

## 7.11 POMALIDOMIDE

### Capsules, 3 mg and 4 mg; Pomalyst®; Celgene Pty Ltd.

#### 1 Purpose of Application

- 1.1 The re-submission proposed a re-specified base case and revised inputs to the economic model following the July 2014 PBAC consideration. Pomalidomide is proposed for treatment in combination with dexamethasone, of patients with relapsed and/or refractory multiple myeloma who have received and failed prior treatment with both lenalidomide and bortezomib.

#### 2 Requested listing

- 2.1 Minor amendments to the restriction suggested by the PBAC in paragraph 7.11 of the July 2014 ratified minutes have been accepted in full. The listing would be a written Authority item, for a maximum quantity of 21 tablets with zero repeats. The initial phase would limit treatment to “patients with multiple myeloma who have previously received and failed treatment with lenalidomide and bortezomib”. Treatment failure would be defined as “confirmed progressive disease during treatment or within 6 months of discontinuing treatment”.

#### 2.2

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
<b>Initial Treatment</b>				
POMALIDOMIDE				
Capsules 3 mg	21	0	Pomalyst®	Celgene
Capsules 4 mg	21	0		
<b>Continuing Treatment</b>				
POMALIDOMIDE				
Capsules 3 mg	21	0	Pomalyst®	Celgene
Capsules 4 mg	21	0		

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<b>Category / Program</b>	Section 100 – Highly Specialised Drugs Program
<b>Prescriber type:</b>	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
<b>Condition:</b>	Multiple myeloma
<b>PBS Indication:</b>	Multiple myeloma
<b>Treatment phase:</b>	Initial
<b>Restriction Level / Method:</b>	<input type="checkbox"/> Restricted benefit <input checked="" type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	The treatment must be in combination with dexamethasone, AND Patient must have undergone or be ineligible for a primary stem cell transplant, AND Patient must have received and failed treatment with lenalidomide and bortezomib, AND Patient must not be receiving concomitant PBS-subsidised thalidomide, lenalidomide or bortezomib
<b>Definitions</b>	Treatment failure is defined as confirmed progressive disease during treatment or within 6 months of discontinuing treatment

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<b>Clinical criteria:</b>	Patient must have previously received an authority prescription for pomalidomide, AND Patient must not have progressive disease, AND The treatment must be in combination with dexamethasone.
<b>Definitions</b>	Treatment failure is defined as confirmed progressive disease during treatment or within 6 months of discontinuing treatment

2.3 Listing was sought on a cost-utility basis compared to high dose dexamethasone (HDD).

*For more detail on PBAC's view, see section 7 "PBAC outcome"*

### 3 Background

3.1 Pomalidomide was TGA registered on 1 July 2014: “Pomalidomide, in combination with dexamethasone, is indicated for the treatment of patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy”.

3.2 A major submission for pomalidomide for multiple myeloma was rejected at the July 2014 PBAC meeting. The PBAC considered that cost-effectiveness had not been demonstrated. The true ICER had not been adequately estimated by the sponsor and the most plausible ICERs calculated after the final input from the sponsor were unacceptably high and highly uncertain. The following table provides a summary of the key differences between the previous submission and this current resubmission, including PBAC comments on the July 2014 submission.

**Key differences between the July 2014 submission and the November 2014 resubmission**

	July 2014 submission		November 2014 resubmission	
Requested PBS listing	Initial and continuing treatment for multiple myeloma, in combination with dexamethasone, for patients who have failed or were intolerant to lenalidomide and bortezomib treatment.		Amendments to the restriction suggested by the PBAC have been accepted in full.	
	<b>PBAC comment:</b> <ul style="list-style-type: none"> <li>• specify written Authority required</li> <li>• the words “or are intolerant to” should be removed</li> <li>• a definition of treatment failure should be included, defined as confirmed progressive disease during treatment or within 6 months of discontinuing treatment</li> </ul>			
Requested price (DPMQ)	3 mg capsule	██████ (public) ██████ (private)	3 mg capsule	██████ (public) ██████ (private)
	4mg capsule	██████ (public) ██████ (private)	4mg capsule	██████ (public) ██████ (private)
Main comparator	High dose dexamethasone (HDD)		High dose dexamethasone (HDD)	
	<b>PBAC comment:</b> The PBAC accepted that HDD was the appropriate comparator, while noting that other salvage therapies would also be replaced in practice			
Clinical evidence	One head-to-head randomised trial (MM-003) comparing pomalidomide plus low dose dexamethasone (LDD) to HDD. Results are likely to be confounded by the cross-over. <u>Benefits/harms summary</u> The comparison of pomalidomide plus LDD and HDD resulted in: <ul style="list-style-type: none"> <li>• A median 7.9 weeks improvement in PFS (HR=0.49 (0.39, 0.61)) and 19.1 weeks improvement in OS</li> </ul>		No new data presented.	

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	<p>(HR=0.70 (0.54, 0.92)) (March 2013 data cut-off).</p> <ul style="list-style-type: none"> <li>Approximately 33 additional episodes of grade 3 or 4 neutropenia, 5.7 episodes of grade 3 or 4 leukopenia and an additional 9.3 episodes of grade 3 or 4 febrile neutropenia over an average treatment duration of 5.5 months.</li> </ul>	
Clinical claim	Pomalidomide plus LDD is superior in terms of comparative effectiveness and slightly inferior in terms of comparative safety compared to HDD	
	<b>PBAC comment:</b> PBAC accepted both claims	
Economic evaluation	<p><u>Structure:</u> Simple 3 state markov-model: stable disease, progressive disease, and dead.  <u>Time horizon:</u> 10 years  <u>Adjustment for cross-over:</u> Two-stage Weibull approach to adjust for cross-over was used.  <u>Treatment effect:</u> Parametric modelling: Extreme value for PFS, log-normal for OS  <u>Utilities:</u> Sourced from van Agthoven 2004: 0.81 for stable disease; 0.645 for progressive disease  <u>AE costs and disutility:</u>  Submission model:  POM: cost \$ [REDACTED]; disutility 0.007  HDD: cost \$ [REDACTED]; disutility 0.002  Pre-PBAC response model:  POM: cost \$ [REDACTED]; disutility 0.007  HDD: cost \$ [REDACTED]; disutility 0</p> <p><u>Base case (submission):</u> \$ [REDACTED]  <u>ICERs based on weighted goodness of fit (pre-PBAC response):</u>  10 years = \$ [REDACTED]  7 years = \$ [REDACTED]  5 years = \$ [REDACTED]  3 years = \$ [REDACTED]</p>	<p><u>Structure:</u> Simple 3 state markov-model: stable disease, progressive disease, and dead.  <u>Time horizon:</u> 5 years  <u>Treatment effect:</u> weighted goodness of fit, as per July 2014 pre-PBAC response  <u>Utilities:</u> trial-based (Trial MM-003): 0.71 for stable disease; 0.47 for progressive disease  <u>AE costs and disutility:</u>  POM: cost \$ [REDACTED]; disutility 0.007  HDD: cost \$ [REDACTED]; disutility 0  Base case: \$ [REDACTED]</p> <p>The resubmission model is structurally unchanged from the version provided with the pre-PBAC response, which incorporated a number of alternative parametric extrapolations of progression free (PFS) and overall survival (OS) outcomes, including a weighted average of the different models based on goodness of fit statistics.</p> <p><i>See below for detail on changes to inputs, as suggested by PBAC (July 2014 minutes, para 7.8)</i></p>
	<p><b>PBAC comment:</b>  Model structure was reasonable. However several model inputs were not reasonable, including the extrapolation, utilities, time horizon, and cost offsets:</p> <ul style="list-style-type: none"> <li>Time horizon: a more conservative model duration of 5 years would be more reasonable given that this is a last-line therapy, and the median OS of 54 weeks is only in the pomalidomide plus LDD arm of the MM-003 trial.</li> <li>Extrapolation method: The PBAC agreed with the ESC, that using goodness of fit measures for each of the extrapolation methods to inform a weighted</li> </ul>	

	<p>average, would be a more reasonable approach.</p> <ul style="list-style-type: none"> <li>• Utilities: the trial based utilities would be more appropriate.</li> <li>• Cost offsets: costs for anti-thrombotic prophylaxis should be included in the economic analysis.</li> </ul> <p>Modifying several of these inputs resulted in an estimated ICER between \$75,000 – \$105,000/QALY.</p>	
Number of patients	Up to [REDACTED] in year 5	No new estimates presented
Est. net cost to Govt	\$ [REDACTED] in year 5	No new estimates presented. <i>Updated estimates with new price offer: \$ [REDACTED] in year 5.</i>
PBAC decision	Reject	

*For more detail on PBAC’s view, see section 7 “PBAC outcome”*

#### **4 Clinical place for the proposed therapy**

- 4.1 Pomalidomide should be a last line option for the treatment of multiple myeloma, a rapidly progressive disease for which there is no effective cure.

*For more detail on PBAC’s view, see section 7 “PBAC outcome”*

#### **5 Comparator**

- 5.1 The PBAC has accepted that high dose dexamethasone (HDD) is the appropriate comparator, while noting that other salvage therapies would also be replaced in practice (paragraph 7.3 of the July 2014 Minutes).

*For more detail on PBAC’s view, see section 7 “PBAC outcome”*

#### **6 Consideration of the evidence**

##### **Sponsor hearing**

- 6.1 There was no hearing for this item as it was a minor submission.

##### **Consumer comments**

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

##### **Clinical trials**

- 6.3 No new clinical data were presented in the resubmission.
- 6.4 Based on the primary clinical trial, MM-003, the PBAC considered that pomalidomide has superior effectiveness compared with HDD, showing an improvement of 7.9 weeks in PFS and 19.1 weeks in OS (paragraph 7.5 of the July 2014 Minutes).

6.5 The PBAC considered that pomalidomide has inferior, but manageable, safety compared with HDD (paragraph 7.6 of the July 2014 Minutes).

### Economic analysis

6.6 The resubmission model was structurally unchanged from the version provided with the pre-PBAC response for the July 2014 submission, which incorporated a number of alternative parametric extrapolations of progression free (PFS) and overall survival (OS) outcomes, including a weighted average of the different models based on goodness of fit statistics.

6.7 The PBAC considered that several inputs into the final model were not reasonable, including the extrapolation of PFS and OS outcomes, the utility values employed, time horizon considered, and the range of cost offsets included. Specifically:

- The time horizon of 10 years was not considered appropriate, and the PBAC believed that a more conservative model duration of 5 years would be more reasonable;
- The extrapolation method has considerable impact on the estimated ICER and PBAC agreed with the ESC, that using goodness of fit measures for each of the extrapolation methods to inform a weighted average, would be a more reasonable approach;
- The PBAC considered that using the trial based utilities would be more appropriate; and
- The PBAC noted that costs for anti-thrombotic prophylaxis should be included in the economic analysis.

6.8 These changes have been incorporated within a revised base case analysis, the main parameters of which are summarised in the table below.

Name	Estimate
<b>General model parameters</b>	
Time horizon (years)	5 years
<b>PFS and OS extrapolations</b>	
Data cut off	September 2012
PFS extrapolation	Weighted average
OS extrapolation	Weighted average
<b>Utility weights</b>	
Stable disease (Both groups)	0.71
Progressive disease (Both groups)	0.47
<b>Drug and administration costs</b>	
Pomalidomide DPMQ (21 x 4 mg)	
Dexamethasone DPMQ (30 x 4 mg)	\$12.74
<b>Weekly health state costs</b>	
Stable disease (Both groups)	\$
Progressive disease (Both groups)	\$
<b>Concomitant antithrombotic medications</b>	
Average cost per cycle (HDD)	\$
Average cost per cycle (POM + LDD)	\$
<b>Adverse events</b>	
Average cost per patient treated (HDD)	\$

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Average cost per patient treated (POM + LDD)	\$ [REDACTED]
Average utility decrement per patient treated (HDD)	-0.000
Average utility decrement per patient treated (POM + LDD)	-0.007

Source: Table D-1 of the resubmission, p 12. Section D Workbook, control worksheet

- 6.9 A new addition to the model was the incorporation of differential costs of anti-thrombotic prophylaxis between the groups, estimated using data from the MM-003 trial, as provided in the pre-PBAC response from July 2014 (Supplementary Table 14.1.8) in conjunction with available PBS item costs.
- 6.10 The PBAC stated in July 2014 (paragraph 7.10) that the base case would need to be respecified as per the PBAC's recommendations, and a price reduction would be required to achieve an ICER in the range of \$45,000/QALY - \$75,000/QALY.
- 6.11 The new base case ICER presented in the resubmission was \$45,000/QALY - \$75,000/QALY. A summary of overall incremental costs and outcomes, both discounted and undiscounted, along with relevant ICERs is presented in the table below.

	Discounted	Undiscounted
<b>Incremental result</b>		
Costs	[REDACTED]	[REDACTED]
Lys	[REDACTED]	[REDACTED]
QALYs	[REDACTED]	[REDACTED]
<b>ICER</b>		
Cost/LY	[REDACTED]	[REDACTED]
Cost/QALY	[REDACTED]	[REDACTED]

Source: Table D-6 of the resubmission, p16. Section D Workbook, Control Panel

Abbreviations: LY = life year; QALY = quality adjusted life year.

- 6.12 A number of sensitivity analyses were presented in the resubmission (see tables below).

**Description and rationale for the sensitivity analyses presented**

Analysis	Rationale for the values selected
Time horizon	The time horizon was varied between 3, 5 and 10 years
Parametric models	Best fitting models in place of weighted average: <ul style="list-style-type: none"> <li>• Extreme value for PFS</li> <li>• Log normal for OS</li> </ul>
Utility values	The utility for stable disease was varied as follows: <ul style="list-style-type: none"> <li>• Parity between groups at 0.71 (average best on treatment value from MM-003)</li> <li>• Parity between groups at 0.61 (baseline value from MM-003)</li> <li>• Different between groups at 0.74 and 0.61 (as per MM-003)</li> </ul>
Concomitant medication	The estimated cost of concomitant medications were varied arbitrarily as follows: <ul style="list-style-type: none"> <li>• Different at \$ [REDACTED] per month for POM+LDD and \$ [REDACTED] for HDD</li> <li>• Equal at \$ [REDACTED] per month for each of POM+LDD and HDD</li> </ul>

Source: Table D-7 of the resubmission, p17.

**One way sensitivity analysis results**

Analysis	Base Case	Worst Case		Best Case	
	Value	Value	Cost/QALY	Value	Cost/QALY
Time horizon (years)	5	3	[REDACTED]	10	[REDACTED]

Parametric models	Weighted	NA	NA	Best fitting	
Utilities for stable disease	0.71	0.61		0.74; 0.61	
Concomitant medications	\$ ; \$	\$ ; \$		\$ ; \$	

Source: Source: Table D-7 of the resubmission, p17.  
Section D Workbook; Variables

- 6.13 The resubmission stated (p17) “at the revised price, an equally realistic base case, employing a five year time horizon, differential trial based utility values for stable disease as per the MM-003 trial and the best fitting extrapolation models for PFS and OS as per the original submission, generates a discounted ICER of \$ per QALY gained, suggesting that the “true” ICER is likely to lie at the lower end of this indicative range”.
- 6.14 The PBAC noted that the base case, with the PBAC specified model inputs, resulted in an ICER of \$45,000/QALY - \$75,000/QALY. The PBAC considered that this was the most realistic estimate of the cost-effectiveness of pomalidomide. The PBAC therefore considered that even with the proposed price reduction in the submission, pomalidomide was not acceptably cost-effective. The PBAC considered that a further price reduction would be required to give an ICER of between \$45,000/QALY - \$75,000/QALY.

#### Drug cost/patient/year

- 6.15 \$ for scripts per year for the 4mg strength and public hospital price. This compares to a cost/patient/year of \$493 for HDD.

#### Estimated PBS usage & financial implications

- 6.16 The resubmission did not provide an update of the financial implications.
- 6.17 In July 2014, the PBAC agreed with the ESC view that the reliability of the financial estimates was questionable. The sponsor used a duration of therapy that is inflated beyond that in the trial to calculate estimated PBS usage. The PBAC agreed with ESC that this was unreasonable (paragraph 7.9 of the July 2014 Minutes).
- 6.18 In this resubmission, the sponsor continued to disagree with this conclusion and believed the utilisation and financial estimates are reliable, and potentially even conservative.
- 6.19 Estimated financial implications over the first 5 years of listing, updated with the new price offer, are summarised below.

**Estimated use and financial implications**

	Year 1	Year 2	Year 3	Year 4	Year 5
<b>Estimated extent of use</b>					
Number treated	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Scripts <sup>a</sup>	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
<b>Estimated net cost to PBS/RPBS</b>					
Net cost to PBS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Net cost to RPBS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
<b>Estimated total net cost</b>					
Net cost to PBS/RPBS	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Net impact on other healthcare budgets	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
<b>Total net cost to Government</b>	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

Source: Section E workbook from July 2014 major submission, with November 2014 prices.

The redacted table above shows that at Year 5, the estimated number treated is less than 10,000 and the net cost to Government is \$10 - \$20 million.

- 6.20 The PBAC considered that financial estimates in the resubmission remain unchanged from July 2014. The PBAC considered that this was still a point of uncertainty. The Committee recommended that the estimated patient numbers should be recalculated [redacted]. This would provide an upper estimate of eligible patients noting that not all patients will go on to be treated with pomalidomide.
- 6.21 As previously agreed by the PBAC in July 2014, the prevalence based approach used by the sponsor to model the financial estimates is unreasonable. The PBAC recommended that utilisation should be calculated using the number of patients initiating pomalidomide multiplied by the average duration of use. The PBAC considered that mean treatment duration in the MM-003 trial was [redacted] and that average PBS use may be slightly higher, therefore an average treatment duration of [redacted] could be used as the basis for the financial estimates.
- 6.22 The PBAC considered that a Risk Share Arrangement (RSA) may be appropriate to contain risks associated with the cost of the drug to the PBS. The RSA could be based on the financial estimates, revised as per the PBAC's recommendations above.

*For more detail on PBAC's view, see section 7 "PBAC outcome"*

**7 PBAC Outcome**

- 7.1 The PBAC recommended the listing of pomalidomide for the treatment of multiple myeloma under the Section 100 Highly Specialised Drugs Program (HSDP).
- 7.2 The PBAC noted that the submission agreed to the PBAC's previous recommendations regarding the restriction. The PBAC reiterated its advice that a written Authority application, administered by the Department of Human Services in

Tasmania would be appropriate to confine use to the population of patients in whom the drug is cost effective.

- 7.3 The PBAC was satisfied that pomalidomide provides, for some patients, a significant improvement in efficacy over HDD.
- 7.4 The PBAC reiterated its view from July 2014 that there may be a clinical place for the drug in patients who have failed bortezomib and lenalidomide.
- 7.5 The resubmission nominated HDD as the comparator. This was previously accepted by the PBAC.
- 7.6 As previously, the PBAC considered that the claims of superior comparative effectiveness and inferior comparative safety to HDD were reasonable.
- 7.7 The PBAC noted that the resubmission had refined the inputs to the economic model as specified by the Committee in July 2014. This included changing the time horizon to 5 years, using a weighted goodness of fit extrapolation method, using the trial based utilities and including cost offsets for anti-thrombotic prophylaxis.
- 7.8 The PBAC noted that the financial estimates in the resubmission remain unchanged from July 2014. The PBAC recommended a method for revising the financial estimates [REDACTED]. The PBAC also recommended a RSA, if appropriate, to mitigate the risks associated with the cost of the drug to the PBS.
- 7.9 In accordance with subsection 101(3BA) of the *National Health Act 1953*, the PBAC advised that it is of the opinion that, on the basis of the material available to it at its November 2014 meeting, pomalidomide should not be treated as interchangeable on an individual patient basis with any other drug(s) or medicinal preparation(s).
- 7.10 The PBAC advised that pomalidomide is not suitable for prescribing by nurse practitioners.
- 7.11 The PBAC recommended that the Safety Net 20 Day Rule should not apply.
- 7.12 The PBAC noted that this submission is not eligible for an Independent Review.

**Outcome:**

Recommended

**8 Recommended listing**

8.1 Add new item:

Restriction to be finalised.

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
POMALIDOMIDE Capsules 3 mg	21	0	Pomalyst®	Celgene
Capsules 4 mg	21	0		

<b>Category / Program</b>	Section 100 – Highly Specialised Drugs Program
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<b>Definitions</b>	Treatment failure is defined as confirmed progressive disease during treatment or within 6 months of discontinuing treatment

## 9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

## 10 Sponsor's Comment

The sponsor had no comment.