



Multiple myeloma

Continuing PBS authority application

Supporting information

Important information

You must lodge this form for a patient **continuing** PBS subsidised treatment with bortezomib, in the current treatment cycle, as monotherapy or in combination with a corticosteroid and/or cyclophosphamide for multiple myeloma.

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

All assessments, pathology tests and diagnostic imaging studies must be made within one month of the date of application.

The information on this form is correct at the time of publishing and is subject to change.

Authority prescription form

Note: As of 1 December 2011 prescribing requirements for intravenous chemotherapy have changed. The medical practitioner must specify on the prescription the dose to be administered in micrograms per infusion. The prescription must be written for one infusion and up to 15 repeats.

A completed authority prescription form must be attached to this form.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

Phone approvals

Under no circumstance will phone approvals be granted for complete authority applications or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment in the current treatment cycle

Bortezomib patients

Beyond four cycles:

- To assess eligibility for continuing PBS subsidised bortezomib treatment beyond four cycles, the patient must have achieved at least a partial response at the completion of cycle four.
- The results of the response assessment must be included in a written application to Medicare Australia for further treatment.
- Continuing PBS subsidised supply will not be approved if there is more than six months between the initial application and subsequent application.

Beyond eight cycles:

- To assess eligibility for continuing PBS subsidised bortezomib treatment beyond eight cycles, the patient must have achieved at least a partial response at the completion of cycle eight.

- The results of the response assessment must be included in a written application to Medicare Australia for further treatment.
- Continuing PBS subsidised supply will not be approved if there is more than ten months between the initial application and an application following completion of eight treatment cycles.

Complete response:

- No more than two cycles of treatment after the cycle in which a complete response was confirmed will be authorised.
- Confirmation of complete response requires two determinations, a minimum of six weeks apart.

Applications for PBS subsidised treatment with bortezomib that extend beyond 11 cycles in the current treatment cycle, will not be approved.

Lenalidomide patients

Continuing PBS subsidised treatment, as monotherapy or in combination with dexamethasone, for patients who do not have progressive disease may be obtained by phone, call **1800 700 270** (call charges may apply) and select option 1, between 8.00 am and 5.00 pm EST, Monday to Friday.

Assistance

If you need assistance completing this form or need more information call **1800 700 270** (call charges may apply) and select option 1, between 8.00 am and 5.00 pm EST, Monday to Friday or go to **www.medicareaustralia.gov.au** > **For health professionals** > **PBS** > **Specialised drugs (PBS) J-Z** > **Multiple myeloma**

Lodgement

Send the completed authority application form, a completed authority prescription form and all relevant pathology reports to:

Medicare Australia
Prior written approval of specialised drugs
Reply Paid 9826
Hobart TAS 7001

Print in **BLOCK LETTERS**

Tick where applicable



Multiple myeloma PBS authority application

Patient's details

1 Medicare/DVA card number
 - - Ref no.

2 Mr Mrs Miss Ms Other
 Family name
 First given name

3 Date of birth
 / /

Prescriber's details

4 Prescriber number

5 Family name
 First given name

6 Work phone number

Alternative phone number

Fax number

Conditions and criteria

7 To qualify for PBS authority approval, under this criterion, the following conditions must be met.

The patient:

will receive treatment with bortezomib as monotherapy or in combination with a corticosteroid and/or cyclophosphamide

Provide the patient's Body Surface Area (BSA)
 m²

Provide the dose of bortezomib (BSA x 1300).
 mcg

The dose must be written as micrograms on the prescription **and, in the current treatment cycle has previously received**

four treatment cycles of bortezomib at the time of application

or

eight treatment cycles of bortezomib at the time of application

and

can demonstrate at least a partial response to bortezomib treatment by either:

a) at least a 50 per cent reduction in the level of serum monoclonal (M) protein

or

b) at least a 90 per cent reduction in 24 hour urinary light chain M protein excretion, or to less than 200 mg/24 hours. If M protein and Bence-Jones protein are unmeasurable:

c) at least a 50 per cent reduction in the difference between involved and uninvolved serum free light chain (FLC) levels.

If none of the above are measurable:

d) at least a 50 per cent reduction in bone marrow plasma cells

or

e) no increase in size or number of lytic bone lesions (development of compression fracture does not exclude response).

or

f) at least a 50 per cent reduction in the size of soft tissue plasmacytoma by clinical or applicable radiographic examination (Magnetic Resonance Imaging (MRI) or Computer Tomography (CT) scan).

or

g) normalisation of corrected serum calcium to less than or equal to 2.65 mmol/L.


or

has achieved a complete response

and

has not received two treatment cycles after first achieving a confirmed complete response.

Attachments

 Attach all relevant pathology, diagnostic imaging reports, clinical examination reports and a completed authority prescription form.

Prescriber's declaration

8 I declare that:

- the information on this form is correct.

Prescriber's signature Date

Privacy note

The information provided on this form will be used to assess eligibility of a nominated person to receive PBS subsidised treatment. The collection of this information is authorised by the *National Health Act 1953*. This information may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.