

5.09 LENALIDOMIDE, Capsule 20 mg, Lenalide[®], Juno Pharmaceuticals Pty Ltd

1 Purpose of Submission

- 1.1 The Category 4 submission requested the Authority Required Section 100 Highly Specialised Drugs (HSD) program listing of lenalidomide capsule 20 mg (Lenalide[®]) under the same the same circumstances as the 5 mg, 10 mg, 15 mg, and 25 mg listed strengths of lenalidomide.

2 Background

Registration status

- 2.1 Lenalidomide was first registered by the Therapeutic Goods Administration (TGA) on 20 December 2007 for Multiple Myeloma (MM), Myelodysplastic Syndromes (MDS), and Mantle Cell Lymphoma (MCL) under the Revlimid[®] brand.
- 2.2 Revlimid 20 mg was first registered by the TGA on 11 November 2015.
- 2.3 Lenalide 20 mg was registered by the TGA on 23 July 2021.

Previous PBAC consideration

- 2.4 At its November 2008 meeting, the PBAC first recommended lenalidomide for the treatment of patients with relapsed/refractory multiple myeloma (RRMM) for whom thalidomide therapy has failed or in whom there is severe intolerance/toxicity to thalidomide (paragraph 12, lenalidomide, (Public Summary Document (PSD)) – November 2008 PBAC Meeting).
- 2.5 At its August 2019 meeting, the PBAC recommended the listing of lenalidomide in combination with bortezomib and dexamethasone (RVd) for the treatment of patients with newly diagnosed multiple myeloma (NDMM) (paragraph 7.1, lenalidomide, (PSD) – August 2019 PBAC Meeting).
- 2.6 Lenalidomide is currently listed as an Authority Required Section 100 HSD listing for the treatment of patients with NDMM, progressive MM, RRMM, and myelodysplastic syndrome. Lenalidomide is used for the treatment of NDMM as a monotherapy, doublet therapy, and triplet therapy.

3 Requested listing

3.1 The submission requested the addition of a new 20 mg strength of lenalidomide with the same restrictions as the other listed strengths of lenalidomide. For brevity, only the proposed new content has been included (in italics).

Monotherapy for NDMM (initial and continuing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
<i>lenalidomide 20 mg capsule, 28</i>	<i>NEW (HSD Public)</i>	1	28	2	<i>Lenalide</i>
	<i>NEW (HSD Private)</i>				
Restriction Summary / Treatment of Concept					
Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)					
Indication: Multiple myeloma					
Treatment Phase: Initial treatment with lenalidomide monotherapy in newly diagnosed disease					
Restriction Summary/ Treatment of Concept					
Treatment Phase: Continuing treatment with lenalidomide monotherapy following initial treatment with lenalidomide therapy in newly diagnosed disease					

Doublet therapy for NDMM

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
<i>lenalidomide 20 mg capsule, 21</i>	<i>NEW (HSD Public)</i>	1	21	0	<i>Lenalide</i>
	<i>NEW (HSD Private)</i>				
Restriction Summary/ Treatment of Concept					
Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)					
Indication: Multiple myeloma					
Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation					
Restriction Summary/ Treatment of Concept					
Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond					

Triplet therapy for NDMM

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 14	NEW (HSD Public)	1	14	3	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Multiple myeloma				
	Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle				
Restriction Summary/ Treatment of Concept					
	Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)				

Triplet therapy for NDMM (initial)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	3	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Multiple myeloma				
	Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle				

Triplet therapy for NDMM (continuing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	1	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Multiple myeloma				
	Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)				

Monotherapy for progressive Multiple Myeloma (initial and continuing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	0	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Multiple myeloma				
	Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease				
Restriction Summary / Treatment of Concept					
	Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease				

Relapsed/refractory Multiple Myeloma (elotuzumab)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	2	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Relapsed and/or refractory multiple myeloma				
	Treatment Phase: Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone				

Relapsed/refractory Multiple Myeloma (carfilzomib)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	2	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Relapsed and/or refractory multiple myeloma				
	Treatment Phase: Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone				

Myelodysplastic syndrome (initial and continuing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	3	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)					
Indication: Myelodysplastic syndrome					
Treatment Phase: Initial treatment					
Restriction Summary/ Treatment of Concept					
Treatment Phase: Continuing treatment					

3.2 While the submission requested that the proposed listings of Lenalide 20 mg be identical to the current restrictions for lenalidomide 5 mg, 10 mg, 15 mg and 25 mg strengths (a total of 9 specific indications in both public and private hospitals), the submission only presented 8 of these indications. The submission did not present a proposed restriction for triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone for the treatment of relapsed and/or refractory multiple myeloma as this indication listed on 1 October 2023. The pre-PBAC response requested to list the 20 mg strength for this indication.

3.3 Furthermore, it was noted that the 5 mg and 10 mg strengths are listed for 9 indications, the 15 mg is listed for 8 indications, and the 25 mg is listed for 7 indications. The 25 mg strength is not listed for initial/continuing monotherapy treatment in NDMM (the only lenalidomide indication with a 28-pack listing), and both the 15 mg and 25 mg strengths are not listed for myelodysplastic syndrome. The pre-PBAC response noted that the 20 mg strength is not present in the dosage modification protocol for these indications and therefore rescinded its request for these indications.

4 Comparator

4.1 The submission nominated the listed strengths of Revlimid (5, 10, 15 and 25 mg) as the comparators. It was noted that all the listed brands of lenalidomide for the same strengths are relevant comparators.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted and welcomed the input from Rare Cancers Australia (RCA) via the Consumer Comments facility on the PBS website. The comments described the benefits of lenalidomide over chemotherapies including the easier management of symptoms such as fatigue, and that it is an oral dose form which can be taken at home. RCA stated that the option of dose adjustment offered by listing this new strength may reduce the degree to which patients experience the side effects of lenalidomide. The PBAC noted that this advice was supportive of the submission's proposition.

Clinical claim

- 5.3 In its assessment of Lenalide 20 mg, the TGA determined that Lenalide was bioequivalent to Revlimid, and the submission has therefore claimed that it is non-inferior in terms of comparative effectiveness and safety to Revlimid 20 mg. The pre-PBAC response claimed that listing this strength would not only improve PFS and OS by allowing for a more accurate dose modification schedule and longer maintenance therapy¹, but would also reduce the pill burden, especially for elderly patients. It was noted that the claimed improvements were not specific to a particular brand.
- 5.4 The PBAC considered that the claim of the non-inferior comparative effectiveness and safety of Lenalide to Revlimid was reasonable.

Economic analysis

- 5.5 The submission presented a cost-minimisation analysis of Lenalide compared with Revlimid. The equi-effective doses were estimated as:
- 1 mg of Lenalide = 1 mg of Revlimid
- 5.6 The cost-minimisation analysis was presented as a comparison of the drug ex-manufacturer price (EMP) and assumed no differences in the utilisation of other healthcare resources relating to the administration of the drugs and management of adverse events.
- 5.7 Table 1 outlines the approved EMP (AEMP) of the listed strengths and the cost per mg.

¹ Ho, M., S. Zanwar, P. Kapoor, M. Gertz, M. Lacy, A. Dispenzieri, S. Hayman, D. Dingli, F. Baudi, E. Muchtar, N. Leung, T. Kourelis, R. Warsame, A. Fonder, L. Hwa, M. Hobbs, R. Kyle, S. V. Rajkumar and S. Kumar (2021). "The Effect of Duration of Lenalidomide Maintenance and Outcomes of Different Salvage Regimens in Patients with Multiple Myeloma (MM)." *Blood Cancer Journal* 11(9): 158

Table 1: Cost per mg of currently PBS listed strengths for all lenalidomide brands

Strength	Pack size	AEMP	Cost per mg
Lenalidomide 5 mg	14, 21, 28	\$774.17	\$11.06*
Lenalidomide 10 mg	14, 21, 28	\$1,014.20	\$7.24*
Lenalidomide 15 mg	14, 21, 28	\$1,221.50	\$5.82*
Lenalidomide 25 mg	14, 21	\$1,598.14	\$4.57*

Source: PBS Website (current as at 1 September 2023)

AEMP = approved ex-manufacturer price

* Cost per mg was corrected from the submission using the appropriate calculation: $AEMP / (\text{pricing quantity} * \text{strength})$

5.8 The submission requested that the EMP for the 20 mg strength of Lenalide be equivalent to the weighted average price per mg of the listed strengths of Lenalide using the utilisation proportions in Australia in the calendar year of 2022 for each listed strength, adjusted with utilisation assumptions, as the weights. The submission requested that a weighted price of \$94.23 per mg be applied to all indications and pack sizes. This price was incorrectly calculated as it did not factor in the pricing quantity of the pack. The proposed price corrected is \$6.73 per mg. The pre-PBAC response acknowledged and accepted this correction. The PBS utilisation data used in the Section 3 model of the submission shows the usage per PBS item code (i.e. by strength and indication) but does not outline the proportion of usage in initial versus continuing/maintenance treatment, nor does it show how long a patient uses each strength for. It is therefore unclear from the PBS data what proportion of use of each strength was used to achieve a 20 mg dose.

5.9 The submission calculated the utilisation of each strength as the number of supplies of that strength in the calendar year of 2022 divided by the total number of supplies of lenalidomide in the same year to derive the utilisation proportions. The submission then adjusted these proportions based on assumptions of the forecasted usage in initial and continuing treatment derived from the following studies:

- Impact of lenalidomide dose on progression-free survival in patients with relapsed or refractory multiple myeloma²
- Realistic Lenalidomide Dose Adjustment Strategy for Transplant-Ineligible Elderly Patients with Relapsed/Refractory Multiple Myeloma: Japanese Real-World Experience³

It was noted that these studies address patients with MM in the relapsed/refractory setting.

5.10 The assumed utilisation proportions are outlined in Table 2.

² Ho, M. *et al.* (2021) *The effect of duration of lenalidomide maintenance and outcomes of different salvage regimens in patients with multiple myeloma (MM)*, *Blood Cancer Journal*, 11(158). Available at: <https://www.nature.com/articles/s41408-021-00548-7> (Accessed: 26 September 2023).

³ Nakaya, A. *et al.* (2017) 'Realistic lenalidomide dose adjustment strategy for transplant-ineligible elderly patients with relapsed/refractory multiple myeloma: Japanese real-world experience', *Acta Haematologica*, 138(1), pp. 55–60. doi:10.1159/000477792.

Table 2: Utilisation assumptions used to derive the weighting of the proposed EMP

	Strength	Proportion of patients using this strength
Starting dose	25 mg ^a	10%
	20 mg	4%
	15 mg	20%
	10 mg	45%
	5 mg	21%
Treatment dose (longest period)	25 mg	9%
	20 mg	4%
	15 mg	16%
	10 mg	46%
	5 mg	25%

Source: Section 3 model of submission, Assumptions_Juno sheet.

^a 25 mg starting dose avg No. Cycles = 9

Maintenance = 22 months

- 5.11 The adjusted utilisation proportions used to derive the weighting that served the basis of the proposed EMP for lenalidomide 20 mg assumed a 4% uptake. It is unclear why the sponsor has assumed a 4% uptake and what proportion of this 4% was a combination of 5 mg and 15 mg capsules versus two 10 mg capsules.
- 5.12 The submission stated that the introduction of a 20 mg strength may result in cost savings to the government because it is expected to replace other strengths (15 mg + 5 mg, and 2 x 10 mg) that have a higher cost per mg during the stepwise dosing reduction approach. This is presented in Table 3, where the cost of Lenalide in the current available strengths has been compared to the proposed cost using the forecasted utilisation with the addition of the 20 mg strength as the weighting. It is unclear why the sponsor has only included Lenalide utilisation and not that of the other brands of lenalidomide on the PBS.

Table 3: Cost savings of the new strengths

	Strength	Utilisation proportions	Costs per pack (14 size)
Current utilisation (2022)	5 mg	12%	\$774.17
	10 mg	39%	\$1,014.20
	15 mg	25%	\$1,221.50
	25 mg	24%	\$1,598.14
Weighted average costs per pack			\$1,173.76
Proposed utilisation <i>adjusted based on assumptions of forecasted trends in lenalidomide utilisation</i>	5 mg	23%	\$774.17
	10 mg	46%	\$1,014.20
	15 mg	18%	\$1,221.50
	20 mg	4%	\$1,884.57
	25 mg	9%	\$1,598.14
Weighted average costs per pack			\$1,084.90
Average savings per pack			\$88.86

Source: Table 3-4 of the submission.

Secretariat additions in italics

5.13 The average savings per pack was calculated by subtracting the weighted average cost per pack in the proposed (adjusted) utilisation scenario from that of the current utilisation scenario.

5.14 A summary of the proposed price for Lenalide 20mg is presented in Table 4.

Table 4: Proposed price of Lenalide 20 mg

Medicine	Strength (mg)	Pack size	Source	Proposed AEMP	Weighted average price per mg	Proposed DPMQ
Lenalide	20	14	S100 HSD Public	\$1,884.57	\$6.73*	\$1,884.57
Lenalide	20	14	S100 HSD Private	\$1,884.57	\$6.73*	\$2,089.11
Lenalide	20	21	S100 HSD Public	\$2,826.86	\$6.73*	\$2,826.86
Lenalide	20	21	S100 HSD Private	\$2,826.86	\$6.73*	\$3,074.24
Lenalide	20	28	S100 HSD Public	\$3,769.15	\$6.73*	\$3,769.15
Lenalide	20	28	S100 HSD Private	\$3,769.15	\$6.73*	\$3,972.43

Source: Table 3-3 of the submission.

* Prices corrected to account for pricing quantity in the calculation of the proposed price.

5.15 Noting that the price per mg of lenalidomide decreases as the strength increases, and that the 15 mg is \$5.82 per mg whereas the 25 mg is \$4.57, logically the price of the 20 mg strength ought to be less than \$5.82 per mg. While the pre-PBAC response raised that there was a clinical advantage to listing a 20 mg strength as it would allow for more accurate dose modification, it proposed cost-minimising to the 15 mg strength as a base case scenario and offered an alternative and more conservative scenario of cost-minimising to the 25 mg strength. It was noted that this strength is the least costly comparator on a per milligram basis.

5.16 At its July 2023 PBAC meeting the PBAC noted the differing price per mg for the different presentations of enoxaparin and recommended that it be listed on a cost-minimisation basis with the least costly alternative enoxaparin presentation on a per milligram basis.

Estimated PBS usage and financial implications

5.17 The submission used PBS utilisation data obtained from January 2017 to December 2022 to estimate the future market growth of the Lenalide market (16%).

5.18 The submission assumed the current indexation arrangements will remain constant through the forward estimates period and therefore stated that the total cost to Government will be slightly overestimated in the outer years.

5.19 The submission's estimates are based on the assumption that prescribers have been using either a 5 mg and 15 mg capsule combination or two 10 mg capsules to achieve a 20 mg dose on the PBS and that a portion of the utilisation of these strengths will decrease as they are substituted for the 20 mg strength. The uptake assumption was derived from the utilisation proportions noted in Table 3 (i.e. by taking 4% of the existing lenalidomide market). Table 5 outlines the expected reduction of utilisation in the other strengths to constitute the 4% uptake of the 20 mg strength.

Table 5: Estimated reduction of services of lenalidomide

Strength	% starting	% maintenance	Adjusted for cycle	Adjusted uptake rate
25mg	10%	9%	9%	4%*9% = 0.4%
20mg	4%	4%	4%	-
15mg	20%	16%	18%	4%*18%= 0.7%
10mg	45%	46%	46%	4%*46%= 1.8%
5mg	21%	25%	23%	4%*23%= 0.9%

Source: Submission table 4-5

- 5.20 The submission assumed that these practices may result in inefficient treatment dosing, as well as higher prescribing costs, given that the costs per mg are higher for the 5 mg, 10 mg and the 15 mg strengths, respectively, relative to the proposed price of the new 20 mg presentation. This is not correct as the proposed price per mg for the 20 mg strength is greater than that of the 15 mg strength.
- 5.21 Table 6 presents the estimated financial impact Lenalide 20 mg to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process, however, there may be fewer calls to Services Australia from prescribers seeking to increase the quantity of the 10 mg strength to make up a 20 mg dose.
- 5.22 The submission estimated that the listing of Lenalide 20 mg would result in savings to the PBS/RPBS budget. The financial model provided with the submission applied a substitution ratio of 2:1 for the 5 mg and 15 mg strengths and the pre-PBAC response clarified this was to avoid the double counting of patients. The model is designed in such a way to accommodate for double counting hence the ratio ought to be 1:1 because every 15 mg capsule will be replaced with a 20 mg capsule and likewise for the 5 mg capsule, whereas 2 capsules of the 10 mg strength will be replaced with 1 capsule of the 20 mg strength. Furthermore, the quantity of the 5 mg and 15 mg being substituted with the 20 mg were not the same. Using a 1:1 ratio would capture in the model the additional patients taking just the 15 mg capsule that the submission has assumed will have a dose escalation to the 20 mg capsule. Additionally, the different fees and mark ups for private and public hospital settings were input incorrectly into the model.
- 5.23 Having corrected the substitution ratios and the different DPMQs for public and private hospitals, the listing of Lenalide 20 mg at the proposed price would have resulted in a cost to the PBS/RPBS rather than a save. Table 6 has been corrected to reflect the revised estimates.

Table 6: Net financial implications to the PBS/RPBS budgets (Lenalide®)

	2023	2024	2025	2026	2027	2028
PBS						
New listing	\$ ¹	\$ ¹	\$ ¹	\$ ¹	\$ ¹	\$ ¹
Changed listing	-\$ ²	-\$ ²	-\$ ²	-\$ ²	-\$ ²	-\$ ²
Net cost to PBS	\$ ¹	\$ ¹	\$ ¹	\$ ¹	\$ ¹	\$ ¹
RPBS						
New listing	\$ ¹	\$ ¹	\$ ¹	\$ ¹	\$ ¹	\$ ¹
Changed listing	-\$ ²	-\$ ²	-\$ ²	-\$ ²	-\$ ²	-\$ ²
Net cost to RPBS	\$ ¹	\$ ¹	\$ ¹	\$ ¹	\$ ¹	\$ ¹
Net cost PBS / RPBS	\$¹	\$¹	\$¹	\$¹	\$¹	\$¹

Source: Table 4-7 of the submission.

Corrected values in italics.

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

- 5.24 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of Lenalide 20 mg was a saving of \$0 to < \$10 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million). Using the proposed EMP with the corrected financial estimates model, the estimated net financial impact to the PBS/RPBS for the listing of Lenalide 20 mg was a cost of \$0 to < \$10 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million). The cost is likely because the proposed AEMP was greater than the savings realised from the reduction in the usage of the 5, 10 and 15 mg strengths.
- 5.25 The Secretariat conducted a sensitivity analysis using the AEMP of the 15 mg strength instead of the proposed AEMP and the estimated net financial impact to the PBS/RPBS for the listing of Lenalide 20 mg became a save of \$0 to < \$10 million over six years (\$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6). Using the pre-PBAC proposed AEMP equivalent to the 25 mg strength, the listing of Lenalide 20 mg will result in an estimated save of \$0 to < \$10 million over six years (\$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6).

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of a 20 mg strength of lenalidomide under the same circumstances as, and on a cost-minimisation basis to, lenalidomide 25 mg on a per mg basis, as it is the current least costly comparator per mg.
- 6.2 The PBAC considered that listing the 20 mg strength would provide clinicians greater flexibility in dose adjustment. It also considered that the estimated 4% uptake of the new strength was underestimated as it is likely that the 20 mg strength will be incorporated into clinical guidelines as a subsidised dosing option.
- 6.3 The PBAC considered that the 25 mg strength of lenalidomide across all brands was a relevant comparator, noting that the submission had nominated all the strengths of the Revlimid brand as the comparator. The PBAC noted that the restrictions requested were the same as that of the 25 mg strength and noted that the pre-PBAC response

had proposed the 25 mg strength as a suitable pricing comparator. The PBAC therefore considered that the 25 mg strength was the most appropriate comparator.

- 6.4 The PBAC noted that the financial estimates model presented in the submission used a 2:1 ratio for both the 5 mg : 20 mg substitution and the 15 mg : 20 mg substitution to accommodate for double counting of patients. The PBAC noted that the way the model template is designed avoids double counting, and therefore considered the ratios ought to be 1:1 in both instances. The PBAC also noted that the fees and mark ups for private and public hospital settings were incorrect and that, having corrected these numbers, there was an estimated save to the PBS/RPBS of \$0 to < \$10 million over six years (\$0 to < \$10 million in Year 1 to \$0 to < \$10 million in Year 6) when cost-minimised to the 25 mg strength. The PBAC considered that this revised approach to the financial model was appropriate and that the estimated save was acceptable.
- 6.5 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because the 20 mg strength is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the other listed strengths, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.6 The PBAC noted that this submission is not eligible for an independent review as it was recommended.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new item:

Doublet therapy for NDMM

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	0	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Multiple myeloma				
	Treatment Phase: Initial treatment in combination with dexamethasone, of newly diagnosed disease in a patient ineligible for stem cell transplantation				
Restriction Summary/ Treatment of Concept					

Public Summary Document – November 2023 PBAC Meeting

	Treatment Phase: Continuing treatment until progression in patients initiated on dual combination therapy (this drug and dexamethasone), or, in patients initiated on triple therapy (this drug, bortezomib and dexamethasone during treatment cycles 1 up to 8) and are now being treated with treatment cycle 9 or beyond
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Triplet therapy for NDMM

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 14	NEW (HSD Public)	1	14	3	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Multiple myeloma				
	Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 21-day treatment cycle				
Restriction Summary/ Treatment of Concept					
	Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 to 8 inclusive (administered using 21-day treatment cycles)				

Triplet therapy for NDMM (initial)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	3	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)				
	Indication: Multiple myeloma				
	Treatment Phase: Initial treatment with triple therapy (this drug, bortezomib and dexamethasone) for the first 4 treatment cycles (cycles 1 to 4) administered in a 28-day treatment cycle				

Triplet therapy for NDMM (continuing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	1	Lenalide
	NEW (HSD Private)				
Restriction Summary/ Treatment of Concept					
	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				

Public Summary Document – November 2023 PBAC Meeting

	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)
	Indication: Multiple myeloma
	Treatment Phase: Continuing treatment of triple therapy (this drug, bortezomib and dexamethasone) for treatment cycles 5 and 6 (administered using 28-day treatment cycles)

Monotherapy for progressive Multiple Myeloma (initial and continuing)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	0	Lenalide
	NEW (HSD Private)				

Restriction Summary/ Treatment of Concept

	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)
	Indication: Multiple myeloma
	Treatment Phase: Initial treatment as monotherapy or dual combination therapy with dexamethasone for progressive disease

Restriction Summary/ Treatment of Concept

	Treatment Phase: Continuing treatment as monotherapy or dual combination therapy with dexamethasone following initial treatment for progressive disease
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Relapsed/refractory Multiple Myeloma (elotuzumab)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	2	Lenalide
	NEW (HSD Private)				

Restriction Summary/ Treatment of Concept

	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)
	Indication: Relapsed and/or refractory multiple myeloma
	Treatment Phase: Triple combination therapy consisting of elotuzumab, lenalidomide and dexamethasone

Relapsed/refractory Multiple Myeloma (carfilzomib)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
LENALIDOMIDE					
lenalidomide 20 mg capsule, 21	NEW (HSD Public)	1	21	2	Lenalide
	NEW (HSD Private)				

Restriction Summary/ Treatment of Concept

	Category / Program: Section 100 – Highly Specialised Drugs Program (HB/HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners

	Restriction type: <input checked="" type="checkbox"/> Authority Required (online PBS Authorities system or via post/HPOS upload)
	Indication: Relapsed and/or refractory multiple myeloma
	Treatment Phase: Triple combination therapy consisting of carfilzomib, lenalidomide and dexamethasone

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

8 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.

9 Sponsor's Comment

The sponsor had no comment.