

14.02 LENALIDOMIDE

Capsule, 5 mg, 10 mg, 15 mg, 25 mg Revlimid[®], Celgene Pty Ltd

1 Purpose of Application

- 1.1 To seek the PBAC's advice on the extension of the listing for lenalidomide to remove the requirement for thalidomide trial prior to lenalidomide use, and to allow retreatment with lenalidomide in relapse or refractory multiple myeloma (RRMM)

2 Background

- 2.1 At the March 2016 meeting, the PBAC recommended that the requirement for progression, intolerance or contraindication to thalidomide in order to qualify for lenalidomide treatment in RRMM be removed from the lenalidomide restriction. The PBAC also recommended that re-treatment with lenalidomide be incorporated within the RRMM restriction to allow patients who cease treatment after initial successful disease control and then experience disease progression to access lenalidomide again. This would also enable patients re-accessing lenalidomide to be eligible for pomalidomide should subsequent failure of lenalidomide treatment occur.
- 2.2 The sponsor has requested that matters relating to the price and expected patient numbers relating to these recommendations be clarified by the committee.

3 PBAC Outcome

- 3.1 The committee advised that removal of the requirement for a contraindication to or failure of thalidomide in RRMM, and allowing lenalidomide retreatment should be included in the RRMM risk share agreement, and at the same price as treatment for RRMM.
- 3.2 The committee also advised that neither of these changes are expected to increase utilisation or patients numbers.
- 3.3 The committee noted that multiple myeloma is a relapsing disease, and patients generally move through a number of different treatments. The committee therefore considered that currently thalidomide was displacing, rather than replacing lenalidomide treatment and that removing this requirement would not affect utilisation.
- 3.4 The committee considered that allowing retreatment with lenalidomide in patients who had previously responded would delay treatment, but not extend the duration of treatment. The committee also noted that patients may be currently seeking to remain on lenalidomide for a longer period than would otherwise be the case due to

the inability for patients to take a treatment holiday; as such this change could potentially reduce usage.

- 3.5 Based on these factors, the PBAC considered that these changes to the listing should be cost neutral and these changes could be included within the existing RRMM Deed arrangements without requiring any increases in the caps.

Outcome:

Recommended

4 Recommended listing

- 4.1 Add new item: retreatment restriction to be finalised

- 4.2 Amend existing item:

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
LENALIDOMIDE			Revlimid	Celgene
Tablet, 5 mg	21	0		
Tablet, 10 mg				
Tablet, 15 mg				
Tablet, 25 mg				

Category / Program	Section 100 – Efficient funding of Chemotherapy
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Multiple myeloma
PBS Indication:	Multiple myeloma
Treatment phase:	Initial treatment
Restriction Level / Method:	<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
Clinical criteria:	<ul style="list-style-type: none"> • The condition must be confirmed by a histological diagnosis, <p>AND</p> <ul style="list-style-type: none"> • The treatment must be as monotherapy; OR • The treatment must be in combination with dexamethasone, <p>AND</p> <ul style="list-style-type: none"> • Patient must have progressive disease after at least one prior therapy, <p>AND</p> <ul style="list-style-type: none"> • Patient must have undergone or be ineligible for a primary stem cell transplant, <p>AND</p> <ul style="list-style-type: none"> • Patient must have experienced treatment failure after a trial of at least four

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	<p>(4) weeks of thalidomide at a dose of at least 100 mg daily or have failed to achieve at least a minimal response after eight (8) or more weeks of thalidomide-based therapy for progressive disease,</p> <p>AND</p> <ul style="list-style-type: none"> • Patient must not be receiving concomitant PBS-subsidised bortezomib
<p>Prescriber Instructions</p>	<p>Progressive disease is defined as at least 1 of the following:</p> <p>(a) at least a 25% increase and an absolute increase of at least 5 g per L in serum M protein (monoclonal protein); or</p> <p>(b) at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg per 24 hours; or</p> <p>(c) in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase of the difference between involved free light chain and uninvolved free light chain; or</p> <p>(d) at least a 25% relative increase and at least a 10% absolute increase in plasma cells in a bone marrow aspirate or on biopsy; or</p> <p>(e) an increase in the size or number of lytic bone lesions (not including compression fractures); or</p> <p>(f) at least a 25% increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging); or</p> <p>(g) development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol per L not attributable to any other cause).</p> <p>Oligo-secretory and non-secretory patients are defined as having active disease with less than 10 g per L serum M protein.</p> <p>The authority application must be made in writing and must include:</p> <p>(1) a completed authority prescription form; and</p> <p>(2) a completed Multiple Myeloma lenalidomide Authority Application - Supporting Information Form, which includes details of the histological diagnosis of multiple myeloma, prior treatments including name(s) of drug(s) and date of most recent treatment cycle and record of prior stem cell transplant or ineligibility for prior stem cell transplant; details of thalidomide treatment failure; details of the basis of the diagnosis of progressive disease or failure to respond; and nomination of which disease activity parameters will be used to assess response; and</p> <p>(3) duration of thalidomide and daily dose prescribed; and</p> <p>(4) a signed patient acknowledgment.</p> <p>To enable confirmation of eligibility for treatment, current diagnostic reports of at least one of the following must be provided:</p> <p>(a) the level of serum monoclonal protein; or</p> <p>(b) Bence-Jones proteinuria - the results of 24-hour urinary light chain M protein excretion; or</p> <p>(c) the serum level of free kappa and lambda light chains; or</p> <p>(d) bone marrow aspirate or trephine; or</p> <p>(e) if present, the size and location of lytic bone lesions (not including compression fractures); or</p> <p>(f) if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination i.e. MRI or CT-scan; or</p> <p>(g) if present, the level of hypercalcaemia, corrected for albumin concentration.</p> <p>As these parameters will be used to determine response, results for either (a) or (b) or (c) should be provided for all patients. Where the patient has oligo-secretory or non-secretory multiple myeloma, either (c) or (d) or if relevant (e), (f) or (g) should be</p>

	<p>provided. Where the prescriber plans to assess response in patients with oligo-secretory or non-secretory multiple myeloma with free light chain assays, evidence of the oligo-secretory or non-secretory nature of the multiple myeloma (current serum M protein less than 10 g per L) must be provided.</p> <p>Patients receiving lenalidomide under the PBS listing must be registered in the i-access risk management program.</p>
Administrative Advice	<p>Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</p> <p>Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au</p> <p>Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p> <p>Special Pricing Arrangements apply.</p>

5 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.

6 Sponsor's Comment

The sponsor had no comment.