

## **6.12 PEMBROLIZUMAB, Solution concentrate for I.V. infusion 100 mg in 4 mL, Keytruda<sup>®</sup>, Merck Sharp & Dohme (Australia) Pty Ltd**

### **1 Purpose of Submission**

- 1.1 The Category 3 submission requested the addition of a new regimen of 400 mg every six weeks (herein referred to as 400 mg Q6W) for pembrolizumab for the treatment of urothelial cancer, colorectal cancer, primary mediastinal B-cell lymphoma and classical Hodgkin's lymphoma indications.
- 1.2 The submission also requested the 400 mg Q6W dosing be extended to recommended but not yet implemented pembrolizumab listings for Stage IV clear cell variant renal cell carcinoma (RCC), advanced endometrial cancer, squamous cell carcinoma of the head and neck (SCCHN) and oesophageal carcinoma which were considered by PBAC at its March 2022 meeting.

### **2 Background**

#### ***Registration status***

- 2.1 On 2 November 2021 the Therapeutic Goods Administration (TGA) extended pembrolizumab 400 mg Q6W for all approved indications for adult patients.
- 2.2 Currently, the TGA recommended doses of pembrolizumab in adults are 200 mg every 3 weeks (herein referred to as 200 mg Q3W) or 400 mg Q6W.

#### ***Previous PBAC consideration***

- 2.3 At its March 2020 meeting, the PBAC recommended listing for pembrolizumab to include the additional dosing regimen 400 mg Q6W for stage IV metastatic NSCLC, unresectable stage III or stage IV malignant melanoma and resected stage IIIB, stage IIIC or stage IIID malignant melanoma. On the 1 September 2020 pembrolizumab 400 mg Q6W was listed on the PBS for the treatment of stage IV metastatic NSCLC, unresectable stage III or stage IV malignant melanoma and resected stage IIIB, stage IIIC or stage IIID malignant melanoma.
- 2.4 All other pembrolizumab indications currently listed or PBAC recommended but not yet implemented provide for the 200 mg Q3W dosing regimen.

### **3 Requested listing**

- 3.1 The submission requested additional listings of pembrolizumab with new maximum amounts of 400 mg and 3 repeats for each TGA registered indication where this new dosing regimen was either: (i) already present on the PBS, (ii) recommended by the PBAC, but yet to be implemented at the time of the July 2022 PBAC meeting. No other changes to the existing PBS restrictions were proposed.
- 3.2 An abridged version of Secretariat suggested additions are in italics and deletions are in strikethrough. This is provided in Table 1.

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**Table 1: Essential information of requested listings for pembrolizumab 100 mg injection, 1 vial**

Indication	Restriction type	PBS item code	Max. Amount	No. of Rpts
Relapsed or Refractory Hodgkin lymphoma	Authority Required	11330H (Public)	<del>200 mg</del>	<del>3</del>
		11352L (Private)	400 mg	6
Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer	Authority Required (STREAMLINED)	11646Y (Public)	<del>200 mg</del>	<del>3</del>
		11632F (Private)	400 mg	6
Relapsed or refractory primary mediastinal B-cell lymphoma	Authority Required	12129J (Public)	<del>200 mg</del>	<del>3</del>
		12126F (Private)	400 mg	6
Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer	Authority Required	12615Y (Public)	<del>200 mg</del>	<del>3</del>
		12605K (Private)	400 mg	6
Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma — <del>3</del> weekly treatment regimen	Authority Required	12120X (Public)	<del>200 mg</del>	<del>7</del>
		12130K (Private)	400 mg	7
Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma — <del>6</del> weekly treatment regimen	Authority Required (STREAMLINED)	12127G (Public)	<del>400 mg</del>	<del>3</del>
		12125 (Private)	400 mg	3
Unresectable Stage III or Stage IV malignant melanoma — <del>3</del> weekly treatment regimen	Authority Required (STREAMLINED)	10436G (Public)	<del>200 mg</del>	<del>7</del>
		10424P (Private)	400 mg	7
		10493G (Public)	<del>200 mg</del>	<del>5</del>
		10475H (Private)	400 mg	5
Unresectable Stage III or Stage IV malignant melanoma — <del>6</del> weekly treatment regimen	Authority Required (STREAMLINED)	12124D (Public)	<del>400 mg</del>	<del>3</del>
		12122B (Private)	400 mg	3
		12128H (Public)	400 mg	3
		12123C (Private)	400 mg	3
Stage IV (metastatic) non-small cell lung cancer (NSCLC) — <del>3</del> weekly treatment regimen	Authority Required (STREAMLINED)	11492W (Public)	<del>200 mg</del>	<del>6</del>
		11494Y (Private)	400 mg	6
Stage IV (metastatic) non-small cell lung cancer (NSCLC) — <del>6</del> weekly treatment regimen	Authority Required (STREAMLINED)	12119W (Public)	<del>400 mg</del>	<del>3</del>
		12121Y (Private)	400 mg	3
Advanced or metastatic gastro-oesophageal cancers	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Stage IV clear cell variant renal cell carcinoma (RCC)	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Advanced, metastatic or recurrent endometrial carcinoma	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Stage IV clear cell variant renal cell carcinoma (RCC)	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Advanced or metastatic gastro-oesophageal cancers	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6

**Table 2: Essential restriction changes of requested listings for pembrolizumab 100 mg injection, 1 vial**

	<b>Restriction changes</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 7 doses under this restriction
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 35 cycles in a lifetime
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing treatment with this drug at a dose of up to 200 mg, administered once every 3 weeks – prescribe up to 6 repeat prescriptions; or</i>
	<i>Patient must be undergoing treatment with this drug at a dose of 400 mg, administered once every 6 weeks - prescribe only up to 3 repeat prescriptions in these circumstances</i>
	<b>Treatment criteria:</b>
	<i>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime</i>
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing treatment through this treatment phase listing once only – for further prescribing, see the ‘Continuing treatment’ phase listing.</i>

- 3.3 The Secretariat noted creating separate listings with a maximum amount of 400 mg and 3 repeats to provide for 400 mg Q6W dosing would result in substantial PBS item code proliferation due to separate codes for: Initial and Continuing treatments, Section 100 (Efficient Funding of Chemotherapy) Public and Private hospital program and the large number of existing and recommended indications. This would result in difficulty in identifying the relevant restriction for a particular patient by prescribers, as well as difficulty for the general public when reading the PBS.
- 3.4 Instead, the Secretariat suggested amending all current pembrolizumab listings and pembrolizumab listings that have been recommended, but not yet implemented, to increase the maximum amount from 200 mg to 400 mg to allow for the proposed dosing regimen whilst retaining the current/recommended number of repeat prescriptions and include an extra set of treatment criteria which directs the number of repeats to prescribe based on dosing.
- 3.5 The Secretariat proposed to remove the treatment criteria that specifies the number of doses allowed e.g. *“The treatment must not exceed a total of 7 doses under this restriction”*. As the number of total doses are already determined by: (i) the stated number of repeats, (ii) whether re-entry is permitted, (iii) whether administrative

notes ‘No increases in Maximum Amount or Number of repeats’ are present. There is also the inclusion of treatment criteria which directs the number of repeats to prescribe based on dosing.

- 3.6 The Secretariat noted 35 cycles (24 months) is only applicable to Q3W. The Secretariat proposed 400 mg with 3 repeats (4 doses) would provide a sufficient amount for 6 months of treatment for all indications under the Q6W dosing regimen. The Secretariat proposes replacing the treatment criterion ‘The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction’ from the restriction with ‘Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime’.
- 3.7 Currently, Pembrolizumab 200 mg Q3W with 6 repeats and 400 mg Q6W with 3 repeats are under separate listings for the treatment of NSCLC and melanoma. The Secretariat proposes retaining the 200 mg with 6 repeats listing, amending the maximum amount to 400 mg and discontinuing 400 mg with three repeats listings. The listing with fewer repeat is more suited to Supply only arrangements.

*For more detail on PBAC’s view, see section 5 PBAC outcome.*

## 4 Consideration of the evidence

### ***Sponsor hearing***

- 4.1 There was no hearing for this item.

### ***Consumer comments***

- 4.2 The PBAC noted that no consumer comments were received for this item.

### ***Clinical trials***

- 4.3 The submission did not present any clinical evidence for pembrolizumab administered at 400 mg Q6W. The submission provided pharmacokinetic (PK) modelling data from the clinical study, KN-555 (see Table 3 below). The submission stated the clinical trial was included in the TGA submission to support its application of expanding pembrolizumab’s TGA approved indications to include 400 mg Q6W.

**Table 3: Trials and associated reports presented in the submission**

<b>Trial ID</b>	<b>Protocol title/ Publication title</b>
KN-555	Phase 1 randomised, cross-over, multicentre, open-label, bioavailability and safety study of pembrolizumab in participants with advanced melanoma.

*Source: page 11 of main body submission*

- 4.4 The TGA Delegate Overview (p7) noted that the PK exposure data presented in TGA submission demonstrated that:

- The 400 mg Q6W lead to similar to exposures to that of the approved 200 mg or 2 mg/kg at Q3W dosing regimen and highest clinically tested 10 mg/kg Q2W dosing regimens.
- The observed concentrations for 400 mg Q6W were well within the 90% prediction intervals of simulated concentrations using the model.
- All subjects tolerated initial treatment at 400 mg Q6W and have moved on to subsequent cycles.

The TGA Delegate Overview (p21) also stated that the clinical data did not “suggest any detriment in efficacy and safety with the use of pembrolizumab dose of 400 mg Q6W, and no major differences in efficacy and safety are anticipated in combination with other agents”.

- 4.5 As a Category 3 submission, no evaluation of the clinical evidence was undertaken.

### ***Economic analysis***

- 4.6 The submission did not request any change to the price per vial of pembrolizumab. The proposed dispensed price for maximum amount (DPMA) for the requested PBS listings was based on the current ex-manufacturer price per 100 mg vial.

### ***Estimated PBS utilisation and financial implications***

- 4.7 The submission used a market share approach against 200 mg Q3W dosing regimen to estimate the utilisation and financial implications to the Government when adding the 400 mg Q6W dosing regimen on the PBS.
- 4.8 The submission used the PBS and RPBS service volumes from January to December 2021 for each currently listed PBS indication and estimated that █% of scripts would be impacted by the change to 400 mg Q6W dosing regimen.
- 4.9 The submission estimated a saving to the PBS of \$0 to < \$10 million in Year 6 of listing, with a total net saving to the PBS of \$0 to < \$10 million over the first 6 years of listing. This is summarised *in Table 4 below*.

**Table 4: Estimated use and financial implications for pembrolizumab fixed dose 400 mg Q6W**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated total number of pembrolizumab 200 mg Q3W</b>						
before listing pembrolizumab 400 mg Q6W	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>
after listing pembrolizumab 400 mg Q6W	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>	█ <sup>1</sup>
<b>Total number of pembrolizumab 400 mg Q6W scripts dispensed</b>						
	█ <sup>2</sup>	█ <sup>2</sup>	█ <sup>2</sup>	█ <sup>2</sup>	█ <sup>2</sup>	█ <sup>2</sup>
<b>Estimated financial implications of pembrolizumab fixed dose 400mg Q6W</b>						
Cost to PBS/RPBS less copayments	\$█ <sup>3</sup>	\$█ <sup>3</sup>	\$█ <sup>3</sup>	\$█ <sup>3</sup>	\$█ <sup>3</sup>	\$█ <sup>3</sup>
<b>Estimated financial implications for pembrolizumab 200 Q3W</b>						
Cost to PBS/RPBS less copayments	-\$█ <sup>3</sup>	-\$█ <sup>3</sup>	-\$█ <sup>3</sup>	-\$█ <sup>3</sup>	-\$█ <sup>3</sup>	-\$█ <sup>3</sup>
<b>Net financial implications</b>						
Net cost to PBS/RPBS	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>
Net cost to MBS	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>
Net cost to Government	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>	-\$█ <sup>4</sup>

Source: Financial table workbook (Pembrolizumab \_UCM) supplied with the submission

The redacted values correspond to the following ranges:

<sup>1</sup> 10,000 to < 20,000

<sup>2</sup> 500 < 5,000

<sup>3</sup> \$10 million to < \$20 million

<sup>4</sup> \$0 to < \$10 million

- 4.10 The submission considered that the addition of the 400 mg Q6W dosing regimen is not expected to result in an increase in the treatment uptake rate of patients treated with pembrolizumab or to change the use of other immunotherapy oncology drugs.
- 4.11 The submission also claimed the 400 mg Q6W regimen will provide flexibility and convenience for managing patient care. Patients will experience less frequent dosing and visits to the treating hospital. This would lead to a decrease in resource utilisation in infusion centres, allowing for less administrative burden.
- 4.12 As a Category 3 submission, the financial estimates have not been independently evaluated.

### **Risk Sharing Arrangements**

- 4.13 There are currently Risk Sharing Arrangements (RSAs) in place for pembrolizumab for each of the relevant indications.

*For more detail on PBAC's view, see section 5 PBAC outcome.*

## 5 PBAC Outcome

5.1 The PBAC recommended the addition of the 400 mg Q6W pembrolizumab dosing regimen for the treatment of:

- Relapsed or Refractory Hodgkin lymphoma
- Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer
- Relapsed or refractory primary mediastinal B-cell lymphoma
- Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer
- Advanced or metastatic gastro-oesophageal cancers
- Stage IV clear cell variant renal cell carcinoma (RCC)
- Advanced, metastatic or recurrent endometrial carcinoma
- Stage IV clear cell variant renal cell carcinoma (RCC)
- Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx
- Advanced or metastatic gastro-oesophageal cancers

5.2 The PBAC considered creating separate listings with a maximum amount of 400 mg and three repeats to provide for 400 mg Q6W dosing for 13 indications would propagate excessive PBS item code creation in the pembrolizumab listings. Instead, the PBAC recommended amending the existing listing as follows:

- Increase the maximum amount from 200 mg to 400 mg for indications that currently have (or have been recommended) with 200 mg Q3W dosing regimen, maintain the existing repeat number, but include criteria on the number of repeats to be sought dependent on the chosen frequency of administration.
- For all indications except for Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma and Unresectable Stage III or Stage IV malignant melanoma to combine Initial and Continuing treatment phases into one listing.

5.3 The PBAC noted that the following pembrolizumab indications are currently subject to a RSA with the sponsor:

- Stage IV (metastatic) non-small cell lung cancer (NSCLC),
- Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma and
- Unresectable Stage III or Stage IV malignant melanoma

The PBAC advised these listings should remain unchanged while the RSAs are still in place.

5.4 The PBAC noted the pre-PBAC response with respect to the non-small cell lung cancer and malignant melanoma listings for pembrolizumab stated amendments to the

maximum amount and other listing changes including an extra set of treatment criteria could result in:

- A reduced ability for the Drug Utilisation Subcommittee (DUSC) to calculate the proportion of patients receiving each dosing regimen that impacts the accuracy of any calculation of the patient time on treatment, which is critical for current and future DUSC reviews and future indications.
  - Unintended consequences in the administration of the current monthly deed rebates, yearly reconciliation processes and requirements in relation to the application of any specific rebates by population.
- 5.5 The PBAC further noted the pre-PBAC response stated to mitigate some of the concerns above, the Sponsor suggested using authority codes to record the dosing regimen by patient, with provision of this data to all parties.
- 5.6 The PBAC acknowledged reimbursement claiming may vary in practice. The PBAC considered the risk of excessive pembrolizumab item codes resulting in poor quality data to be high and advised that combining both dosing regimens, and treatment phases (where required) into one listing is reasonable.
- 5.7 The PBAC advised pembrolizumab for the treatment of mediastinal B-cell lymphoma and Classical Hodgkin’s lymphoma be moved to streamlined authority to be in line with other lymphoma treatments that have streamline authority.
- 5.8 The PBAC noted that no clinical data comparing the 400 mg Q6W dosing regimen to the 200 mg Q3W dosing regimen was provided. However, based on the pharmacokinetic (PK) modelling data evaluated by the TGA, the PBAC considered that the effectiveness and safety of the two dosing regimens would likely be comparable.
- 5.9 The PBAC considered the estimated PBS utilisation and financial implications to be reasonable and noted there would be savings to the Government associated with the addition of the 400 mg Q6W dosing regimen due to reduced administration and dispensing fees from fewer scripts dispensed for the 400 mg Q6W dosing regimen compared to that for the 200 mg Q3W dosing regimen.
- 5.10 The PBAC noted pembrolizumab 400 mg Q6W regimen is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 5.11 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## 6 Recommended listing

### 6.1 Amend existing listings to appear as follows:

#### Essential information of recommended listings for pembrolizumab 100 mg injection, 1 vial

Indication	Restriction type	PBS item code	Max. Amount	No. of Rpts
Relapsed or Refractory Hodgkin lymphoma	Authority Required (STREAMLINED)	11330H (Public)	<del>200 mg</del>	<del>3</del>
		11352L (Private)	400 mg	6
Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer	Authority Required (STREAMLINED)	11646Y (Public)	<del>200 mg</del>	<del>3</del>
		11632F (Private)	400 mg	6
Relapsed or refractory primary mediastinal B-cell lymphoma	Authority Required (STREAMLINED)	12129J (Public)	<del>200 mg</del>	<del>3</del>
		12126F (Private)	400 mg	6
Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer	Authority Required	12615Y (Public)	<del>200 mg</del>	<del>3</del>
		12605K (Private)	400 mg	6
Advanced or metastatic gastro-oesophageal cancers	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Stage IV clear cell variant renal cell carcinoma (RCC)	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Advanced, metastatic or recurrent endometrial carcinoma	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Stage IV clear cell variant renal cell carcinoma (RCC)	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
Advanced or metastatic gastro-oesophageal cancers	Authority Required (STREAMLINED)	NEW (Public)	<del>200 mg</del>	<del>3</del>
		NEW (Private)	400 mg	6
<b>Following Pembrolizumab listings remain unchanged:</b>				
Stage IV (metastatic) non-small cell lung cancer (NSCLC) – 3 weekly treatment regimen	Authority Required (STREAMLINED)	11492W (Public)	200 mg	6
		11494Y (Private)		
Stage IV (metastatic) non-small cell lung cancer (NSCLC)- 6 weekly treatment regimen	Authority Required (STREAMLINED)	12119W (Public)	400 mg	3
		12121Y (Private)		
Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma – 3 weekly treatment regimen	Authority Required	12120X (Public)	200 mg	7
		12130K (Private)		

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Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma – 6 weekly treatment regimen	Authority Required	12127G (Public) 12125E (Private)	400 mg	3
Unresectable Stage III or Stage IV malignant melanoma – 3 weekly treatment regimen	Authority Required (STREAMLINED)	10436G (Public) 10424P (Private)	200 mg	7
		10493G (Public) 10475H (Private)	200 mg	5
Unresectable Stage III or Stage IV malignant melanoma – 6 weekly treatment regimen	Authority Required (STREAMLINED)	12122B (Private) 12128H (Public)	400 mg	2
		12124D (Public) 12123C (Private)	400 mg	3

MEDICINAL PRODUCT Form	PBS item code	Amend Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	11330H (Public) 11352L (Private)	200 mg 400 mg	6
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
<b>Restriction Summary: 10871 / Treatment of Concept: 9863</b>			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)			
<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.			
<b>Administrative Advice:</b> Special Pricing Arrangements apply.			
<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.			
<b>Indication:</b> Relapsed or Refractory Hodgkin lymphoma			
<b>Treatment Phase:</b> Initial treatment			
<b>Clinical criteria:</b> Patient must have undergone an autologous stem cell transplant (ASCT) for this condition and have experienced relapsed or refractory disease post ASCT; or Patient must not be suitable for ASCT for this condition and have experienced relapsed or refractory disease following at least 2 prior treatments for this condition			
<b>AND</b>			
<b>Clinical criteria:</b> Patient must not have received prior treatment with a PD-1 (programmed cell death-1) inhibitor for this condition			
<b>AND</b>			
<b>Clinical criteria:</b> The treatment must be the sole PBS-subsidised therapy for this condition			
<b>AND</b>			
<b>Clinical criteria:</b> The treatment must not exceed a total of 7 doses under this restriction			

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Insert	<b>Treatment criteria:</b>
	Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR
	Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions
<b>Restriction Summary 10690 / ToC: 9864: Authority Required</b>	
	<b>Indication:</b> Relapsed or Refractory Hodgkin lymphoma
	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b>
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 35 cycles in a lifetime
	<b>Treatment criteria:</b>
	Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR
	Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions
	<b>AND</b>
	<b>Treatment criteria:</b>
	Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime

		Amend	
MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	11646Y (Public)	200 mg	6
	11632F (Private)	400 mg	
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
		<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals	
		<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners	
		<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)	
		<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.	
		<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.	
		<b>Administrative Advice:</b> Special Pricing Arrangements apply.	
		<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.	
<b>Restriction Summary 9896 / ToC: 9921: Authority Required: Streamlined</b>			
		<b>Indication:</b> Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer	

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	<b>Treatment Phase:</b> Initial treatment
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The condition must have progressed on or after prior platinum based chemotherapy; or
	The condition must have progressed on or within 12 months of completion of adjuvant platinum-containing chemotherapy following cystectomy for localised muscle-invasive urothelial cancer; or
	The condition must have progressed on or within 12 months of completion of neoadjuvant platinum-containing chemotherapy prior to cystectomy for localised muscle-invasive urothelial cancer
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have a WHO performance status of 2 or less
	<b>AND</b>
	<b>Clinical criteria:</b>
	<del>The treatment must not exceed a total of 7 doses under this restriction</del>
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR</i>
	<i>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i>
	<b>Administrative Advice:</b>
	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.
	<b>Restriction Summary 9967 / ToC: 9894: Authority Required: Streamlined</b>
	<b>Indication:</b> Locally advanced (Stage III) or metastatic (Stage IV) urothelial cancer
	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b>
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have stable or responding disease
	<b>AND</b>
	<b>Clinical criteria:</b>
	<del>The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction</del>
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR</i>
	<i>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i>
	<b>AND</b>
	<b>Treatment criteria:</b>
	<i>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime</i>

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MEDICINAL PRODUCT Form		PBS item code	Amend Max. Amount	№.of Rpts
PEMBROLIZUMAB Injection		12129J (Public) 12126F (Private)	200 mg 400 mg	6
<b>Available brands</b>				
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)				
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals				
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)				
<b>Administrative Advice:</b> No increase in the maximum amount or number of units may be authorised.				
<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.				
<b>Administrative Advice:</b> Special Pricing Arrangements apply.				
<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.				
<b>Restriction Summary 10702 / ToC: 10702</b>				
<b>Indication:</b> Relapsed or refractory primary mediastinal B-cell lymphoma				
<b>Treatment Phase:</b> Initial treatment				
<b>Clinical criteria:</b> The condition must be diagnosed as primary mediastinal B-cell lymphoma through histological investigation combined with at least one of: (i) positron emission tomography - computed tomography (PET-CT) scan, (ii) PET scan, (iii) CT scan, with the results retained in the patient's medical records				
<b>AND</b>				
<b>Clinical criteria:</b> Patient must have been treated with rituximab-based chemotherapy for this condition				
<b>AND</b>				
<b>Clinical criteria:</b> Patient must be experiencing relapsed/refractory disease				
<b>AND</b>				
<b>Clinical criteria:</b> Patient must be autologous stem cell transplant (ASCT) ineligible following a single line of treatment; or Patient must have undergone an autologous stem cell transplant (ASCT); or Patient must have been treated with at least 2 chemotherapy treatment lines for this condition, one of which must include rituximab-based chemotherapy				
<b>AND</b>				
<b>Clinical criteria:</b> 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				
<b>AND</b>				
<b>Clinical criteria:</b> The treatment must be the sole PBS-subsidised therapy for this condition				
<b>AND</b>				
<b>Clinical criteria:</b> The treatment must not exceed a total of 7 doses under this restriction				
<b>Treatment criteria:</b> Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions				

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<b>Restriction Summary 10679 / ToC: 10679</b>	
	<b>Indication:</b> Relapsed or refractory primary mediastinal B-cell lymphoma
	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b>
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not develop disease progression while receiving PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 35 cycles in a lifetime
	<b>Treatment criteria:</b>
	Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR
	Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions
	<b>AND</b>
	<b>Treatment criteria:</b>
	Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime

MEDICINAL PRODUCT Form	PBS item code	Amend Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	12615Y (Public) 12605K (Private)	200 mg 400 mg	6
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)			
	<b>Administrative Advice:</b> 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.		
	<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 888 333.		
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.		
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.		
	<b>Administrative Advice:</b> Special Pricing Arrangements apply.		
<b>Restriction Summary 12033 / ToC: 12033</b>			
	<b>Indication:</b> Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer		

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	<b>Treatment Phase:</b> Initial treatment
	<b>Clinical criteria:</b>
	Patient must be untreated for this PBS indication (i.e untreated for each of: (i) unresectable disease, (ii) metastatic disease)
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have received prior treatment for colorectal cancer with each of: (i) a programmed cell death-1 (PD-1) inhibitor, (ii) a programmed cell death ligand-1 (PD-L1) inhibitor
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have a WHO performance status of 0 or 1
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have deficient mismatch repair (dMMR) colorectal cancer, as determined by immunohistochemistry test
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 7 doses under this restriction
	<b>Treatment criteria:</b>
	Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR
	Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions
<b>Restriction Summary 12065 / ToC: 12065</b>	
	<b>Indication:</b> Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer
	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b>
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have progressive disease while receiving PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 35 cycles or up to 24 months of treatment in a lifetime for this condition
	<b>Treatment criteria:</b>
	Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR
	Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions
	<b>AND</b>
	<b>Treatment criteria:</b>
	Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime
<b>Remove Restriction Summary 12014 / ToC: 11993 for 1 August 2022</b>	
	<b>Indication:</b> Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer
	<b>Treatment Phase:</b> Transitioning from non-PBS to PBS-subsidised treatment – Grandfather treatment
	<b>Clinical criteria:</b>
	Patient must have received non-PBS-subsidised treatment with this drug for this condition prior to 1 August 2021
	<b>AND</b>

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

6.2 For indications ‘Stage IV (metastatic) non-small cell lung cancer (NSCLC)’ (concept 21331), ‘Unresectable Stage III or Stage IV malignant melanoma’ (concept 8676) and ‘Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma’ (concept 24811), leave these listings unamended. These indications currently have separate Q3W and Q6W listings on the PBS while the RSAs are still in place.

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	12119W (Public) 12121Y (Private)	400 mg	3
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)			
<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.			
<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.			
<b>Administrative Advice:</b> Special Pricing Arrangements apply.			
<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.			
<b>Restriction Summary 10703 / ToC: 10704: Authority Required: Streamlined</b>			
<b>Indication:</b> Stage IV (metastatic) non-small cell lung cancer (NSCLC)			

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	<b>Treatment Phase:</b> Initial treatment - 6 weekly treatment regimen
	<b>Clinical criteria:</b>
	Patient must not have previously been treated for this condition in the metastatic setting
	<b>AND</b>
	<b>Clinical criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have a WHO performance status of 0 or 1
	<b>AND</b>
	<b>Clinical criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 4 doses under this restriction
	<b>Administrative Advice:</b> 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.
<b>Restriction Summary 10674 / ToC: 10693: Authority Required: Streamlined</b>	
	<b>Indication:</b> Stage IV (metastatic) non-small cell lung cancer (NSCLC)
	<b>Treatment Phase:</b> Continuing treatment - 6 weekly treatment regimen
	<b>Clinical criteria:</b>
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have developed disease progression while being treated with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 18 cycles or up to 24 months of treatment under this restriction

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	11492W (Private) 11494Y (Public)	200 mg	6
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)			
<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised.			
<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.			

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	<b>Administrative Advice:</b> Special Pricing Arrangements apply.
	<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.
<b>Restriction Summary 10673 / ToC: 10681: Authority Required: Streamlined</b>	
	<b>Indication:</b> Stage IV (metastatic) non-small cell lung cancer (NSCLC)
	<b>Treatment Phase:</b> Initial treatment - 3 weekly treatment regimen
	<b>Clinical criteria:</b> Patient must not have previously been treated for this condition in the metastatic setting
	<b>AND</b>
	<b>Clinical criteria:</b> 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
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must have a WHO performance status of 0 or 1
	<b>AND</b>
	<b>Clinical criteria:</b> 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
	<b>AND</b>
	<b>Clinical criteria:</b> The treatment must not exceed a total of 7 doses under this restriction
	<b>Administrative Advice:</b> 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.
<b>Restriction Summary 10691/ ToC: 10682: Authority Required: Streamlined</b>	
	<b>Indication:</b> Stage IV (metastatic) non-small cell lung cancer (NSCLC)
	<b>Treatment Phase:</b> Continuing treatment - 3 weekly treatment regimen
	<b>Clinical criteria:</b> Patient must have previously received PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not have developed disease progression while being treated with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b> The treatment must not exceed a total of 35 cycles or up to 24 months of treatment under this restriction

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	12122B (Private) 12128H (Public)	400 mg	2
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			

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	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Administrative Advice:</b> Special Pricing Arrangements apply.
	<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.
<b>Restriction Summary 10677 / ToC: 10689: Authority Required: Streamlined</b>	
	<b>Indication:</b> Unresectable Stage III or Stage IV malignant melanoma
	<b>Treatment Phase:</b> Initial treatment - 6 weekly treatment regimen
	<b>Clinical criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 3 doses under this restriction
	<b>Administrative Advice:</b> 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.

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	10493G (Public) 10475H (Private)	200 mg	5
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners		
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)		
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.		
	<b>Administrative Advice:</b> Special Pricing Arrangements apply.		
	<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.		
<b>Restriction Summary 10686 / ToC: 10696: Authority Required: Streamlined</b>			
	<b>Indication:</b> Unresectable Stage III or Stage IV malignant melanoma		

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	<b>Treatment Phase:</b> Initial treatment - 3 weekly treatment regimen
	<b>Clinical criteria:</b>
	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
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have experienced disease progression whilst on adjuvant PD-1 inhibitor treatment or disease recurrence within 6 months of completion of adjuvant PD-1 inhibitor treatment if treated for resected Stage IIIB, IIIC, IIID or IV melanoma
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must not exceed a total of 6 doses under this restriction
	<b>Administrative Advice:</b> 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.

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	12127G (Public) 12125E (Private)	400 mg	3
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required			
<b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a> ) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).			
<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised			
<b>Administrative Advice:</b> No increase in the maximum amount or number of units may be authorised.			
<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.			
<b>Administrative Advice:</b> Special Pricing Arrangements apply.			
<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.			
<b>Restriction Summary 10700 / ToC: 10688</b>			
<b>Indication:</b> Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma			
<b>Treatment Phase:</b> Initial treatment - 6 weekly treatment regimen			
<b>Clinical criteria:</b>			
The treatment must be adjuvant to complete surgical resection			
<b>AND</b>			
<b>Clinical criteria:</b>			

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	Patient must have a WHO performance status of 1 or less
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have received prior PBS-subsidised treatment for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must commence within 12 weeks of complete resection
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy
	<b>Administrative Advice:</b> 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.
<b>Restriction Summary 10676 / ToC: 10676</b>	
	<b>Indication:</b> Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
	<b>Treatment Phase:</b> Continuing treatment - 6 weekly treatment regimen
	<b>Clinical criteria:</b>
	Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have experienced disease recurrence
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	No. of Rpts
PEMBROLIZUMAB Injection	12130K (Public) 12120X (Private)	200 mg	7
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners		
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required		
	<b>Administrative Advice:</b> No increase in the maximum quantity or number of units may be authorised		
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.		
	<b>Administrative Advice:</b> Special Pricing Arrangements apply.		

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	<b>Administrative Advice:</b> Patient should be treated with the recommended dose of pembrolizumab according to the TGA-approved Product Information.
<b>Restriction Summary 10699 / ToC: 10687</b>	
	<b>Indication:</b> Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
	<b>Treatment Phase:</b> Initial treatment - 3 weekly treatment regimen
	<b>Clinical criteria:</b> The treatment must be adjuvant to complete surgical resection
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must have a WHO performance status of 1 or less
	<b>AND</b>
	<b>Clinical criteria:</b> The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not have received prior PBS-subsidised treatment for this condition
	<b>AND</b>
	<b>Clinical criteria:</b> The treatment must commence within 12 weeks of complete resection
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy
	<b>Administrative Advice:</b> 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.
<b>Restriction Summary 10684 / ToC: 10695</b>	
	<b>Indication:</b> Resected Stage IIIB, Stage IIIC or Stage IIID malignant melanoma
	<b>Treatment Phase:</b> Continuing treatment – 3 weekly treatment regimen
	<b>Clinical criteria:</b> Patient must have previously been issued with an authority prescription for this drug for adjuvant treatment following complete surgical resection
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not have experienced disease recurrence
	<b>AND</b>
	<b>Clinical criteria:</b> The treatment must be the sole PBS-subsidised therapy for this condition
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not receive more than 12 months of combined PBS-subsidised and non-PBS-subsidised adjuvant therapy

6.3 For pembrolizumab indications that have been recommended by the PBAC, but yet to be implemented at the time of this July 2022 PBAC meeting, replace the recommended listings appearing in the relevant PSD with the following:

March 2022 PBAC meeting – Item 6.07 (PBA/2021/00876) – replace the recommended listing relating to pembrolizumab appearing in the PSD with the following:

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MEDICINAL PRODUCT Form	PBS item code	Max. Amount	№.of Rpts
PEMBROLIZUMAB Injection	New (Public) New (Private)	400 mg	6
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
<b>Restriction Summary [new 1] / Treatment of Concept: [new 2]</b>			
	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners		
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new 2]		
	<b>Administrative Advice:</b> No increase in the maximum amount or number of units may be authorised.		
	<b>Episodicity:</b> [blank]		
	<b>Severity:</b> Advanced, metastatic or recurrent		
	<b>Condition:</b> endometrial carcinoma		
	<b>Indication:</b> Advanced, metastatic or recurrent endometrial carcinoma		
	<b>Treatment Phase:</b> Initial treatment		
	<b>Clinical criteria:</b>		
	Patient must have received prior treatment with platinum-based chemotherapy.		
	<b>AND</b>		
	<b>Clinical criteria:</b>		
	The condition must be untreated with each of: (i) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (ii) tyrosine kinase inhibitor therapy		
	<b>AND</b>		
	<b>Clinical criteria:</b>		
	Patient must have a World Health Organisation (WHO) Eastern Cooperative Oncology Group (ECOG) performance status score of no higher than 1 prior to treatment initiation		
	<b>AND</b>		
	<b>Clinical criteria:</b>		
	The treatment must be in combination with PBS-subsidised lenvatinib for this condition, unless the patient has a contraindication/intolerance to lenvatinib requiring a temporary/permanent discontinuation of lenvatinib, in which case it is being prescribed as monotherapy		
	<b>Treatment criteria:</b>		
	<i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR</i>		
	<i>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i>		
	<b>Administrative Advice:</b>		
	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		
<b>Restriction Summary [new 3] / Treatment of Concept: [new 4]</b>			
	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals		
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners		
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new 4]		
	<b>Indication:</b> Advanced, metastatic or recurrent endometrial carcinoma		

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	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b>
	Patient must have previously received PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have developed disease progression while receiving PBS-subsidised treatment with this drug for this condition.
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be in combination with PBS-subsidised lenvatinib for this condition, unless the patient has a contraindication/intolerance to lenvatinib requiring a temporary/permanent discontinuation of lenvatinib, in which case it is being prescribed as monotherapy
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR</i>
	<i>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i>
	<b>AND</b>
	<b>Treatment criteria:</b>
	<i>Patient must not be undergoing continuing PBS-subsidised treatment where this benefit is extending treatment beyond 24 cumulative months from the first administered dose, once in a lifetime</i>
<b>Restriction Summary [new 5] / Treatment of Concept: [new 6]</b>	
	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new 6]
	<b>Indication:</b> Advanced, metastatic or recurrent endometrial carcinoma
	<b>Treatment Phase:</b> Transitioning from non-PBS to PBS-subsidised supply – ‘Grandfather’ arrangements
	<b>Clinical criteria:</b>
	Patient must have received non-PBS subsidised treatment with this drug for this condition prior to [insert listing date]
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have met each of the following at the time non-PBS subsidised treatment was initiated: (i) was treated with platinum-based chemotherapy, (ii) was untreated with each of: (a) programmed cell death-1/ligand-1 (PD-1/PDL-1) inhibitor therapy, (b) tyrosine kinase inhibitor therapy, (iii) had a WHO performance status no higher than 1
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must not have developed disease progression while receiving treatment with this drug for this condition.
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing combination therapy consisting of: (i) this drug, (ii) PBS-subsidised lenvatinib; or</i>
	<i>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to lenvatinib requiring temporary/permanent discontinuation – document the details in the patient’s medical records</i>
	<b>AND</b>
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR</i>
	<i>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i>
	<b>AND</b>
	<b>Treatment criteria:</b>
	<i>Patient must not be undergoing continuing treatment where this benefit is extending treatment beyond 24 cumulative</i>

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	months from the first administered dose, once in a lifetime
	<b>Administrative advice:</b> 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.
	<b>Administrative advice:</b> This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

March 2022 PBAC meeting – Item 6.08 (PBA/2022/0005) – replace the recommended listing relating to pembrolizumab appearing in the PSD with the following:

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	№.of Rpts
PEMBROLIZUMAB Injection	New (Public) New (Private)	400 mg	6
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
<b>Restriction Summary [new 1] / Treatment of Concept: [new 2]</b>			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required – Streamlined [new 2]			
<b>Administrative advice:</b> No increase in the maximum amount or number of units may be authorised.			
<b>Indication:</b> Stage IV clear cell variant renal cell carcinoma (RCC)			
<b>Treatment Phase:</b> Initial treatment			
<b>Clinical criteria:</b>			
Patient must have/have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk); document the IMDC risk classification score in the patient's medical records			
<b>AND</b>			
<b>Clinical criteria:</b>			
The condition must be untreated			
<b>AND</b>			
<b>Clinical criteria:</b>			
Patient must have a WHO performance status of 2 or less			
<b>Treatment criteria:</b>			
Patient must be undergoing combination therapy consisting of: (i) this drug, (ii) PBS-subsidised lenvatinib; or			
Patient must be undergoing monotherapy with this drug due to an contraindication/intolerance to lenvatinib requiring temporary/permanent discontinuation – document the details in the patient's medical records			
<b>AND</b>			
<b>Treatment criteria:</b>			
Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR			
Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions			
<b>Administrative Advice:</b>			
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			

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	<b>Administrative Advice:</b> No increase in the maximum amount or number of units may be authorised.
	<p><b>Administrative Advice:</b>  A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: <a href="https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma">https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma</a>.</p> <p>One point is assigned for each of:  (i) a time of diagnosis to systemic therapy of less than 1 year  (ii) a Karnofsky Performance Status of less than 80%  (iii) a haemoglobin less than the lower limit of normal  (iv) a corrected calcium level greater than the upper limit of normal  (v) a neutrophil count greater than the upper limit of normal  (vi) a platelet count greater than the upper limit of normal</p> <p>Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.</p> <p>Favourable IMDC risk is a score of 0.  Intermediate IMDC risk is a score of 1 to 2.  Poor IMDC risk is a score of 3 to 6.</p> <p>Document any IMDC risk score assessment in the patient's medical records</p>
<b>Restriction Summary [new 3] / Treatment of Concept: [new 4]</b>	
	<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction Type</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new 4]
	<b>Indication:</b> Stage IV clear cell variant renal cell carcinoma (RCC)
	<b>Treatment Phase:</b> Transitioning from non-PBS to PBS-subsided treatment – 'Grandfather' arrangements
	<b>Clinical criteria:</b>
	Patient must be currently receiving non-PBS subsidised treatment with this drug, with treatment having commenced prior to [insert listing date]
	<b>AND</b>
	<b>Clinical criteria:</b>
	Patient must have/have had a prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk classification score at treatment initiation with this drug of either: (i) 1 to 2 (intermediate risk), (ii) 3 to 6 (poor risk - document the IMDC risk classification score in the patient's medical records
	<b>AND</b>
	<b>Clinical criteria:</b>
	The treatment must be occurring in a patient where each of the following is true: (i) the patient's WHO performance status was no higher than 2 at treatment initiation, (ii) this drug is being prescribed as either: (a) in combination with only lenvatinib, (b) as monotherapy where there was a contraindication/intolerance to lenvatinib – document the details in the patient's medical records, (iii) the condition was untreated at the time of treatment initiation, (iv) disease progression has not occurred whilst on treatment, (v) treatment is occurring with a dosing regimen specified in this drug's approved Australian Product Information, (vi) this prescription does not extend treatment beyond 24 months from the first administered dose
	<b>Treatment criteria:</b>
	Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR
	Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions
	<b>Administrative Advice:</b>

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	<p>A prognostic International Metastatic Renal Cell Carcinoma Database Consortium (IMDC) survival risk score can be calculated here: <a href="https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma">https://www.mdcalc.com/imdc-international-metastatic-renal-cell-carcinoma</a>.</p> <p>One point is assigned for each of:</p> <ul style="list-style-type: none"> <li>(i) a time of diagnosis to systemic therapy of less than 1 year</li> <li>(ii) a Karnofsky Performance Status of less than 80%</li> <li>(iii) a haemoglobin less than the lower limit of normal</li> <li>(iv) a corrected calcium level greater than the upper limit of normal</li> <li>(v) a neutrophil count greater than the upper limit of normal</li> <li>(vi) a platelet count greater than the upper limit of normal</li> </ul> <p>Stated normal reference ranges may vary depending on the laboratory providing the measurement. 'Normal' here refers to the individual laboratory's stated normal reference range.</p> <p>Favourable IMDC risk is a score of 0. Intermediate IMDC risk is a score of 1 to 2. Poor IMDC risk is a score of 3 to 6.</p> <p>Document any IMDC risk score assessment in the patient's medical records</p>
	<p><b>Administrative advice:</b> 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.</p>
	<p><b>Administrative advice:</b> This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.</p>
	<p><b>Administrative advice:</b> 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</p>
	<p><b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals</p>
	<p><b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners</p>
	<p><b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [new 6]</p>
	<p><b>Indication:</b> Stage IV clear cell variant renal cell carcinoma (RCC)</p>
	<p><b>Treatment Phase:</b> Continuing treatment</p>
	<p><b>Clinical criteria:</b> Patient must have previously received PBS-subsidised treatment with this drug for this condition</p>
	<p><b>AND</b></p>
	<p><b>Clinical criteria:</b> Patient must not have developed disease progression while receiving treatment with this drug for this condition</p>
	<p><b>Treatment criteria:</b> <i>Patient must be undergoing combination therapy consisting of: (i) this drug, (ii) PBS-subsidised lenvatinib; or</i></p>
	<p><i>Patient must be undergoing monotherapy with this drug due to a contraindication/intolerance to lenvatinib requiring temporary/permanent discontinuation – document the details in the patient's medical records</i></p>
	<p><b>AND</b></p>
	<p><b>Treatment criteria:</b> <i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions;</i></p>
	<p><i>OR</i></p>
	<p><i>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i></p>
	<p><b>AND</b></p>
	<p><b>Treatment criteria:</b></p>

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Patient must be undergoing continuing treatment that does not extend the treatment duration beyond 24 cumulative months from the first administered dose, once in a lifetime
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March 2022 PBAC meeting – Item 7.09 (deferred item 7.09 from the November 2021 PBAC meeting) (PBA/2022/TBD) – replace the recommended listing relating to pembrolizumab appearing in the PSD with the following:

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	№.of Rpts
Injection	New (Public) New (Private)	400 mg	6
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg/4 mL injection, 4 mL vial)			
<b>Restriction Summary [new] / Treatment of Concept: [new]</b>			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED)			
<b>Administrative advice:</b> No increase in the maximum amount or number of units may be authorised.			
<b>Administrative Advice:</b> Special Pricing Arrangements apply			
<b>Indication:</b> Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx			
<b>Treatment Phase:</b> Initial treatment			
<b>Clinical criteria:</b>			
The condition must be incurable by local therapies in the locally advanced setting			
<b>AND</b>			
<b>Clinical criteria:</b>			
Patient must not have had systemic therapy for this condition in the recurrent or metastatic setting prior to initiating PBS-subsidised treatment with this drug for this condition			
<b>AND</b>			
<b>Clinical criteria:</b>			
Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if previously treated in the locally advanced setting			
<b>AND</b>			
<b>Clinical criteria:</b>			
Patient must have a WHO performance status of 0 or 1			
<b>AND</b>			
<b>Clinical criteria:</b>			
The treatment must be either (i) the sole PBS-subsidised therapy where the condition expresses programmed cell death ligand 1 (PD-L1) with a combined positive score (CPS) $\geq 20$ in the tumour sample (ii) in combination with platinum-based chemotherapy, unless contraindicated or not tolerated			
<b>Treatment criteria:</b>			
Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR			
Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions			

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	<b>Administrative Advice:</b> 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.
<b>Restriction Summary [new] / Treatment of Concept: [new]</b>	
	<b>Indication:</b> Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx
	<b>Treatment Phase:</b> Continuing treatment
	<b>Clinical criteria:</b> Patient must have previously received PBS-subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not have developed disease progression while being treated with this drug for this condition
	<b>Treatment criteria:</b> <i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i>
	<b>AND</b>
	<b>Treatment criteria:</b> <i>Patient must be undergoing continuing treatment that does not extend the treatment duration beyond 24 cumulative months from the first administered dose, once in a lifetime</i>
<b>Restriction Summary [new] / Treatment of Concept: [new]</b>	
	<b>Indication:</b> Recurrent or metastatic squamous cell carcinoma of the oral cavity, pharynx or larynx
	<b>Treatment Phase:</b> Transitioning from non-PBS to PBS-subsidised supply – ‘Grandfather’ arrangements
	<b>Clinical criteria:</b> Patient must have previously received non-PBS subsidised treatment with this drug for this condition prior to [listing date]
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not have had systemic therapy for this condition in the recurrent or metastatic setting prior to initiating non PBS-subsidised treatment with this drug for this condition;
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not have experienced disease recurrence within 6 months of completion of systemic therapy if treated in the locally advanced setting prior to non-PBS subsidised treatment with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b> The treatment must be either (i) the sole PBS-subsidised therapy where the condition expresses programmed cell death ligand 1 (PD-L1) with a combined positive score (CPS) $\geq 20$ in the tumour sample (ii) in combination with platinum based chemotherapy, unless contraindicated or not tolerated
	<b>AND</b>
	<b>Clinical criteria:</b> Patient must not have developed disease progression while being treated with this drug for this condition
	<b>AND</b>
	<b>Clinical criteria:</b>

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	Patient must have had a WHO performance status of 0 or 1 prior to initiation of non-PBS-subsidised treatment with this drug for this condition
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions; OR</i>
	<i>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i>
	<b>AND</b>
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing continuing treatment that does not extend the treatment duration beyond 24 cumulative months from the first administered dose, once in a lifetime</i>
	<b>Administrative Advice:</b> 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.
	<b>Administrative advice:</b> 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.
	<b>Administrative advice:</b> This grandfather restriction will cease to operate from 12 months after the date specified in the clinical criteria.

May 2022 Intra-cycle PBAC meeting – Item 4.03 (deferred item 7.09 from the November 2021 PBAC meeting) for advanced/metastatic gastro-oesophageal cancers (PBA/2021/00587):

MEDICINAL PRODUCT Form	PBS item code	Maximum amount	No. of Repeats
PEMBROLIZUMAB Injection	New (Public) New (Private)	400 mg	6
<b>Available brands</b>			
Keytruda (pembrolizumab 100 mg injection, 1 vial)			
<b>Restriction Summary [New RS1] / Treatment of Concept: [New TOC1]</b>			
<b>Category / Program:</b> Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners			
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (STREAMLINED) [New TOC1]			
<b>Episodicity:</b> [blank]			
<b>Severity:</b> Advanced or metastatic			
<b>Condition:</b> gastro-oesophageal cancers			
<b>Indication:</b> Advanced or metastatic gastro-oesophageal cancers			
<b>Treatment Phase:</b> [blank]			
<b>Clinical criteria:</b>			
The condition must be a gastro-oesophageal cancer type as specified in the drug's 'Indications' section of the approved Australian Product Information			
<b>AND</b>			
<b>Clinical criteria:</b>			
The treatment must be prescribed in accordance with the drug's 'Indications' section of the approved Australian Production Information with respect to each of: (i) concomitant drugs/therapies, (ii) line of therapy (i.e. prior treatments, if any)			
<b>AND</b>			
<b>Clinical criteria:</b>			
Patient must have/have had, at the time of initiating treatment with this drug, a WHO performance status no higher than 1			
<b>Treatment criteria:</b>			
Patient must not be undergoing treatment with this drug as a PBS-benefit where the treatment duration extends beyond the			

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	following, whichever comes first: (i) disease progression despite treatment with this drug, (ii) 24 cumulative months from the first administered dose; annotate any remaining repeat prescriptions with the words 'cancelled' where this occurs
	<b>AND</b>
	<b>Treatment criteria:</b>
	<i>Patient must be undergoing treatment with this drug administered once every 3 weeks – prescribe up to 6 repeat prescriptions;</i>
	<i>OR</i>
	<i>Patient must be undergoing treatment with this drug administered once every 6 weeks - prescribe up to 3 repeat prescriptions</i>
	<b>CAUTION:</b>
	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.
	<b>Administrative advice:</b> No increase in the maximum amount or number of units may be authorised.
	<b>Administrative Advice:</b> No increase in the maximum number of repeats may be authorised.
	<b>Administrative Advice:</b> Special Pricing Arrangements apply.

***This restriction may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.***

## **7 Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **8 Sponsor's Comment**

The sponsor had no comment.