11.12 PEMBROLIZUMAB

Solution concentrate for I.V. infusion 100 mg in 4 mL,
Keytruda®,
Merck Sharp & Dohme (Australia) Pty Ltd

1 Purpose of Submission

1.1 To consider an updated proposal from Merck Sharp & Dohme for a multi-indication (broad) listing for pembrolizumab in advanced or metastatic cancers.

2 Background

Previous PBAC considerations

2.1 The PBAC's most recent consideration of a multi-indication listing for pembrolizumab was at the July 2025 meeting where it did not recommend the listing.

2.2 The PBAC also considered a proposal for a broad listing for nivolumab and ipilimumab at its July 2025 and September 2025 meetings. It deferred the July proposal and recommended the listing based on the proposal provided to the September 2025 Intracycle meeting.

2.3 The PBAC had also previously considered broad listings for PD-(L)1 inhibitors at the September 2024 and December 2023 meetings.

3 Outline of October 2025 Proposal

3.1 This revised proposal (October 2025 Proposal) presents a simplified Risk Sharing Arrangement (RSA) structure compared to the July 2025 proposal, however it is based on the same general approach. The proposal:

- applies a weighted price for indications PBS-listed and two indications recommended but not yet implemented, based on existing/recommended prices and forecast script volumes.
- Sets the first cap (SC1) in the proposed RSA at the forecast utilisation of the existing PBS listed indications after which a rebate is applied to account for use in the extended circumstances. The sponsor has consolidated the rebates for different circumstances of use (extended indications, retreatment, rare cancers, etc.) into a single discount of [redacted]% for use beyond SC1.
- Sets a second cap (SC2) at the total forecast utilisation and proposed a [redacted]% rebate for utilisation beyond this.

3.2 The proposal included updated utilisation and modelling based on the PBAC's advice provided in July 2025. The Secretariat has provided comments on the revised modelling in Section 7.

3.3 The sponsor provided the following table (Table 1) that outlines its key changes between the July 2025 and October 2025 proposals:

Table 1: Key changes between the July 2025 and October 2025 proposals

Component	Not recommended (July 2025)	Resubmission (Nov 2025)	Key changes
Scope of indications	All current and future TGA indications in the advanced or metastatic setting	All unresectable advanced and metastatic cancers except tumour types that are known to be unresponsive to a PD-1 inhibitor	The proposed restriction does not specify pembrolizumab's TGA approved indications, thereby enabling access for some patients with ultra-rare tissue types which are unlikely to have a registered TGA indication.
Pricing structure	A single weighted, effective AEMP. A PVA was proposed with increasing rebates over 3 or 4 tiers[1]	A single weighted, effective AEMP. A PVA is proposed with a rebate applied after reaching the first tier cap (i.e. 2 tiers in total)	The single weighted, effective AEMP is now based on both existing listed indications and two indications that have been recommended by the PBAC but not yet implemented [July 2025 PSD 6.15, par 10.10] The PVA structure has been simplified to reflect the PBAC's advice that a simplified RSA structure with a consolidated discount beyond Tier 1 would be preferable [July 2025 PSD 6.15, par 10.13]
Prices (AEMP)	Tier 1: $[redacted] Tier 2: $[redacted] Tier 3: $[redacted] Tier 4: $[redacted] Nb. Represents prices offered in the pre-PBAC response	Tier 1: $[redacted] Tier 2: $[redacted]	The lower Tier 1 price reflects the inclusion of cSCC and 1L Oesophageal cancer in the first tier [July 2025 PSD 6.15, par 10.10] The Tier 2 price is lower due to the simplified pricing structure, along with some further reductions in the pricing assumptions for Tier 2 indications and treatment settings as outlined in the submission.
Budget impact	$[redacted] over 6 years	$[redacted] over 6 years	The increased budget impact reflects a broader scope that now includes use beyond TGA-approved indications, such as in patients with rare cancers. It also reflects methodological differences: the July 2025 submission was based on MSD's internal commercial forecasts, while the November submission followed the Section 4 template per PBAC guidelines (outlined in the submission). The approach used in this submission has been aligned with the Department of Health and is considered more consistent with usual PBAC methods.

Abbreviations: PD-(L)1 = programmed cell death protein 1/death ligand 1; PVA = price volume arrangement;
[1] The pre-PBAC response presented two options (3 tiers or 4 tiers) for the PBAC to consider.

3.4 In September 2025, the PBAC recommended a broad listing for the related drugs, nivolumab and ipilimumab, for advanced or metastatic cancers. The PSD for this consideration is provided at **Attachment B**.

4 Requested Listing

4.1 Compared to the recommended wording for nivolumab ± ipilimumab, the pembrolizumab proposal is closely aligned but more conservative due to:

- The use of the term **"unresectable"** in the restriction wording for pembrolizumab.
- Additional clinical criteria in the pembrolizumab proposal, including:
  - Exclusion of adjuvant/neoadjuvant/perioperative settings.
  - Requirement to follow clinical guidelines.

4.2 The Secretariat has provided proposed amendments to the proposed restrictions with deletions as strikethrough and additions in italics.

MEDICINAL PRODUCT	**PBS item code**	**Max. Amount**	**№.of Rpts**
PEMBROLIZUMAB Injection	NEW (Public) NEW (Private)	400 mg	7
Available brands			
Keytruda® (pembrolizumab 100 mg/4 ml injection, 4 ml vial)			
Restriction Summary [new] / Treatment of Concept: [new]			
Category / Program: Section 100 – Efficient Funding of Chemotherapy Public/Private Hospitals **Prescriber type**: Medical Practitioners **Restriction Type**: Authority Required (STREAMLINED)			
Indication: Unresectable advanced and metastatic cancers			
Clinical Criteria:			
Treatment must not be used in the adjuvant, neoadjuvant, or perioperative setting			
AND			
Clinical Criteria:			
~~Where available,~~ *The* treatment must be prescribed in accordance with recognised clinical practice guidelines, *where available*			
AND			
Clinical Criteria:			
The treatment must not be used in a tumour that is known to be unresponsive to a PD-1 (programmed cell death-1) inhibitor			
AND			
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			
Administrative Advice: No increase in the maximum amount or number of units may be authorised			
Administrative Advice: No increase in the maximum number of repeats may be authorised			
Administrative Advice: Special Pricing Arrangements apply			

Table 2: Comparison of Restriction Wording and Clinical Criteria

	Pembrolizumab (Oct 2025)	Pembrolizumab (Jul 2025)	Nivolumab ± Ipilimumab (Sep 2025)
Restriction Wording	Unresectable advanced/metastatic cancers	TGA registered advanced/metastatic indications	Advanced/metastatic cancers considered immunotherapy-sensitive
Prescribing Instructions	Excludes adjuvant/neoadjuvant/perioperative; must follow clinical guidelines	Aligned to TGA PI	Minimal clinical criteria; clinician discretion
Retreatment & Extended ToT	Included	Included	Included

4.3 The Secretariat noted the clinical criteria 'The treatment must not be used in a tumour that is known to be unresponsive to a PD-1 (programmed cell death-1) inhibitor' may be open to interpretation and require supporting resources for prescribers to refer to in order to ensure it is applied appropriately.

5 Proposed Pricing

5.1 The proposal used a similar approach to pricing as was undertaken in the July 2025 submission. The sponsor has proposed an initial weighted price that encompasses all currently listed PBS indications and prices as well as two recommended but not yet implemented indications.

5.2 The sponsor notes, based on the PBAC's advice from July, it has also included two indications for which there is a positive PBAC recommendation but that have not yet progressed to listing. The sponsor noted this resulted in a slight overall reduction in the weighted price. *The Secretariat noted pembrolizumab was recommended for high-risk, locally advanced cervical cancer in March 2025, but had not yet proceeded to listing. Advice was sought on whether this indication would be included under the proposed restrictions for the broad listing.*

5.3 The sponsor also highlighted that there had been a change in the data source supporting the modelling of future use of pembrolizumab in these indications. Rather than being based on internal commercial forecasts, current utilisation was projected into the future using the most recent full year of script data (i.e. 2024 data).

5.4 These changes resulted in a small reduction to the calculated weighted price ($ current vs $ in July 2025).

Table 3: Pricing per indication applied in weighted price

Indication	AEMP ($) per 100 mg		Weighting	
NSCLC, Stage IV	-			%
Melanoma, advanced	-			%
UC	-			%
cHL	-			%
TNBC, metastatic	-			%
HNSCC, metastatic	-			%
Cervical, metastatic	-			%
CRC	-			%
PMBCL	-			%
Endometrial, 2L	-			%
RCC, metastatic	-			%
Oesophageal, metastatic	-			%
cSCC	-			%

Source: Appendix 2 Table A of the submission

AEMP = approved ex manufacturer price; cHL = classical Hodgkin's lymphoma; CRC = colorectal cancer; cSCC = cutaneous squamous cell carcinoma; HNSCC = head and neck squamous cell carcinoma; NSCLC = non-small cell lung cancer; PMBCL = primary mediastinal B cell lymphoma; PBS = Pharmaceutical Benefits Scheme; RCC = renal cell carcinoma; TNBC = triple negative breast cancer; UC = urothelial cancer; 2L = second line.

Blue cells indicate a price already established through PBAC process and price is known to MSD (i.e. pembrolizumab has been recommended on a cost-minimisation basis)

5.5 A consolidated price discount was proposed for the additional populations to achieve a % price reduction over the weighted Tier 1 price ($). This figure was calculated based on the submission weighting proposed prices for new indications and in additional treatment setting (i.e. retreatment, use beyond 2 years, rare cancers).

Table 4: Proposed pricing per vial

Tier	Price (AEMP) per vial ($)	Price Q4W ($)	% Discount v Tier 1
1	-	-	--
2	-	-	%

6 Risk sharing arrangement

6.1 The tiered subsidisation caps for both the July and October 2025 proposals are presented in Table 5.

Table 5: Comparison of proposed RSA approach in July and October 2025 proposals

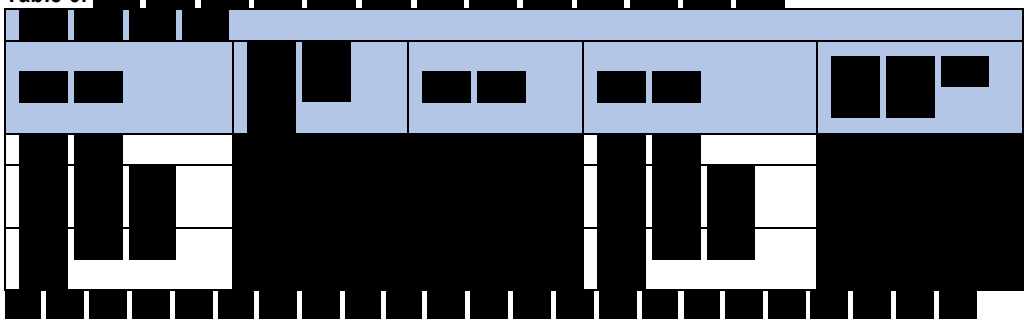
July 2025 pre-PBAC response		Current submission		
Structure	**AEMP ($) per 100 mg**	**Structure**	**AEMP ($) per 100 mg**	**AEMP ($) per Q4W**
Tier 1 Current adv/met indications	-	Tier 1 Current adv/met indications	-	-
Tier 2 All future adv/met indications	-	Tier 2 All future use including future adv/met indications, retreatment, ToT > 2 years, rare/ultra-rare	-	-
Tier 3 Retreatment, ToT >2 years	-			
Tier 4 'allowance'	-			

Adv = advanced; AEMP, approved ex-manufacturer price; met = metastatic, ToT = time on treatment

Committee in Confidence

6.2 [redacted] Table 6 [redacted]

Table 6: [redacted]



6.3 [redacted]

End Committee in Confidence

6.4 While the proposal currently includes a [redacted]% rebate beyond the total estimated utilisation, MSD noted this is based on acceptance of the estimates as provided and any major downward revision in utilisation estimates could jeopardise its willingness to agree to a [redacted]% rebate beyond Tier 2.

6.5 MSD noted this was in part due to the fact the revised proposal is not aligned to TGA registration which introduces financial risk that MSD is reluctant to bear alone.

6.6 The estimated value of the subsidisation caps is outlined in paragraph 7.7.

7 Forecast PBS usage and financial implications

7.1 The PBAC did not recommend a multi-indication (broad) listing for pembrolizumab in advanced or metastatic cancers during its most recent consideration at the July 2025 meeting. In providing this advice, the PBAC considered the proposal for the broad listing did not establish a reliable basis for the financial estimates.

7.2 Furthermore, "the PBAC considered the model provided did not provide sufficient clarity as to the inputs and underlying assumptions driving the outputs and that this difficulty in verifying the outputs of the financial model meant it was not reliable for decision making. The PBAC noted this also diminished the PBAC's ability to provide advice on what it considered would be appropriate amendments to the model and its underlying assumptions to support any future submission. The PBAC noted that the department was not able to validate the presented estimates, in particular the inclusion of formulas to facilitate replicating the calculation of the outputs" (July 2025, Paragraph 10.4).

7.3 The PBAC considered that "the following elements need to be included in a future version of the model in order for the utilisation estimates to be suitable for consideration by the Department of Finance: details on the modelling methodology to enable verification of patient numbers, vials and scripts; inclusion of offset medicines [for the Tier 2b indications]; incorporation of patient copayments; impacts to Services Australia for increased service volumes for pembrolizumab and decreased volumes for affected medicines; appropriate impacts for the MBS, such as administration costs." (July 2025, Paragraph 8.8).

7.4 In this submission, the Sponsor has used a multi-model approach, comprising fifteen (15) PBAC utilisation and cost models (UCM). Comprising Summary financial impact (Model 1), Current listings (Model: 2), Future indications (Models 3-12), Removal of Once In a lifetime (OIAL) (Model 13), Removal of 2 year stopping rule (Model 14) and Rare cancers (Model 15). This approach was discussed and agreed with the Department prior to the current submission.

7.5 The review undertaken by the Drug Utilisation Section (DUS) focused on the structure and arithmetic of the 15 models.

7.6 Overall, the sponsor noted the revised broad listing proposal for pembrolizumab in advanced and metastatic cancer would be for a total of $200 million to < $300 million in year 1 increasing to $300 million to < $400 million in year 6. This would comprise of;

- $200 million to < $300 million in year 1 increasing to $200 million to < $300 million in year 6 to cover Tier 1 indications, which includes 11 indications currently listed on the PBS for advanced and metastatic cancer and 2 which are PBAC recommended, and
- $80 million to < $90 million in year 1 increasing to $100 million to < $200 million in year 6 to cover Tier 2 indications, which captures the impact of expanding access to pembrolizumab for advanced and metastatic cancers across numerous indications and settings, including allowing treatment for patients with rare cancers who are unlikely to have a registered TGA indication.

7.7 Table 7 shows the financial impact of the proposed listing over the forward estimates:

Table 7: Financial impact of the proposal over the forward estimates

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
Pembrolizumab (Effective Price)							
Tier 1 (Current, Models 2-3)	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][2]
Tier 2 (Future, OIAL, Beyond 2 yrs, Rare: Models 4-15)	$[redacted][3]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][5]
Estimated cost to PBS/RPBS	$[redacted][1]	$[redacted][6]	$[redacted][6]	$[redacted][6]	$[redacted][6]	$[redacted][6]	$[redacted][2]
Other Medicines (Published Price)							
Lenvatinib	$[redacted][7]	$[redacted][8]	$[redacted][8]	$[redacted][8]	$[redacted][8]	$[redacted][9]	$[redacted][1]
Enfortumab vedotin	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][10]
Offset Medicines	-$[redacted][11]	-$[redacted][11]	-$[redacted][11]	-$[redacted][11]	-$[redacted][11]	-$[redacted][11]	-$[redacted][11]
Total Estimated cost to PBS/RPBS	$[redacted][6]	$[redacted][6]	$[redacted][6]	$[redacted][6]	$[redacted][6]	$[redacted][6]	$[redacted][2]

Source: Model 1 - UCM_MSD Multicancer_Net Impact. Includes patient co-payments.
Reflects corrections made to structure and arithmetic during the DUS review.

The redacted values correspond to the following ranges:
[1] *$200 million to < $300 million*
[2] *> $1 billion*
[3] *$80 million to < $90 million*
[4] *$100 million to < $200 million*
[5] *$700 million to < $800 million*
[6] *$300 million to < $400 million*
[7] *$20 million to < $30 million*
[8] *$30 million to < $40 million*
[9] *$40 million to < $50 million*
[10] *$900 million to < $1 billion*
[11] *net cost saving*

Current Listings (Model 2)

7.8 The current listings include 11 indications. The methods and assumptions used are described in the resubmission. The data sources and calculations were checked and confirmed by the department.

7.9 The methods and assumptions used to develop the utilisation estimates for the July 2025 submission and the resubmission are compared in Table 8. Overall, the total net cost to the PBS and RPBS is 11 percent higher in the resubmission compared to the July 2025 submission from the revised modelling (see Table 9 below).

Table 8: Methods and assumptions used to forecast the utilisation of the current listing for pembrolizumab (Model 2)

	July 2025 submission	December 2025 resubmission	Comments
Indications	Advanced carcinoma of the cervix; Recurrent, unresectable or metastatic triple negative breast cancer; 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; Unresectable or metastatic deficient mismatch repair (dMMR) colorectal cancer; Primary mediastinal B cell lymphoma (PMBCL); Locally advanced or metastatic (Stage IV) urothelial cancer; Relapsed or refractory Hodgkin Lymphoma; Stage IV metastatic non-small cell lung cancer (NSCLC); and Unresectable Stage III or IV malignant melanoma.	No changes in indications compared to the July 2025 submission.	The PBS item code list used for the data extraction was checked on 31 October 2025. All relevant items were represented. Item codes 12120X, 12125E, 12127G and 12130K were excluded as these include Stage III melanoma. However these codes also include continuing treatment for Stage IV melanoma and their exclusion would give a small underestimate for the future supply of scripts.
Projected prescriptions	Commercial forecasting and assumptions were used where the treatment uptake curves were derived from several factors including Start share, Peak share, Curve type and Time to peak. The vial and script numbers could not be verified as only limited information was able to be made available from the commercial model.	• A separate sheet is included for each indication to calculate the base number of scripts for 2025. • The base number of prescriptions is sourced from the Services Australia PBS Item Report. This provides data based on the date of processing of a PBS claim. • For each indication, data is extracted for the 2024 calendar year. • The public vs. private split and breakdown by concessional status is based on the results provided by Services Australia for 2024. • The scripts are broken down by Q6W and Q3W dosing based on the PBS item number. The Q6W scripts are converted to Q3W scripts by dividing the number of scripts by 2. • An annual growth rate of 1.6% is applied to forecast the scripts for every indication. • The scripts for triple negative breast cancer and cervical cancer are combined.	• The resubmission estimates the number of scripts for 2025 and then applies an annual growth rate of 1.6%. The growth rate is for the general population and is not specific to the actual growth in PBS prescriptions for each individual indication. • The listings for pembrolizumab have two dosing schedules, every 3 weeks (Q3W), and every 6 weeks (Q6W). The resubmission converts all prescriptions to a common denominator (i.e. Q3W) as counting prescriptions for the Q6W dosing would underestimate the number of prescriptions as each prescription covers twice the Q3W dose. • For listings that do not have a separate item code for the Q3W and Q6W dose, the resubmission uses the melanoma and NSCLC listings as a proxy to estimate a dosing split of Q3W [redacted]%: Q6W [redacted]%.

Table 9: Current Listings: Comparison of the utilisation estimates for the resubmission versus the July 2025 submission (Tier 1, Model 1)

Indication	Parameter	July 2025 submission (v 30 May 2025)							Current submission							% difference
		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1-6	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1-6	
TNBC + Cervical	Scripts	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][3]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][4]	-33%
	Net ($m)	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][6]	[redacted][5]	[redacted][5]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][8]	-35%
Endometrial	Scripts	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][1]	10%
	Net ($m)	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][9]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][9]	-13%
RCC	Scripts	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][3]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][4]	-39%
	Net ($m)	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][10]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][11]	-52%
RHNSCC	Scripts	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][14]	[redacted][2]	[redacted][2]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][14]	-5%
	Net ($m)	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][12]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][5]	[redacted][12]	1%
CRC	Scripts	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][4]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][14]	91%
	Net ($m)	[redacted][5]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][15]	[redacted][9]	[redacted][9]	[redacted][9]	[redacted][9]	[redacted][9]	[redacted][9]	[redacted][13]	165%
PMBCL	Scripts	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][2]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][2]	5%
	Net ($m)	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	27%
UC	Scripts	[redacted][2]	[redacted][2]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][4]	524%
	Net ($m)	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][15]	523%
cHL	Scripts	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][1]	8%
	Net ($m)	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][5]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][7]	[redacted][9]	30%
NSCLC	Scripts	[redacted][14]	[redacted][14]	[redacted][14]	[redacted][14]	[redacted][14]	[redacted][14]	[redacted][17]	[redacted][14]	[redacted][14]	[redacted][14]	[redacted][14]	[redacted][14]	[redacted][14]	[redacted][17]	3%
	Net ($m)	[redacted][12]	[redacted][12]	[redacted][13]	[redacted][13]	[redacted][13]	[redacted][13]	[redacted][18]	[redacted][12]	[redacted][13]	[redacted][13]	[redacted][13]	[redacted][13]	[redacted][13]	[redacted][18]	-1%
Melanoma	Scripts	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][19]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][20]	59%
	Net ($m)	[redacted][9]	[redacted][9]	[redacted][9]	[redacted][9]	[redacted][9]	[redacted][9]	[redacted][13]	[redacted][11]	[redacted][11]	[redacted][11]	[redacted][11]	[redacted][11]	[redacted][11]	[redacted][9]	66%
Total net PBS/RPBS cost ($m):								[redacted][21]							[redacted][21]	11%

Source:
Utilisation and cost model for the July 2025 submission (version 30 May 2025). 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx', sheets '7. Scripts Proposed – T1' and '15. Impact – Proposed (Eff)'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '2. UCM_MSD_multicancer_Current.xlsx'.

The redacted values correspond to the following ranges:
[1] 5,000 to >10,000
[2] 500 to < 5,000
[3] 20,000 to < 30,000
[4] 10,000 to < 20,000

[5] *$10 million to < $20 million*
[6] *$80 million to < $90 million*
[7] *$0 to < $10 million*
[8] *$50 million to < $60 million*
[9] *$20 million to < $30 million*
[10] *$70 million to < $80 million*
[11] *$30 million to < $40 million*
[12] *$90 million to < $100 million*
[13] *$100 million to < $200 million*
[14] *30,000 to < 40,000*
[15] *$40 million to < $50 million*
[16] *< 500*
[17] *200,000 to < 300,000*
[18] *$600 million to < $700 million*
[19] *40,000 to < 50,000*
[20] *60,000 to < 70,000*
[21] *> $1 billion*

Future Listings (Model 3-12)

7.10 There are 16 future indications in the proposal and of these, the hepatocellular carcinoma (HCC) is new compared to the July 2025 submission and two (2) indications are PBAC recommended but not yet implemented, namely, 1L oesophageal cancer (recommended by the PBAC in May 2022) and cutaneous squamous cell carcinoma (recommended by the PBAC in November 2023).

7.11 An epidemiological approach was used to estimate the financial implications associated with the future listings. The methods and assumptions used are described in the resubmission and are reproduced in Table 10 below. The structure and arithmetic of the models were checked by the Department.

Table 10: Standard assumptions adopted in the utilisation estimates

Variable	Approach and standard assumptions
Epidemiology	Wherever possible, estimates are sourced from standardised, validated and Australian sources. Typically these are: • Australian Institute of Health and Welfare (AIHW) incidence, prevalence and mortality data • PBS Statistics • PBAC Minutes, Public Summary Documents and DUSC reports
Eligibility	Proportion of patients who will be: • considered for immunotherapy/PD-(L)1 treatment as opposed to other drug classes or surgery • ECOG (0-1) status representing 80% (default), unless otherwise noted e.g. certain indications with typically more frail patients, or existing PBAC precedent determined from PSDs • Tested for biomarkers (where applicable) e.g. HER2, MMR, MSI, TMB
Uptake	Upon eligibility, the peak uptake of pembrolizumab (i.e. proportion of patients electing treatment) is considered to be: • [redacted]% for first to market indications • [redacted]% for second to market indications These peak uptakes are typically achieved by Year 2 for first to market indications and Year 3 for second to market indications, unless otherwise noted.
Time on treatment	Wherever possible, estimates are sourced from the clinical trial, existing PBAC minutes and PSDs, submitted pricing packages, or derived in a methodical approach using published sources.

7.12 In the resubmission, the Sponsor has stated that "compared with the previous submission, which relied on MSD's commercial forecasts, the approach taken to calculate the utilisation estimates in this resubmission is more consistent with the typical approach used in PBAC submissions. For example, unlike the previous submission, the revised utilisation estimates do not consider the impact of future competitor launches given that the likelihood and timing of those potential launches are inherently uncertain."

7.13 Overall, the total net cost to the PBS and RPBS is 57 per cent higher in the resubmission compared to the July 2025 submission from the revised modelling (see Table 11 below).

Table 11: Future Listings: Comparison of the utilisation estimates for the resubmission versus the July 2025 submission

Tier #	Model #	Indication	Parameter	July 2025 Submission							Current Submission							% difference
				Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1-6	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1-6	
1	3	Oesophageal (KN590)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-4%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	31%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	16%
	3	cSCC (KN629)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-61%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-35%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	-46%
2	4	Ovarian (KNB96)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	263%[1]
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	269%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	332%
	5	TMB-H (KN158)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	242%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	356%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	469%
	6	MSI-H (KN158/164)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	71%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	168%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	234%
	7	7. 1L nccRCC (KNB61)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	90%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	187%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	80%
	7	1LccRCC (KN581)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-15%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	16%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	9%
	8	UC (KN052/KNA39)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	59%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	166%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	136%
	9	pMMR 1L Endo (KN868)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-11%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-36%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	-66%
	10	HCC (New)	Patient #	-	-	-	-	-	-	-	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	*N/A*
			Scripts	-	-	-	-	-	-	-	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	*N/A*
			Net ($m)	-	-	-	-	-	-	-	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	*N/A*
	11	HER2+ Gastric (KN811)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	23%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	112%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	88%
	12	Mesothelioma (KN483)	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-7%
			Scripts	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	-26%
			Net ($m)	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	-23%
	12	1L Biliary	Patient #	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	55%

		(KN966)	Scripts	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][3]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][4]	150%
			Net ($m)	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][10]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][12]	98%
	12	Merkel CC (KN913)	Patient #	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	-17%
			Scripts	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][3]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	-16%
			Net ($m)	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][10]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][10]	-13%
	12	dMMR 1L Endo (KN868)	Patient #	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	-62%
			Scripts	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][4]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][3]	-29%
			Net ($m)	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][12]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][11]	-26%
	12	1L HER2-Gastric (KN859)	Patient #	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]	-24%
			Scripts	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][4]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][3]	16%
			Net ($m)	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][12]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][12]	3%
Total Net PBS/RBS Cost ($m):										$[redacted][18]							$[redacted][19]	57%

Source:
Utilisation and cost model for the July 2025 submission (version 30 May 2025). 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx'
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025) - Models 3-12. The above figures reflect the corrections made by DUS during the review as described in Table 12 below.

The redacted values correspond to the following ranges:
[1] *< 500*
[2] *500 to < 5,000*
[3] *5,000 to < 10,000*
[4] *10,000 to < 20,000*
[5] *20,000 to < 30,000*
[6] *30,000 to < 40,000*
[7] *50,000 to < 60,000*
[8] *100,000 to < 200,000*
[9] *$0 to < $10 million*
[10] *$10 million to < $20 million*
[11] *$20 million to < $30 million*
[12] *$30 million to < $40 million*
[13] *$50 million to < $60 million*
[14] *$70 million to < $80 million*
[15] *$90 million to < $100 million*
[16] *$100 million to < $200 million*
[17] *$200 million to < $300 million*
[18] *$300 million to < $400 million*
[19] *$500 million to < $600 million*
[20] *$40 million to < $50 million*

7.14 The structural or arithmetic errors that were corrected during the review by the Drug Utilisation Section are detailed in Table 12 below.

Table 12: Structure and arithmetic errors corrected during DUS review

Model #	Indication	Issue	Correction Made	Source
9	pMMR 1L Endo (KN868)	Correction to arithmetic. The Stage I/II EC assumption of [redacted]% was missing in the calculation of the Stage I/II recurrent EC patients.	Corrected formula to be consistent with the description provided by the Sponsor.	Worksheet 10. Registry, Cell L199 – Q199
		Correction to structure. Prevalent population proposed is based on the patients in 2026, which double counts with the incident patients commencing in 2026.	Updated the prevalent population based to the patients in 2025.	Worksheet 10. Registry, Cell K207 – K210

7.15 The key inputs and assumptions used to develop the utilisation estimates for each of the future indications in the resubmission are compared to the July 2025 submission (where appropriate) in Table 13 - Table 28 below.

Table 13: sSCC (KN629) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 3 cSCC (KN629)	July Submission		Current Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
New PD-(L)1 patients	[redacted][1]	MSD assumption	[redacted][2]	Departmental Estimates
Treatment				
Peak brand share	[redacted]%	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Year 3-6: [redacted]%	MSD assumption
Time on treatment (ToT)	*Not Specified*		57.97 weeks	Cemiplimab March 2022 PSD Table 14 p. 44
Time to peak	24 months	MSD assumption	[redacted]% in Year 1, [redacted]% in Year 2, [redacted]% in Years 3-6	MSD assumption, for indications where there is another PD-(L)1 available on the PBS
Dosage Regimen	*Not Specified*		200 mg Q3W	MSD assumption

Source: 1. Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '5. Patients - T2b'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '3. UCM_MSD Multicancer_PBAC Recommended'.
cSCC = Metastatic or locally advanced cutaneous squamous cell carcinoma

The redacted values correspond to the following ranges:
[1] 5,000 to < 10,000
[2] 500 to < 5,000

Table 14: Oesophageal (KN590) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Oesophageal cancers (KN590)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
New PD-(L)1 patients	[redacted][1]	MSD assumption	1,289	Departmental Estimates
Proportion of gastro (HER 2 negative)-oesophageal cancers which is oesophageal			46%	AIHW Book 1b & Gravalos, C.2008 for HER2-ve prevalence
Treatment				
Peak brand share	[redacted]%	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Year 3-6: [redacted]%	MSD assumption, for indications where there is another PD-(L)1 available on the PBS
Time on treatment (ToT)	*Not Specified*		32.88 weeks	Pembrolizumab Nov 2021 with Mar 2022 Addendum Table 13 p. 27
Time to peak	[redacted]months	MSD assumption	[redacted]% in Year 1, [redacted]% in Year 2, [redacted]% in Years 3-6	MSD assumption, for indications where there is another PD-(L)1 available on the PBS
Dosage Regimen	*Not Specified*		200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '5. Patients - T2b'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '3. UCM_MSD Multicancer_PBAC Recommended'.

The redacted values correspond to the following ranges:
[1] 500 to < 5,000

Table 15: Ovarian (KNB96) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 4 Ovarian (KNB96)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population(s)				
A: Incident - De novo				
Incidence – Ovarian cancer and serous carcinoma of fallopian tubes	1,854	AIHW (2024) 2025 Value	1,854	AIHW (2024) 2025 Value
Incidence – epithelial tumours	84%	Olaparib July 2020 Paragraph 6.44	84%	Olaparib July 2020 Paragraph 6.44
Stage III-IV (de novo) (1L)			70%	Olaparib July 2020 p. 7 Cancer Council 2024 NGOR Annual Report 2023
B: Recurrent				
Stage III-IV (recurrent) (1L) - 5 year			25%	Garzon et al 2020
Platinum resistant / recurrent (2L)	[redacted]%	MSD assumption (KANTAR)	[redacted]%	MSD assumption, applied to sum of de novo and recurrent patients. Represents PROC patients eligible for pembrolizumab i.e. net 75% of patients removed from 1L population owing to earlier line disease control, ineligibility (platinum sensitive), or death
Eligibility				
Treatment rate (2L)	[redacted]%	MSD assumption		
Stage IV which are 2L drug treatable	[redacted]%	MSD assumption		
Braca WT	[redacted]%	MSD assumption		
ECOG 0 to 1			[redacted]%	MSD assumption
Elect IO class treatment			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 class share	[redacted]%	MSD assumption		
Peak brand share	[redacted]%	MSD assumption		
Time to peak (Months)		MSD assumption	*Not Applicable*	
Treatment Uptake Rate			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	MSD assumption, based on existing pembrolizumab precedents. For indications where there is no other PD-(L)1 available on the PBS, time to peak uptake is 1 year ([redacted]% of peak uptake in year 1, [redacted]% in year 2-6).
Time on treatment (ToT) (Months)	9.7	Based on trial-specific KM curve	7.5 months 32.59 weeks	Based on trial-specific KM curve
Dosage Regimen	*Not Specified*		200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '4. UCM_MSD Multicancer_Ovarian'.

Table 16: TMB-H (KN158) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 5 TMB-H (KN158)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population(s)				
Incidence – All cancer types included in KN158 study	58,785	AIHW (2024)	58,790	AIHW (2024) – Book 1e, projected incidence in 2026
Stage IV (advanced/metastatic)	13,294	AIHW (2024) - Mortality Rate	13,221	AIHW (2024) – Book 1e, projected incidence in 2026
Eligibility				
Stage IV which are 2L drug treatable	[redacted]%	MSD assumption		
Treatment rate (2L)	[redacted]%	MSD assumption		
ECOG 0 to 1			70%	T-DXd PSD
Biomarker testing rate	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Biomarker prevalence	3.0%	Internal RWE Report from Omico	4.05%	Internal RWE Report from Omico
Treatment				
Peak PD-(L)1 class share	[redacted]%	MSD assumption		MSD assumption
Treatment Uptake Rate			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	MSD assumption, for indications where there is no other PD-(L)1 available on the PBS, time to peak uptake is 1 year ([redacted]% of peak uptake in year 1, [redacted]% in year 2-6).
Peak brand share	[redacted]%	MSD assumption		
Time on treatment (ToT) (Months)	9.0	Based on trial-specific KM curve	7.3 months 31.63 weeks	Based on trial-specific KM curve
Time to peak (Months)	[redacted]	MSD assumption		
Dosage Regimen	*Not Specified*		200 mg Q3W	

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '5. UCM_MSD Multicancer_TMB'.

Table 17: MSI-H (KN158/164) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 6 MSI-H (KN158/164)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population(s)				
Incidence – all cancer types included in KN158	58,785	AIHW (2024)	58,790	AIHW (2024) – Book 1e, projected incidence in 2026
Stage IV (advanced/metastatic)	13,294	AIHW (2024) - Mortality Rate	13,221	AIHW (2024) – Book 1e, projected incidence in 2026
Eligibility				
Stage IV which are 2L drug treatable	[redacted]%	MSD assumption		
Treatment rate (2L)	[redacted]%	MSD assumption		
ECOG 0 to 1			70%	In line with previous PBAC accepted estimates for late line patients (T-DXd PSD: Table 34, p77)
Biomarker testing rate	[redacted]%	MSD assumption	[redacted]%	MSD assumption based on clinician feedback
Biomarker prevalence	3.8%	Internal RWE Report from Omico	3.1%	Internal RWE Report from Omico
Treatment				
Peak PD-(L)1 class share	[redacted]%	MSD assumption		
Peak brand share	[redacted]%	MSD assumption		
Time to peak	[redacted]months	MSD assumption		
Treatment Uptake Rate			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	MSD assumption, for indications where there is no other PD-(L)1 available on the PBS, time to peak uptake is 1 year ([redacted]% of peak uptake in year 1, [redacted]% in year 2-6).
Time on treatment (ToT)	7.3 months	Based on trial-specific KM curve	7.3 months 31.63 weeks	Based on trial-specific KM curve
Dosage Regimen			200 mg Q3W	

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '6. UCM_MSD Multicancer_MSI-H'.

Table 18: 1L nccRCC (KNB61) Comparison of the key inputs and assumptions for the July 2025 vs resubmission.

Model 7 1L nccRCC (KNB61)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population(s)				
A: Incident - De novo metastatic				
Incident - total - Kidney Cancer - Projected (AIHW)	4,926	AIHW (2024) 2025 Value	5,079	AIHW (2024) – Book 1e, projected incidence in 2026
Renal cell carcinoma	90%	Cancer Council (2025)	90%	Cabozantinib nccRCC 03-2024 PSD
Clear cell incidence	20%	Cancer Council Victoria (2024)	20%	Cancer Council Victoria (2024)
de novo metastatic patients at diagnosis	25%	Gupta et al (2008) DUSC June 2014 review - pazopanib and sunitinib for RCC	25%	Gupta et al (2008), DUSC June 2014 review - pazopanib and sunitinib for RCC
B: Recurrent				
Earlier stage disease (Stage I-III) at diagnosis	[redacted][1] Patients	MSD assumption KANTAR	75%	1-25% (de novo metastatic patients at diagnosis)
Recurrence Rate			25%	Tyson & Chang (2017) Pembrolizumab + Lenvatinib 1L RCC March 2022 PSD
Eligibility				
Intermediate/Poor/favorable risk	[redacted]%	MSD assumption		
Treatment rate	[redacted]%	MSD assumption		
ECOG 0 to 1			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 class share	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Peak brand share	[redacted]%	MSD assumption		
Treatment Uptake Rate			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	MSD assumption, for indications where there is no other PD-(L)1 available on the PBS, time to peak uptake is 1 year ([redacted]% of peak uptake in year 1, [redacted]% in year 2-6).
Time on treatment (ToT) (Months)	11.0	Based on trial-specific KM curve, blended across groups	14.73 Months 64.01 weeks	Accepted DoT for RCC (Pembrolizumab+Lenvatinib 1L RCC March 2022 PSD). Assumption DoT is consistent across RCC subtypes.
Time to peak	[redacted]months	MSD assumption		
Dosage Regimen			200 mg Q3W	

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '7. UCM_MSD Multicancer_RCC'.

The redacted values correspond to the following ranges:
[1] < 500

Table 19: 1L ccRCC (KN581) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 7 1LccRCC (KN581)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population(s)				
A: Incident - De novo metastatic				
Incident - total - Kidney Cancer - Projected (AIHW)	4,926	AIHW (2024) 2025 Value	5,079	AIHW (2024) – Book 1e, projected incidence in 2026
Renal cell carcinoma	90%	Cancer Council (2025)	90%	Cabozantinib nccRCC 03-2024 PSD Pembrolizumab adj RCC 11-2024 PSD
Clear cell incidence	80%	Cancer Council Victoria (2024)	80%	Cancer Council Victoria (2024)
de novo metastatic patients at diagnosis	25%	Gupta et al (2008) DUSC June 2014 review - pazopanib and sunitinib for RCC	25%	Gupta et al (2008) DUSC June 2014 review - pazopanib and sunitinib for RCC
B: Recurrent				
Earlier stage disease (Stage I-III) at diagnosis	[redacted][1] Patients	MSD assumption KANTAR	75%	1-25% (de novo metastatic patients at diagnosis)
Recurrence Rate			25%	Tyson & Chang (2017) Pembrolizumab + Lenvatinib 1L RCC March 2022 PSD
Eligibility				
Favorable risk	[redacted]%	MSD assumption	23%	Pembrolizumab + Lenvatinib 1L RCC March 2022 PSD
Treatment rate	[redacted]%	MSD assumption		
ECOG 0 to 1			[redacted]%	MSD assumption
Elect IO Class treatment			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 class share	[redacted]%	MSD assumption		
Peak brand share	[redacted]%	MSD assumption		
Tx Uptake Rate			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	MSD assumption
Time on treatment (ToT) (Months)	14.2	Based on trial-specific KM curve, blended across groups	14.73 Months 64.01 weeks	DoT for RCC (Pembrolizumab March 2022)
Time to peak (Months)	[redacted]	MSD assumption		
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '7. UCM_MSD Multicancer_RCC'.

The redacted values correspond to the following ranges:
[1] 500 to < 5,000

Table 20: UC (KN052) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 8 UC (KN052)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
PD-(L)1 Class	[redacted][1]	Internal assumption, approximately in line with enfortumab vedotin November 2024 PSD	1,682	Enfortumab vedotin PBAC PSD November 2024
Eligibility				
Patients eligible for first-line treatment with EV + PEM (E x 90%)			90%	Enfortumab vedotin PBAC PSD November 2024
Apply eligibility adjustment based on ESC calculation (933/1211 = 77.04%)			77.04%	Enfortumab vedotin PBAC PSD November 2024, paragraph 6.76
% of PD-(L)1 Class treated with PD-(L)1 monotherapy	[redacted]%	MSD assumption		
% of PD-(L)1 Class treated with PD-(L)1 + targeted therapy	[redacted]%	MSD assumption		
% of PD-(L)1 Class treated with PD-(L)1 + chemo	[redacted]%	MSD assumption		
Treatment				
Peak brand share	[redacted]%	Internal modelling assumption		
Time on treatment (ToT)	7.5 months	Based on trial-specific KM curve	51.42 Weeks (~11.9 Months)	Enfortumab vedotin PSD November 2024, Para 6.59
Time to peak	[redacted]months	MSD internal modelling assumption		
Treatment Uptake Rate			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	Enfortumab vedotin PBAC Minutes November 2024, Table 16
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '8. UCM_MSD Multicancer_1L UC'.

The redacted values correspond to the following ranges:
[1] 500 to < 5,000

Table 21: pMMR 1L Endo (KN868) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 9 pMMR 1L Endo (KN868)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population(s)				
A: Incident - De novo metastatic/unresectable				
Patients with Uterine Cancer - Projected (AIHW)			3,728	AIHW (2024) 2026 Value
Endometrial Cancer (EC)			95%	95% (Cancer Council)
Stage IIII/V unresectable disease			10%	Dostarlimab PSD November 2023 Table 20 p. 41-43 Dostarlimab PSD March 2022 Table 14 p. 35-36
B: Recurrent from earlier stage				
Stage I/II EC			82%	Dostarlimab PSD November 2023 Table 20 p. 41-43, Dostarlimab PSD March 2022 Table 14 p. 35-36
Stage I/II Recurrent EC			13%	Dostarlimab PSD November 2023 Table 20 p. 41-43
Stage III EC (resectable)			8%	Dostarlimab PSD November 2023 Table 20 p. 41-43, Dostarlimab PSD March 2022 Table 14 p. 35-36
Stage III Recurrent EC			30%	Dostarlimab PSD November 2023 Table 20 p. 41-43
C: Prevalent Population				
Endometrial Cancer (EC)			90%	95% (Cancer Council)
Advanced to metastatic population			10%	*Not Specified*
1 yr Overall Survival			83.5%	AIHW 5yr OS. Dostarlimab PSD November 2023 Table 20 p. 41-43 Pembrolizumab March 2022 with March 2023 Addendum Table 15 p. 34-36
Eligibility				
Patients eligible to receive 1L platinum based chemotherapy			90%	Nivolumab PSD Nov 23-Mar 24 addendum Table 18 p. 43
ECOG 0 to 1			80%	Dostarlimab PSD November 2023 Table 20 p. 41-43
Proportion who have mismatch repair proficiency (pMMR)			73%	Dostarlimab PSD November 2023 Table 20 p. 41-43
Treatment				
Tx Uptake Rate			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	MSD assumption
Time on treatment (ToT) (Months)			7.62	MSD assumption
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '9. UCM_MSD Multicancer_pMMR 1L Endo'.

Table 22: HCC (NEW) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 10 Hepatocellular carcinoma (HCC)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population(s)				
A: Incident - BCLC Stage A ineligible for resection or ablation				
Liver cancer cases (AIHW)			2,913	AIHW, 2025 Value
Hepatocellular carcinoma			82.0%	Atezolizumab + Bevacizumab PSD July 2020, Table 17, pg.31
Total HCC with Child Pugh score A			56.0%	Hong et al 2018
Patients with BCLC Stage A			31.8%	Average across 3 studies NSW/SA: Chandran et al. 2023, Yeoh et al 2024, McNamara et al. 2024
Stage A patients ineligible for resection or ablation			41.4%	Abelmalak et al. 2024 Disease Patterns
B: Recurrent BCLC Stage A (following resection or ablation)				
Eligible for resection			22.4%	Abelmalak et al. 2024 Disease Patterns
recurrence after resection: 1 yr recurrence			11.7%	Abelmalak et al. 2024 Disease Patterns
Eligible for ablation			29.2%	Abelmalak et al. 2024 Propensity Score Matching
recurrence after ablation: 1 yr recurrence			21.4%	Abelmalak et al. 2024 Propensity Score Matching
C: Incident - BCLC Stage B				
BCLC Stage B			23.5%	Average across 3 studies NSW/SA: Chandran et al. 2023, Yeoh et al 2024, McNamara et al. 2024
eligible for TACE			45.7%	Atezolizumab + Bevacizumab PSD July 2020, Table 17, pg.31
D: Incident - BCLC Stage C				
BCLC Stage C			21.0%	Average across 3 studies NSW/SA: Chandran et al. 2023, Yeoh et al 2024, McNamara et al. 2024
eligible for TACE			10.4%	Assumption as per baseline characteristics from LEAP-012 Trial (Kudo et al. 2025)
E: Prevalent				
1 yr Overall Survival			56.1%	Cancer data in Australia, Cancer incidence and survival by subsite - Australian Institute of Health and Welfare (Relative 1 yr survival; Liver cell carcinoma C22.0) https://www.aihw.gov.au/reports/cancer/cancer-data-in-australia/contents/stage
Eligibility				
ECOG 0 to 1			Popn A,B,C: [redacted]% Popn D, E: [redacted]%	MSD assumption
Treatment				
Treatment Uptake Rate			Incident A-D: [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6 Prevalent E: [redacted]%	MSD assumption, for indications where there is no other PD-(L)1 available on the PBS, time to peak uptake is 1 year ([redacted]% of peak uptake in year 1, [redacted]% in year 2-6).
Time on treatment (ToT) (Months)			12.4 Months 53.99 Weeks	median treatment duration, LEAP 12 study- Kudo et al. 2025 Lancet Oncology
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '10. UCM_MSD Multicancer_HCC'.

Table 23: HER2+ Gastric (KN811) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 11 HER2+ Gastric (KN811)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population(s)				
A: Incident				
Incidence – stomach cancer	2,610	AIHW (2024) 2025 Value	2,775	AIHW (2024) – Book 1e, projected incidence in 2026
Adenocarcinoma	90%	Waddell, Verheij et al. (2013)		
Newly diagnosed at Stage IV	[redacted]%	MSD assumption	44.3%	Mortality in 2024 as a surrogate for Stage IV
Proportion of patients with HER2+ve GC			20.0%	Upper limit of estimate 10-20% from Gravalos, C.; Jimeno, A. HER2 in gastric cancer: A new prognostic factor and a novel therapeutic target. Ann. Oncol. 2008, 19, 1523–1529.
B: Recurrent				
Earlier stage disease (Stage I-III) at diagnosis	[redacted][1]	MSD assumption KANTAR		
Eligibility				
HER 2 Testing rate	[redacted]%	MSD assumption		
HER 2+ Prevalence	[redacted]%	MSD assumption		
PDL1 Testing rate	[redacted]%	MSD assumption		
PDL1 CPS>1 prevalence rate	[redacted]%	MSD assumption		
Treatment rate	[redacted]%	MSD assumption		
ECOG 0 to 1			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 class share	[redacted]%	MSD assumption		
Peak brand share	[redacted]%	MSD assumption		
Time to peak	[redacted]months	MSD assumption		
Tx Uptake Rate			90%, 90%, 90%, 90%, 90% Year 1-6	Table 14, Nivolumab PSD November 2021/March 2022 (PBAC comment)
Time on treatment (ToT)	8.7 months	Based on trial-specific KM curve, blended across groups	11.6 Months 50.27 weeks	N-811, Janjigian, YY et al. Lancet 2023; 402: 2197–208
Dosage Regimen			200 mg Q3W	

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '4. Patients - T2a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '11. UCM_MSD Multicancer_ HER 2+ Gastric'.

The redacted values correspond to the following ranges:
[1] < 500

Table 24: Mesothelioma (KN483) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 12 Mesothelioma (KN483)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
New PD-(L)1 patients	[redacted][1]	MSD assumption	[redacted][1]	Department estimated
Treatment				
Peak brand share	[redacted]%	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Year 3-6: [redacted]%	MSD assumption
Time to peak	[redacted]months	MSD assumption	Year 1: [redacted]0% Year 2: [redacted]% Years 3-6: [redacted]%	MSD assumption, for indications where there is another PD-(L)1 available on the PBS
Time on treatment (ToT)			18.86 weeks	NIVO+IPI reported in DUSC report
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '5. Patients - T2b'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '12. UCM_MSD Multicancer_Second to Market'.

The redacted values correspond to the following ranges:
[1] < 500

Table 25: 1L Biliary (KN966) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 12 1L Biliary (KN966)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
New PD-(L)1 patients	[redacted][1]	MSD assumption	[redacted][2]	Department estimated
Treatment				
Peak brand share	[redacted]%	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Year 3-6: [redacted]%	MSD assumption
Time to peak	[redacted] months	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Years 3-6: [redacted]%	MSD assumption, for indications where there is another PD-(L)1 available on the PBS
Time on treatment (ToT)	*Not Specified*		35.7 weeks	Durvalumab PSD July 2023 Table 7, p.12
Dosage Regimen	*Not Specified*		200 mg Q3W	

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '5. Patients - T2b'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '12. UCM_MSD Multicancer Second to Market'.

The redacted values correspond to the following ranges:
[1] < 500
[2] 500 to < 5,000

Table 26: Merkel CC (KN913) Comparison of the key inputs and assumptions for the July 2025 vs resubmission.

Model 12 Merkel CC (KN913)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
New PD-(L)1 patients	[redacted][1]	MSD assumption	[redacted][1]	Department estimated
Treatment				
Peak brand share	[redacted]%	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Year 3-6: [redacted]%	MSD assumption
Time to peak (months)	[redacted]	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Years 3-6: [redacted]%	MSD assumption, for indications where there is another PD-(L)1 available on the PBS
Time on treatment (ToT)			35.43 weeks	Avelumab DUSC report (ToT) w/o tx breaks) p. 2
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '5. Patients - T2b'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '12. UCM_MSD Multicancer_Second to Market'.

The redacted values correspond to the following ranges:
[1] < 500

Table 27: dMMR 1L Endo (KN868) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 12 dMMR 1L Endo (KN868)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
New PD-(L)1 patients	[redacted][1]	MSD assumption	[redacted][1]	Department estimated
Treatment				
Peak brand share	[redacted]%	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Year 3-6: [redacted]%	MSD assumption
Time to peak (months)	-	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Years 3-6: [redacted]%	MSD assumption, for indications where there is another PD-(L)1 available on the PBS
Time on treatment (ToT)			88.94 weeks	Assumed that PEM would be the same as mean ToT reported in Dostarlimab
Dosage Regimen			200 mg Q3W	

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '5. Patients - T2b'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '12. UCM_MSD Multicancer_Second to Market'.

The redacted values correspond to the following ranges:
[1] < 500

Table 28: 1L HER2- Gastric (KN859) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 12 1L HER2- Gastric (KN859)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
New PD-(L)1 patients	[redacted][1]	MSD assumption	[redacted][1]	Department estimated
Eligibility based on AIHW incidence			[redacted]%	MSD assumption
Treatment				
Peak brand share	[redacted]%	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Year 3-6: [redacted]%	MSD assumption
Time to peak	[redacted] months	MSD assumption	Year 1: [redacted]% Year 2: [redacted]% Years 3-6: [redacted]%	MSD assumption, for indications where there is another PD-(L)1 available on the PBS
Time on treatment (ToT)			32.88 weeks	Pembrolizumab Nov 2021 with Mar 2022 Addendum Table 13 p. 27
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '5. Patients - T2b'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '12. UCM_MSD Multicancer_Second to Market'.

The redacted values correspond to the following ranges:
[1] *500 to <5,000*

Removal of Once in a Lifetime (Model 13)

7.16 There are 7 indications in the proposal for the removal of the once-in-a-lifetime restriction for pembrolizumab.

7.17 An epidemiological approach was used to estimate financial implications associated with removing the once-in-a-lifetime restriction for pembrolizumab. The methods and assumptions used are described in the resubmission. The structure and arithmetic of the models were checked by the Department.

7.18 In the resubmission, the Sponsor has stated that "It is assumed that only indications with a PD-(L)1 available in earlier stages or lines of therapy are affected by allowing retreatment."

7.19 Overall, the total net cost to the PBS and RPBS is 49 per cent higher in the resubmission compared to the July 2025 submission from the revised modelling (see Table 29 below).

Table 29: Removal of Once in a Lifetime: Comparison of the utilisation estimates for the resubmission versus the July 2025 submission (Tier 2, Model 13)

Indication	Parameter	July 2025 Submission							Current Submission							% difference
		Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1-6	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1-6	
Renal Cell Carcinoma (KN581)	Patient #	1	8	13	14	15	15	66	5	3	18	23	27	31	**116**	**76%**
	Script	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	**-80%**
	Net ($m)	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	**$[2]**	**151%**
Triple Negative Breast Cancer (KN355)	Patient #	43	52	53	54	55	55	313	5	13	18	21	24	28	**109**	**-65%**
	Script	[1]	[1]	[1]	[1]	[1]	[1]	[3]	[1]	[1]	[1]	[1]	[1]	[1]	[3]	**-42%**
	Net ($m)	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	**$[2]**	**-55%**
Cervical Cancer (KN826)	Patient #	-	10	32	36	38	56	172	7	21	31	38	44	56	**197**	**15%**
	Script	-	[1]	[1]	[1]	[1]	[3]	[3]	[1]	[1]	[3]	[3]	[3]	[3]	[3]	**68%**
	Net ($m)	$ -	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	**$[2]**	**278%**
Endometrial Cancer (KN775)	Patient #	65	150	192	205	214	216	1,040	182	198	204	209	215	220	**1,229**	**18%**
	Script	[3]	[3]	[3]	[3]	[3]	[3]	[4]	[3]	[3]	[3]	[3]	[3]	[3]	[4]	**56%**
	Net ($m)	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[5]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	**$[5]**	**21%**
Urothelial Cancer (EV-302)	Patient #	8	22	36	39	40	41	186	33	84	102	126	140	151	**636**	**241%**
	Script	[1]	[1]	[1]	[1]	[1]	[1]	[3]	[3]	[3]	[3]	[3]	[3]	[3]	[4]	**470%**
	Net ($m)	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	[2]	**$[8]**	**341%**
Esophageal Cancer, Gastroesophageal (KN590, KN811)	Patient #	14	14	15	16	12	13	84	5	12	16	18	20	22	**92**	**9%**
	Script	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[1]	[3]	**133%**
	Net ($m)	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	**$[2]**	**80%**
Non-Small Cell Lung Cancer (KN189, KN407, KN042, KN024)	Patient #	68	70	73	75	77	79	443	59	60	62	63	64	66	**375**	**-15%**
	Script	[3]	[3]	[3]	[3]	[3]	[3]	[3]	[3]	[3]	[3]	[3]	[3]	[3]	[3]	**-32%**
	Net ($m)	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	$[2]	**$[2]**	**-21%**
Total net PBS/RPBS cost ($M):								**$[6]**							**$[7]**	**49%**

Source:
Utilisation and cost model for the July 2025 submission (version 30 May 2025). 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx'
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025) - Model 13. The above figures reflect the corrections made by DUS during the review as described in Table 30 below.

The redacted values correspond to the following ranges:
[1] < 500
[2] $0 to < $10 million
[3] 500 to < 5,000
[4] 10,000 to < 20,000
[5] $20 million to < $30 million
[6] $30 million to < $40 million
[7] $50 million to < $60 million
[8] $10 million to < $20 million

7.20 The structural or arithmetic errors that were corrected during the review by the Drug Utilisation Section are detailed in Table 30.

Table 30: Structure and arithmetic errors corrected during DUS review

Model #	Indication	Issue	Correction Made	Source
13	Urothelial Cancer (EV-302)	Correction to arithmetic (incorrect cell reference). *The Proportion who are eligible for 1L treatment* assumption applied [redacted]%.	Updated to [redacted]% based on the Sponsor's proposal.	10. Registry Population Row 221
		Correction to arithmetic. Class share ([redacted]%) * Brand share ([redacted]%) value applied was [redacted]%.	Product of [redacted]%*[redacted]% = [redacted]%. Updated accordingly.	10. Registry Population Row 237
		Correction to arithmetic. (incorrect cell reference). Second year following CCRT formula applies the population from the wrong year.	Updated to apply the population from the correct year.	10. Registry Population Row 342
		Correction to arithmetic (incorrect cell reference). Referenced *6 month recurrence following surgery (Refractory to IO)* (row 379) instead of *No. of patients treated with adj NIVO each yr* (row 337).	Updated to apply the correct population source.	10. Registry Population Row 382
		Correction to arithmetic. (incorrect cell reference). Second year following surgery formula applies the population from the wrong year.	Updated to apply the population from the correct year.	10. Registry Population Row 383

7.21 The Key inputs and assumptions used to develop the utilisation estimates for each of the future indications in the resubmission are compared to the July 2025 submission in Table 31 - Table 37 below.

Table 31: RCC (KN581) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 13 Renal Cell Carcinoma (KN581)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
Newly Recurrent with Metastatic Disease	[redacted][1]	MSD assumption	671	KNA18 Costing Utilisation Model
Estimated 6 month recurrence following surgery (Refractory to IO)			[redacted]%	MSD assumption
Proportion of patients that develop distant metastasis over 6 years			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	MSD assumption
Eligibility				
Intermediate/Poor	[redacted]%	MSD assumption	77%	Pembrolizumab March 2022 Table 17 p. 29
Treatment				
Peak PD-(L)1 Class share (1)	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Peak brand share	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Treatment uptake rate	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Time on treatment (ToT)	46 weeks 10.75 months	MSD assumption	62.8 weeks	KN581 Pricing Package
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '6. Patients - T3a'.

Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '13. UCM_MSD Multicancer_Removal of OIAL'.

The redacted values correspond to the following ranges:
[1] 500 to < 5,000

Table 32: TNBC (KN355) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 13 Triple Negative Breast Cancer (KN355)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Newly Recurrent with Metastatic Disease	[redacted][1]	MSD assumption	1,297	KN522 Costing Utilisation Model
Decrease in Recurrence from Early Stage		MSD assumption	0.8%	MSD assumption
Proportion of patients develop distant metastasis over 6 years			Year 1: [redacted]% Year 2: [redacted]% Year 3: [redacted]% Year 4: [redacted]% Year 5: [redacted]% Year 6: [redacted]%	MSD assumption
Eligibility				
Testing rate	[redacted]%	MSD assumption	95%	Pembrolizumab PSD March 2023-Accepted by PBAC and DoH. Table 13 p. 28
CPS>10 prevalence rate	[redacted]%	MSD assumption	38%	Pembrolizumab PSD March 2023-Accepted by PBAC and DoH. Table 13 p. 29
ECOG PS 0-1			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 Class share (1)	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Peak brand share	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Treatment uptake rate	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Time on treatment (ToT)	3.6 months (15.6 weeks)	MSD assumption	22.75 weeks	KN355 Pricing Package (45.5 weeks). Halved ToT (applied 22.75 wks) based on SL feedback advising low threshold to switch to 2L sacituzumab govitecan
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '6. Patients - T3a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '13. UCM_MSD Multicancer_Removal of OIAL'.

The redacted values correspond to the following ranges:
[1] 500 to < 5,000

Table 33: Cervical Cancer (KN826) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 13 Cervical Cancer (KN826)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
Newly Recurrent with Metastatic Disease (average)	[redacted][1]	MSD assumption	248	KNA18 Cost Utilisation Model
Estimated 6 month recurrence following surgery (Refractory to IO)			[redacted]%	MSD assumption
Proportion of patients develop distant metastasis over 6 years			Year 1: [redacted]% Year 2: [redacted]% Year 3: [redacted]% Year 4: [redacted]% Year 5: [redacted]% Year 6: [redacted]%	MSD assumption
Eligibility				
Proportion who are ECOG PS 0-1			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 Class share	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Peak brand share	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Treatment uptake rate	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Time on treatment (ToT)	*9.9 months (42.9 weeks)*	MSD assumption	22.75 weeks	KN581 Pricing Package
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '6. Patients - T3a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '13. UCM_MSD Multicancer_Removal of OIAL'.

The redacted values correspond to the following ranges:
[1] < 500

Table 34: Endometrial Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 13 Cervical Cancer (KN826)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
Newly Recurrent with Metastatic Disease	[redacted][1]	MSD assumption	520	Derived from UCM 7+8
Eligibility				
Testing rate	[redacted]%	MSD assumption		
dMMR prevalence	[redacted]%	MSD assumption		
pMMR prevalence	[redacted]%	MSD assumption		
Receiving 2L PEM+LEN			[redacted]%	MSD assumption
Treatment				
dMMR peak PD-(L)1 Class share	[redacted]%	MSD assumption		
pMMR peak PD-(L)1 Class share	[redacted]%	MSD assumption		
Peak PD-(L)1 Class share			[redacted]%	MSD assumption
Peak brand share			[redacted]%	MSD assumption
Time on treatment (ToT) dMMR	14.9 months	MSD assumption	44.1 weeks	KN775 Pricing Package
Time on treatment (ToT pMMR	11.2 months	MSD assumption		
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '6. Patients - T3a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '13. UCM_MSD Multicancer_Removal of OIAL'.

The redacted values correspond to the following ranges:

[1] *< 500*

Table 35: UC (EV-302) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 13 UC (EV-302)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
Newly Recurrent with Metastatic	[redacted][1]	MSD assumption	721	KN522 Costing Utilisation Model
Decrease in Recurrence from Early			[redacted]%	MSD assumption
Proportion of patients that develop distant metastasis over 6 years			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Years 1-6	MSD assumption
Eligibility				
1L Treatment			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 Class share	[redacted]%	MSD Assumption	[redacted]%	MSD assumption
Peak brand share	[redacted]%	MSD Assumption	[redacted]%	MSD assumption
Treatment uptake rate	[redacted]%	MSD Assumption	[redacted]%	MSD assumption
Time on treatment (ToT)	8.7 Months (37.7 weeks)	MSD Assumption	51.42 weeks	Paragraph 6.59 enfortumab vedotin PSD
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '6. Patients - T3a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '13. UCM_MSD Multicancer_Removal of OIAL'.

The redacted values correspond to the following ranges:
[1] *500 to < 5,000*

Table 36: Gastroesophageal (KN590/811) Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 13 Esophageal Cancer, Gastroesophageal (KN590, KN811)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
PD-(L)1 experienced patients	[redacted][1]	MSD assumption	412	Nivolumab July 2022 Table 15 p29
Decrease in Recurrence from Early			[redacted]%	MSD assumption
Proportion of patients that develop distant metasis over 6 years			[redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]%, [redacted]% Year 1-6	MSD assumption
Eligibility				
ECOG 0 to 1			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 Class share (1)	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Peak brand share	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Treatment uptake rate	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Time on treatment (ToT)			32.88 weeks	Pembrolizumab Nov 2021 with Mar 2022 Addendum Table 13 p. 27
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '6. Patients - T3a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '13. UCM_MSD Multicancer_Removal of OIAL'.

The redacted values correspond to the following ranges:
[1] *500 to < 5,000*

Table 37: NSCLC Comparison of the key inputs and assumptions for the July 2025 vs resubmission

Model 13 NSCLC (KN189/407/042/024)	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
Patients treated with PD-(L)1 in early stage NSCLC in 2024	[redacted][1]	MSD assumption	296	Calculated
Proportion Newly Recurrent Patients: PD-1 Experienced			[redacted]%	MSD assumption
Eligiblity				
1L NSCLC therapy (non-squamous/squamous)			[redacted]%	MSD assumption
Treatment				
Peak PD-(L)1 Class share (1)	[redacted]%	MSD assumption	[redacted]%	MSD assumption.
Peak brand share	[redacted]%	MSD assumption	[redacted]%	MSD assumption.
Treatment uptake rate	[redacted]%	MSD assumption	[redacted]%	MSD assumption
Time on treatment (ToT)	Not Specified		38.5 weeks	NSCLC Pricing Package
Dosage Regimen			200 mg Q3W	MSD assumption

Source: Utilisation and cost model for the July 2025 'Pembro_Utilisation_Cost_Model_30MAY2025_circ.xlsx' (version 30 May 2025), sheets '6. Patients - T3a'.
Utilisation and cost model for the December 2025 resubmission (version 10 Oct 2025). '13. UCM_MSD Multicancer_Removal of OIAL'.

The redacted values correspond to the following ranges:
[1] *< 500*

Removal of 2 year stopping rule (Model 14)

7.22 The resubmission estimates the impact of removing the two-year stopping rule based on:

- the patient forecasts presented in the individual epidemiological models for the future listings; and
- for the current listings where utilisation was projected using a market share approach, the number of patients is estimated by dividing the total number of scripts by the calculated number of scripts per patient for each indication.

7.23 The July 2025 submission included patients with TMB-H and MSI-H pan tumours. Patients with these pan tumours, as well as patients with melanoma and rare cancers, are excluded from the financial estimates presented in the resubmission as the stopping rule is not considered to have a meaningful impact for these patient groups.

7.24 Refer to Table 38 below for a comparison of the methods to estimate the additional time on treatment beyond two years presented in the July 2025 submission versus the resubmission. As for the July 2025 resubmission, real-world data from a French National Health Insurance database, including patients with advanced lung cancer, is used to estimate the proportion of patients who are supplied pembrolizumab beyond two years (Rousseau et al., 2024). The study found 4.3 per cent of patients received treatment for more than 29 months with a median treatment time of 33.2

months. The median time on treatment for the current PBS listings of pembrolizumab was derived from previously accepted estimates for these indications, calculated as 10.8 months. A weighted time on treatment for the future and current listings was calculated as: (95.7% x 10.8m) + (4.3% x 33.2m) = 11.8 months. The additional months of treatment beyond two years was estimated to be 0.96.

7.25 Table 39 presents a comparison of the utilisation for the July 2025 submission versus the resubmission. The revised modelling results in a net cost to the PBS and RPBS that is around 41 per cent lower than the July 2025 submission (six-year net cost of $80 million to < $90 million versus $100 million to < $200 million).

Table 38: Comparison of assumptions used in the July 2025 versus resubmission for use beyond 2 years to estimate the number of eligible and treated patients

	July Submission		Proposed Submission	
Parameter	**Value**	**Source**	**Value**	**Source**
Population				
Patients Currently listed (excluding melanoma) (average[1])	[7]	MSD assumption	[6]	Calculated. UCM_MSD Multicancer_Current, Sheet '3a. Scripts - proposed'
PBAC recommended (average[1])			[6]	UCM_MSD Multicancer_PBAC Recommended, Sheet '2a. Patients - incident'
Ovarian (average[1])	[5]	July submission 4. Patients - T2a	[5]	UCM_MSD Multicancer_Ovarian, Sheet '2a. Patients - incident'
RCC, fav risk and ncc (average[1])	[5]	July submission 4. Patients - T2a	[5]	UCM_MSD Multicancer_RCC, Sheet '2a. Patients - incident'
1L UC (average[1])	[6]	July submission 4. Patients - T2a	[6]	UCM_MSD Multicancer_1L UC, Sheet '2a. Patients - incident'
pMMR 1L Endo (average[1])[2]			[5]	UCM_MSD Multicancer_pMMR 1L Endo, Sheet '2d. Patients - DTG'
HCC (average[1])[3]			[5]	UCM_MSD Multicancer_HCC, Sheet '2d. Patients - DTG'
HER 2+ Gastric (average[1])	[5]	July submission 4. Patients - T2a	[5]	UCM_MSD Multicancer_HER 2+ Gastric, Sheet '2a. Patients - incident'
Second to market (average[1])	[6]	July submission 4. Patients - T2a	[6]	UCM_MSD Multicancer_Second to Market, Sheet '2a. Patients - incident'
TMB-H pan tumour (average[1])[4]	[5]	July submission 4. Patients - T2a		
MSI-H pan tumour (average)[4]	[5]	July submission 4. Patients - T2a		
Treatment				
Proportion of patients with > 2year ToT	4.3%	Rousseau 2024	4.3%	Rousseau 2024
Proportion of patients with < 2year ToT	95.7%	Rousseau 2024	95.7%	Rousseau 2024
Median ToT for patients recieveing treatment > 2year, months	33.2	Rousseau 2024	33.2	Rousseau 2024
Median ToT across metastatic indications (excl. adv melanoma) (months)	9	MSD assumption	10.8	Calculated. Median time on treatment for currently listed converted to months
ToT (adjusted)	10.0	Calculated	11.8	Calculated
Additional months on treatment	1.04	Calculated	0.96	Calculated
Scripts / treatment			15.64	Calculated
Dosage Regimen			200 mg Q3W	MSD assumption

Note: ToT, time on treatment.

[1] Based on an average of the patient forecast over 6 years.
[2] July submission included pMMR 1L Endo in Second to Market.
[3] New indications included in resubmission.
[4] Excluded in the resubmission.

The redacted values correspond to the following ranges:
[5] < 500
[6] 500 to < 5,000
[7] 5,000 to < 10,000

Table 39: Comparison of the utilisation forecasts for use beyond 2 years presented in the July 2025 submission versus the resubmission

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Years 1-6
Patient forecast							
July 2025 submission	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Resubmission	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Difference (%)	-14.2%	-20.6%	-17.2%	-17.7%	-16.8%	-16.8%	-17.3%
Prescription forecast							
July 2025 submission	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Resubmission	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Difference (%)	-21.0%	-26.9%	-23.7%	-24.2%	-23.4%	-23.4%	-23.8%
Net PBS and RPBS expenditure (effective prices)							
July 2025 submission	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Resubmission	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Difference (%)	-38.9%	-43.5%	-41.0%	-41.4%	-40.7%	-40.7%	-41.1%

The redacted values correspond to the following ranges:
[1] 5,000 to < 10,000
[2] 50,000 to < 60,000
[3] 40,000 to < 50,000
[4] 10,000 to < 20,000
[5] 70,000 to < 80,000
[6] $10 million to < $20 million
[7] $20 million to < $30 million
[8] $100 million to < $200 million
[9] $80 million to < $90 million

Rare Cancers (Model 15)

7.26 The utilisation of pembrolizumab for rare cancers was not estimated in the July 2025 submission.

7.27 The department has checked and confirmed the methods and data sources for the assumptions used to derive the forecasted utilisation of pembrolizumab for rare cancers described in Table 4-16 of the resubmission.

7.28 The number of incident patients with rare cancer is sourced from the Australian Institute of Health and Welfare (AIHW) Cancer Australia Overview (2024). This source was accepted for the September 2025 recommendation for nivolumab (Public Summary Document nivolumab, July and September 2025, Table 10). In addition to patients with a rare cancer (n=19,861), the resubmission also includes patients with less common cancer (n=20,371) and unknown primary cancer (n=2,630) in the eligible population.

7.29 Mortality is used as a surrogate for the assumption of the proportion of patients with an advanced or metastatic rare, less common or unknown primary cancer. The percentage of all deaths in 2024 that were rare plus less common cancer patients was 30.5%. The recommendation for nivolumab in September 2025 included an assumption that 47.2 per cent or rare cancers are regional or metastatic (Public Summary Document nivolumab, July and September 2025, Table 10).

7.30 To derive the number of patients supplied pembrolizumab, the resubmission assumes that:

- patients would have an ECOG performance status of 0-1 (per cent);
- patients would have prior therapy before immuno-oncology (65 per cent, based on De Heus et al. (2021) finding per cent of rare cancer patients had two or more types of treatment); and
- per cent of patients would elect immuno-oncology and per cent of these patients would be supplied pembrolizumab.

7.31 For the September 2025 recommendation for nivolumab, PBAC accepted the assumptions based on data from Omico that 51.64 per cent of rare cancer patients would have a sub type of cancer suitable for immuno-oncology and 18.52 per cent of patients would be eligible for treatment (Public Summary Document nivolumab, July and September 2025, Table 10).

PBS Medicines likely to be affected

7.32 This section outlines the PBS medicines that will likely be replaced by listing pembrolizumab on the PBS for the indications included in this proposal.

7.33 For indications not yet listed on the PBS, alternative treatments were identified based on currently available PBS therapies, past PBAC decisions, and EviQ guidelines and are described in the resubmission. The structure and arithmetic of the models that included affected medicines were checked by the Department.

7.34 Overall, based on the published prices, the total net reduction in cost to the PBS and RPBS is provided in Table 40 below. However, this will reduce substantially once the effective prices are used given that several of the affected medicines have a Special Pricing Arrangement (SPA) in place.

Table 40: Reduced cost to the PBS/RPBS for affected medicines

Affected medicine	Year 1 ($)	Year 2 ($)	Year 3 ($)	Year 4 ($)	Year 5 ($)	Year 6 ($)	Years 1-6 ($)
Nivolumab	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Cemiplimab	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Cisplatin	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Gemcitabine	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Cabozantinib	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Sunitinib	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Ipilimumab	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Avelumab	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Durvalumab	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Dostarlimab	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Sacituzumab govitecan	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Total net PBS/RPBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]

Source: UCM_MSD Multicancer_Net Impact, Sheet 'Impact – affected (eff)', Row 23-34. The above figures reflect the corrections made by DUS during the review as described in Table 41 below.

The redacted values correspond to the following ranges:
[1] Net cost saving

7.35 The structural or arithmetic errors that were corrected, where models included affected medicines, during the review by the Drug Utilisation Section are detailed in Table 41.

Table 41: Structure and arithmetic errors corrected during DUS review

Model #	Indication	Issue	Correction Made	Source
5	TMB-H (KN158)	Correction to Structure. Duration was applied to the population (DTG) and the Dosing Regimen (4a Scripts).	Removed the adjustment made to the dosing regimen.	4a. Scripts – affected Section 3, row 105, 106
6	MSI-H (KN158/164)	Correction to Structure. Duration was applied to the population (DTG) and the Dosing Regimen (4a Scripts).	Removed the adjustment made to the dosing regimen.	4a. Scripts – affected Section 3, row 105, 106
7	RCC	Correction to dosing calculation. Dosing was presented in months (30 doses per month).	Dosing has been corrected to 7 doses per week.	4a. Scripts – affected Section 4, Row 105
		Correction to dosing calculation. Dosing was presented in months (21 doses per month).	Dosing has been corrected to 4.67 doses per week (1 dose daily for 4 weeks followed by 2-week break).	4a. Scripts – affected Section 4, Row 106
8	UC	Correction to Structure. Duration was applied to the population (DTG) and the Dosing Regimen (4a Scripts).	Removed the adjustment made to the dosing regimen.	4a. Scripts – affected Section 3, row 105, 106
12	1L HER2 – Gastric (KN859)	Correction to dosing calculation. Durvalumab dosing is Q3W for the first 8 weeks and Q4W onwards.	Updated to 8 and 27.7 weeks for initiating and continuing respectively.	2d. Patients – DTG DTG 5
		Correction to structure. Avelumab was linked to the incorrect DTG (linked to Biliary Tract Cancers).	Updated from DTG 5 to DTG 7	4a. Scripts – affected Section 3, row 107
		Correction to structure. Durvalumab was linked to the incorrect DTG (linked to Merkel cell Carcinoma).	Updated from DTG 7 to DTG 5	4a. Scripts – affected Section 3, row 108
		Correction to pricing calculation. Ipilimumab and Avelumab pricing calculations considered weight-based dosing using partial vials.	Updated calculation method using integer vial numbers.	4b. Impact - affected (pub) and 4c. Impact - affected (eff), Section 3, rows 275 & 276
13	OIAL	Correction to Structure. Duration was applied to the population (DTG) and the Dosing Regimen (4a Scripts).	Removed the adjustment made to the dosing regimen.	4a. Scripts – affected Section 3, row 107, 108
15	Rare	Correction to Structure. Duration was applied to the population (DTG) and the Dosing Regimen (4a Scripts).	Removed the adjustment made to the dosing regimen.	4a. Scripts – affected Section 3, row 105, 106

Net prescription processing changes for the DHS

7.36 The net changes to prescriptions captures medicines with increased use: pembrolizumab, lenvatinib and enfortumab vedotin; and medicines with decreased use: nivolumab, cemiplimab, cisplatin, gemcitabine, cabozantinib, sunitinib,

ipilimumab, avelumab, durvalumab, dostarlimab and sacituzumab govitecan as detailed in Table 42 below.

Table 42: Net prescription processing changes

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1-6
Net change in PBS	[redacted][3]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][5]
Net change in RPBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]
Net change in scripts	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][5]

Source: UCM_MSD Multicancer_Net Impact, Sheet 'Net changes - SA, Row 14-27. The above figures reflect the corrections made by DUS during the review.

The redacted values correspond to the following ranges:
[1] 500 to < 5,000
[2] 10,000 to < 20,000
[3] 90,000 to < 100,000
[4] 100,000 to < 200,000
[5] 600,000 to < 700,000

Net changes to MBS items

7.37 This proposal includes changes to the MBS administration fee item (13950), which was applied to all infusion therapies.

7.38 The net cost to the MBS is summarised below in Table 43, which is mostly driven by the administration fees associated with the increased use of pembrolizumab.

Table 43: Net cost to the MBS

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 1-6
PBS							
Increased cost ($million)	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	**$**[redacted][2]
Decreased cost ($million)	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	**-$**[redacted][3]
Net cost ($million)	$[redacted][4]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	$[redacted][1]	**$**[redacted][5]
RPBS							
Increased cost ($million)	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	**$**[redacted][4]
Decreased cost ($million)	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	**-$**[redacted][3]
Net cost ($million)	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	**$**[redacted][4]
Net cost PBS / RPBS ($million)	**$**[redacted][4]	**$**[redacted][1]	**$**[redacted][1]	**$**[redacted][1]	**$**[redacted][1]	**$**[redacted][1]	**$**[redacted][5]

Source: UCM_MSD Multicancer_Net Impact, Sheet 'Net changes - MBS, Row 13-23. The above figures reflect the corrections made by DUS during the review.

The redacted values correspond to the following ranges:
[1] $10 million to < $20 million
[2] $100 million to < $200 million
[3] net cost saving
[4] $0 to < $10 million
[5] $60 million to < $70 million

8 Quality use of medicines

8.1 The sponsor proposed the following activities to support the potential broad listing:

- One-on-one interactions between MSD's Medical Advisors / MSLs and Medical Oncologists both before and after the implementation of the new listing; and

- National- and state-based education events, including MSD's annual Current Trends in Immuno-Oncology (CTIO) conference, which is attended by over 200 Australian Medical Oncologists (approximately 1 in 3 Medical Oncologists).

8.2 The following was also noted in the proposal:

> "Assuming that the broad listing proposal is approved in November 2025 and in the process of implementation in early 2026, MSD intends to dedicate several sessions to this topic at the next CTIO event, which is planned for March 2026.
>
> MSD will also develop written materials for Health Care Professional that clearly outline the clinical settings in which there is evidence to support the use of pembrolizumab.
>
> Through both educational events and written resources, MSD will emphasise the intent of the listing, which is to improve equity of access in advanced and metastatic settings where there is a reasonable expectation of efficacy. The clear expectation is that clinicians will appropriately balance the potential efficacy benefits with risks of harm, noting that they may need to rely upon lower levels of evidence to support prescribing decisions in the context of rare and ultra-rare cancers where registrational studies do not exist."

9 PBAC Outcome

9.1 The PBAC recommended under section 101(3) of the Act, a change to the circumstances under which pembrolizumab is made available as a pharmaceutical benefit under Part VII of the Act to expand its use for advanced and metastatic cancers. The PBAC is satisfied that the extended listing will provide, for some patients, a significant improvement in efficacy over alternate therapies (or watchful waiting). The PBAC's recommendation for listing was based on, among other matters, its assessment that the listing would be cost-effective within the context of a Risk Sharing Arrangement (RSA), specifically where pembrolizumab is added to the same RSA with nivolumab and ipilimumab for advanced and metastatic cancers, and subject to the same pricing structure.

9.2 The PBAC welcomed the revised approach to the restriction criteria and noted this had largely addressed its concerns from the July 2025 submission, particularly regarding access for patients with rare cancers. The PBAC recalled it had recommended nivolumab ± ipilimumab for a broad listing for advanced and metastatic cancers in September 2025.

9.3 The PBAC noted there remained some minor differences between the proposed listing for pembrolizumab and the recommended listing for nivolumab ± ipilimumab. The PBAC considered it would be appropriate for both listings, if implemented, to be consistent. As such, the PBAC did not support the inclusion of additional clinical criteria for pembrolizumab as proposed in the submission and pre-PBAC response and recommend the same restriction criteria be applied as were recommended for nivolumab ± ipilimumab.

9.4 The PBAC noted a weighted price was proposed for the existing advanced/metastatic indications currently PBS-listed, as well as two indications (gastro-oesophageal cancer and cutaneous squamous cell carcinoma) that have a positive PBAC recommendation but are not yet implemented. The PBAC noted the weighted price would apply to estimated utilisation for the indications included in the calculation of the weighted price. This was intended to effectively maintain the existing prices for current listings and established cost-effective prices for indications where a recommendation has been made but not yet implemented. The PBAC considered this was appropriate.

9.5 The PBAC noted there was a significant increase in the modelled utilisation and financial impact in the current proposal compared to the July 2025 consideration. The PBAC considered that, given the level of uncertainty within the predicted utilisation, consideration of the overall financial impact across the broad listings was a relevant factor and the proposed additional financial impact in Tier 2 for pembrolizumab was substantial.

9.6 The PBAC considered that the models provided, after application of the amendments suggested by the Drug Utilisation Section, were suitable for informing Tier 1 of the RSA.

9.7 The PBAC noted the proposed modelling included some Tier 2 indications for which no additional utilisation was expected beyond that which was considered for nivolumab ± ipilimumab. In particular, it highlighted it expected pembrolizumab to substitute into the utilisation for rare cancers. The PBAC further noted that, in its pre-PBAC response, the sponsor removed pembrolizumab (in combination with Lenvatinib) in HCC from the modelling due to the interim analysis for LEAP-012 which did not achieve statistical significance for the primary endpoint of overall survival and was therefore expected to result in minimal uptake under the broad listing.

9.8 The PBAC noted the modelling did not differentiate within indications for components of utilisation for the advanced and metastatic setting versus early stage; and did not adequately account for some Tier 2 cancer indications which were not likely to be sensitive to immunotherapy and those cancers where treatment with medicines other than immune therapies were already reimbursed and standard of care. Furthermore, the Tier 2 indications did not account for the positive recommendations or reimbursements for other PD-1/PD-L1 inhibitors. For these reasons the uptake of pembrolizumab would be significantly less than estimated by the submission.

9.9 The PBAC considered it would be appropriate for pembrolizumab to join the RSA recommended for the nivolumab± ipilimumab broad listing in September 2025, should that recommendation proceed to listing, as there would be several indications, including a number which are already PBS-listed, where both pembrolizumab and nivolumab (+/- ipilimumab) would be treatment options in the same or similar population. Therefore, a shared RSA across the immunotherapies would more effectively manage the intended price discounts and total budget impact for the broader listings. The PBAC considered it would be appropriate for the RSA

caps, where established for nivolumab and ipilimumab, to be increased to account for pembrolizumab utilisation across existing/previously recommended (Tier 1) based on the provided modelling.

9.10 The PBAC considered the overall utilisation estimate informing Tier 2 of the RSA should be based on the recommended utilisation for nivolumab ± ipilimumab but that a small increase to the Tier 2 caps would be reasonable to account for any further utilisation following the entry of pembrolizumab. The PBAC considered that a number of adjustments were required to estimate the additional expenditure on pembrolizumab before the precise adjustment in the Tier 2 caps could be determined. These included:

- the removal of mesothelioma, first-line urothelial cancer and HER2- gastric cancer noting these were existing or recommended listings for nivolumab ± ipilimumab;
- removal of the rare cancer population; and
- removal of urothelial cancer from the retreated population.
- the removal of indications which have already been reimbursed or received a positive recommendation for all brands of PD-L(1) inhibitors
- the removal of indications where effective treatments is already reimbursed and standard of care. PD-L(1) inhibitors should not displace treatments which have proven to be effective.
- the removal of indications where PBAC has already determined that treatment is not effective or cost effective.
- removal of tumour types generally considered non-immunosensitive.

9.11 The PBAC considered any adjustment to the caps should ensure the overall intended price discounts were maintained.

9.12 The PBAC considered that the RSA cap rebate levels accepted for nivolumab ± ipilimumab should be maintained, ensuring that the same magnitude of price reduction is applied for broader use beyond existing/recommended listings.

9.13 The PBAC considered high-risk, locally advanced cervical cancer, recommended in March 2025, met the proposed restriction criteria for the broad listing and, as such would be appropriate to be included within the broad listing RSA.

9.14 The PBAC recalled there are outstanding recommendations for pembrolizumab that are not yet implemented that may have impacts on utilisation in the advanced and metastatic cancer setting. The PBAC considered it appropriate that any anticipated changes arising from those listings should be accounted for in the broad listing utilisation estimates informing the RSA.

9.15 The PBAC noted that the financial estimates included indications where pembrolizumab is used in combination with other medicines. The PBAC considered that these indications should only be considered for inclusion in the estimates for the

purposes of the RSA where the other component of the combination had a PBS listing that would allow such use.

9.16 The PBAC considered it would be appropriate for the Department to prepare a review of utilisation three years after implementation of a broad listing. The purpose of this review would be to assess whether the medicines were being used consistent with the intention of the listing and that utilisation was for indications where there was a reasonable expectation of clinical benefit. The PBAC noted that if there were significant utilisation above the estimates or indicators of high levels of inappropriate prescribing under the listing at that time, it may be necessary to make amendments to the restriction wording or authority level to address this.

9.17 The PBAC noted that high-quality QUM activities and strong prescriber engagement will be essential to ensuring the medicines are used as intended. Should both pembrolizumab and nivolumab ± ipilimumab broad listings progress, the PBAC stressed that clear alignment and a coordinated, conjoint approach between the sponsors will be critical to supporting appropriate use. The PBAC highlighted that such alignment, supported by collaboration with clinical and consumer organisations, will be necessary to deliver effective QUM and educational activities that reinforce the intended use of the listing.

9.18 The PBAC noted that pembrolizumab and nivolumab ± ipilimumab had been the focus to date of the proposals for a broad listing for PD-L(1) inhibitors largely owing to the extensive evidence accumulated for the drugs informing safety and efficacy across a broad domain of indications which was reflected in their registered indications in the Australian Register of Therapeutic Goods. The PBAC was open to considering additional PD-L(1) inhibitors seeking to join the broad listings in the future but considered that each drug would need to make a submission that justified the extent to which it could demonstrate efficacy, safety and cost-effectiveness in the broad setting.

9.19 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

10 Recommended listing

10.1 Add the following new listing and restriction to replace all current listings for pembrolizumab across all PBS indications in the metastatic or advanced settings:

MEDICINAL PRODUCT Form	PBS item code	Max. Amount	№.of Rpts
PEMBROLIZUMAB Injection	NEW1 (HS) NEW2 (HB)	400mg	7
Available brands			
Keytruda (pembrolizumab 100 mg/4 ml injection, 4 ml vial)			
Restriction Summary / Treatment of Concept			
Category / Program: Section 100 – Efficient Funding of Chemotherapy Public/Private hospitals			
Prescriber type: Medical Practitioners			
Restriction type: Authority Required (STREAMLINED) [NEW]			
Administrative Advice: No increase in the maximum amount or number of units may be authorised.			
Administrative Advice: No increase in the maximum number of repeats may be authorised.			
Administrative advice: Special Pricing Arrangements apply.			
Indication: 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			

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

11 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.

12 Sponsor's Comment

MSD welcomes the positive recommendation from the PBAC to broaden the Pharmaceutical Benefits Scheme (PBS) listing for pembrolizumab. MSD is working closely with the Department of Health and Aged Care to ensure that Australian patients with advanced or metastatic cancer have equitable access to pembrolizumab as soon as possible.