death ligand-1 (PD-L1) inhibitor for non-small cell lung cancer, **AND**
- Patient must have a WHO performance status of 0 or 1, **AND**
- The condition must not have evidence of an activating epidermal growth factor receptor (EGFR) gene mutation or an anaplastic lymphoma kinase (ALK) gene rearrangement in tumour material.

Authority Required (STREAMLINED)

10125

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

Treatment Phase: Initial treatment 2

Treatment criteria:

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

Clinical criteria:

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

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14298M

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	6,747.37	25.00	Tecentriq SC [RO]

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 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)

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.

atezolizumab 1.875 g/15 mL injection, 15 mL vial

14277K

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	3	0.00	6,747.37	25.00	Tecentriq SC [RO]

Other monoclonal antibodies and antibody drug conjugates

ELRANATAMAB

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

18377

Relapsed or refractory multiple myeloma

Treatment Phase: Continuing treatment

Clinical criteria:

- Patient must have previously received treatment with this drug for this condition, **AND**
- Patient must have had progressive disease after receiving at least 3 prior lines of therapy, including each of the following therapies: (i) a proteasome inhibitor, (ii) an immunomodulatory agent, and (iii) an anti-CD38 monoclonal antibody; **OR**
- Patient must have been refractory to, at least 3 prior lines of therapy, including each of the following therapies: (i) a proteasome inhibitor, (ii) an immunomodulatory agent, (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must not have previously received treatment with another B-cell maturation antigen (BCMA) directed therapy for this condition, **AND**
- Patient must have a WHO performance status of 2 or less prior to initiating treatment with this drug for this condition, **AND**
- Patient must not have developed disease progression while receiving treatment with this drug for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy 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).

Prescribers may request the number of vials in line with the dosing requirement for each stage of treatment with the intention of providing the number of vials for each 4-weeks of treatment (24-weeks of treatment including repeats). Up to 4 vials with 5 repeats may be requested for a patient undergoing treatment in weeks 2-26. Up to 2 vials with 5 repeats may be requested for a patient undergoing treatment from week 27 onwards. Requests beyond what is listed in the TGA approved product information will not be approved.

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

Elranatamab 76 mg/1.9 mL injection, 1.9 mL vial

15331X

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	6,038.00	25.00	Elrexfio [PF]

ELRANATAMAB

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

18709

Relapsed or refractory multiple myeloma

Treatment Phase: Induction treatment (step-up dosing)

Clinical criteria:

- The condition must be confirmed by a histological diagnosis, **AND**
- Patient must have progressive disease after receiving at least 3 prior lines of therapy, including each of the following therapies: (i) a proteasome inhibitor, (ii) an immunomodulatory agent, and (iii) an anti-CD38 monoclonal antibody; **OR**
- Patient must be refractory to, at least 3 prior lines of therapy, including each of the following therapies: (i) a proteasome inhibitor, (ii) an immunomodulatory agent, (iii) an anti-CD38 monoclonal antibody, **AND**
- Patient must have a WHO performance status of 2 or less, **AND**
- Patient must not have previously received treatment with another B-cell maturation antigen (BCMA) directed therapy for this condition, **AND**
- The treatment must be the sole PBS-subsidised systemic anti-cancer therapy for this condition.

According to the TGA-approved Product Information, hospitalisation is recommended at minimum for 48 hours after administration of the first step-up dose, and for 24 hours after administration of the second step-up dose.

Patients who require restarting therapy due to dose delays may access step-up dosing through this induction treatment restriction.

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

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.
Refractory disease is defined as less than or equal to a 25% response to therapy, or progression during or within 60 days after completion of therapy.

Elranatamab 44 mg/1.1 mL injection, 1.1 mL vial

15301H

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	0.00	3,496.00	25.00	Elrexfio [PF]

EPCORITAMAB

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).
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)
16466
Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)
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 discontinued in patients who experience disease progression whilst on treatment.

Treatment criteria:

- Patient must be undergoing treatment with this drug administered weekly in cycles 1 to 3 - prescribe up to 9 repeats; **OR**
- Patient must be undergoing treatment with this drug administered fortnightly in cycles 4 to 9 - prescribe up to 5 repeats; **OR**
- Patient must be undergoing treatment with this drug administered every four weeks in cycles 10 and beyond - prescribe up to 2 repeats.

Epcoritamab 48 mg/0.8 mL injection, 0.8 mL vial

14827J

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	9	0.00	9,230.77	25.00	Epkinly [VE]

EPCORITAMAB

Caution Careful monitoring of patients is required due to risk of developing life-threatening Cytokine Release Syndrome (CRS).
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
19052
Relapsed or refractory diffuse large B-cell lymphoma (DLBCL)
Treatment Phase: Induction treatment
Clinical criteria:

- The condition must have relapsed, or be refractory to, at least two prior systemic therapies, **AND**
- Patient must have a WHO performance status of no higher than 2, **AND**
- Patient must have previously received treatment with chimeric antigen receptor-T (CAR-T) cell therapy for this condition; **OR**
- Patient must be currently unable to receive treatment with CAR-T cell therapy for this condition, **AND**
- Patient must not be eligible for stem cell transplantation, **AND**
- Patient must not have received prior treatment with a PBS-subsidised CD20xCD3 bispecific monoclonal antibody (unless this is for a re-priming cycle with epcoritamab due to missed or delayed dose), **AND**
- The treatment must be discontinued in patients who experience disease progression whilst on treatment.

Prior systemic therapy may include autologous stem cell transplant.

Definition of patients unable to receive treatment with CAR-T cell therapy for this condition include geographical, psychosocial, clinical ineligibility or urgency.

Note A dose of 0.16 mg to be administered on Day 1 with initial 4 mg vial. A dose of 0.8 mg to be administered on Day 8 with the repeat 4 mg vial. Refer to the epcoritamab Therapeutic Goods Administration (TGA) approved Product Information.

Epcoritamab 4 mg/0.8 mL injection, 0.8 mL vial

14803D

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	0.00	769.23	25.00	Epkinly [VE]

IMMUNOSTIMULANTS

IMMUNOSTIMULANTS

Other immunostimulants

MYCOBACTERIUM BOVIS BCG DANISH STRAIN

Restricted benefit

5597

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis BCG Danish strain 30 mg injection, 4 vials

12925G

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
‡3	1	0.00	*1,650.00	25.00	VesiCulture [LM]

MYCOBACTERIUM BOVIS BCG TICE STRAIN

Restricted benefit

5597

Primary and relapsing superficial urothelial carcinoma of the bladder

Mycobacterium bovis BCG Tice strain 500 million CFU injection, 3 vials

5902P

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	1	0.00	399.49	25.00	OncoTICE [MK]

VARIOUS

ALL OTHER THERAPEUTIC PRODUCTS

ALL OTHER THERAPEUTIC PRODUCTS

Detoxifying agents for antineoplastic treatment

FOLINIC ACID

folinic acid 50 mg/5 mL injection, 5 mL vial

5890B

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer	Brand Name and Manufacturer
10	2	0.00	*195.00	25.00	[a] CALCIUM FOLINATE MEDSURGE [DZ]	[a] DBL Leucovorin Calcium [PF]

FOLINIC ACID

Restricted benefit

5973

Megaloblastic anaemias

Clinical criteria:

- The condition must be a result of folic acid deficiency from the use of folic acid antagonists.

folinic acid 15 mg tablet, 10

5904R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	0	0.00	76.00	25.00	Leucovorin Calcium (Hospira Pty Limited) [PF]

MESNA

Restricted benefit

5130

Urothelial toxicity

Treatment Phase: Prophylaxis or reduction of toxicity

Clinical criteria:

- The treatment must be adjunctive therapy to ifosfamide or high dose cyclophosphamide.

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

5960Q

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	51.74	25.00	Uromitexan [BX]

mesna 1 g/10 mL injection, 15 x 10 mL ampoules

5961R

Max.Qty Packs	No. of Rpts	Premium $	DPMQ $	MRVSN $	Brand Name and Manufacturer
1	5	0.00	117.16	25.00	Uromitexan [BX]

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Code	Manufacturer
AE	AFT Pharmaceuticals (AU) Pty Ltd
AF	Alphapharm Pty Ltd
AL	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 LTD
CR	Pharmacor Pty Limited
DZ	Medsurge Healthcare Pty Ltd
EI	Eisai Australia Pty Ltd
EW	Celltrion Healthcare Australia Pty Ltd
FF	Phebra Pty Ltd
GI	Gilead Sciences Pty Limited
GK	GlaxoSmithKline Australia Pty Ltd
HX	Sandoz Pty Ltd
IE	BEONE MEDICINES AUS PTY LTD
IT	InterPharma Pty Ltd
IX	Clinect Pty Ltd
JA	JAZZ PHARMACEUTICALS ANZ PTY LTD
JC	Janssen-Cilag Pty Ltd
JM	Glenmark Pharmaceuticals (Australia) Pty Ltd
JO	Juno Pharmaceuticals Pty Ltd
JU	Juno Pharmaceuticals Pty Ltd
KO	KYOWA KIRIN AUSTRALIA PTY LTD
KS	KSJ GROUP PTY LTD
LL	Astellas Pharma Australia Pty Ltd
LM	Link Medical Products Pty Ltd
MF	Mundipharma Pty Limited
MK	Merck Sharp & Dohme (Australia) Pty Ltd
MQ	Alphapharm Pty Ltd
OC	Accord Healthcare Pty. Ltd.
OD	Accord Healthcare Pty. Ltd.
PF	Pfizer Australia Pty Ltd
RA	Sun Pharma ANZ Pty Ltd
RF	Arrow Pharma 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
SZ	Sandoz Pty Ltd
TK	Takeda Pharmaceuticals Australia Pty. Ltd.
TS	Specialised Therapeutics Australia Pty Ltd
TX	Apotex Pty Ltd
TY	Apotex Pty Ltd
VE	AbbVie Pty Ltd
WG	WAGNER PHARMACEUTICALS PTY LTD
WM	MEDISON PHARMA AUSTRALIA PTY LIMITED
XB	Specialised Therapeutics Alim Pty Ltd
XC	Southern Cross Pharma Pty Ltd
XT	Arrotex Pharmaceuticals Pty Ltd
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ZL	Specialised Therapeutics Pharma Pty Ltd

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