



Multiple myeloma Retreatment PBS authority application Supporting information

Important information

You must lodge this form for a patient starting a second or subsequent treatment cycle with PBS subsidised bortezomib.

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

Patients must have current progressive disease and must have experienced at least a partial response to the most recent treatment cycle of PBS subsidised bortezomib treatment.

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

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

Acknowledgements

The patient and prescriber acknowledgements must be signed by the patient and the prescriber in front of a witness (over 18 years of age).

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

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.

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 Retreatment 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
 / /

Patient's acknowledgement

4 I acknowledge that PBS subsidised retreatment with bortezomib for multiple myeloma will stop if I am not able to meet the criteria required for continuing PBS subsidised treatment.
 My prescriber has explained the nature of the ongoing monitoring and testing required in order to demonstrate an adequate response to treatment.
 Patient's signature

 Date

Prescriber's details

5 Prescriber number

6 Family name
 First given name

7 Work phone number

Alternative phone number

Fax number

Prescriber's acknowledgement

8 I have explained:

- the circumstances governing PBS subsidised retreatment with bortezomib for multiple myeloma.
- the nature of the ongoing monitoring and testing required to demonstrate at least a partial response to treatment.

I believe these to be understood and accepted by the patient.
 Prescriber's signature

 Date

Witness's acknowledgement

9 I have witnessed the signatures of **BOTH** the patient and the prescriber.
 Witness's full name (over 18 years of age)
 Witness's signature

 Date

Conditions and prior treatment

10 To qualify for PBS authority approval, under this criterion, the following conditions must be met.
 The patient:
 has multiple myeloma
and
 has signed the patient's acknowledgement
and
 and 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

- has demonstrated at least a partial response to the most recent treatment cycle of PBS subsidised bortezomib. (Note: Details of this response must be provided if not previously submitted to Medicare Australia.)

and

- has progressive disease as demonstrated by current pathology:
- at least a 25 per cent increase and an absolute increase of at least 5g/L in serum monoclonal protein (serum M protein).
 - at least a 25 per cent increase in 24 hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg/24 hours (Bence Jones protein).
 - oligo-secretory or non-secretory patients only, at least a 50 per cent increase in the difference between involved free light chain and uninvolved free light chain. (A patient is considered as an oligo or non secretor when serum M is < 10 g/L and 24 hour BJP is < 200mg/day.)
 - at least a 25 per cent relative increase and at least a 10 per cent absolute increase in plasma cells in a bone marrow aspirate or on biopsy.
 - an increase in the size or number of lytic bone lesions (not including compression fractures).
 - at least a 25 per cent increase in the size of an existing or the development of a new soft tissue plasmacytoma (determined by clinical examination or diagnostic imaging).
 - development of hypercalcaemia (corrected serum calcium greater than 2.65 mmol/L not attributable to any other cause).

Current Pathology Reports

Either a), b) or c) is to be provided for all patients

11 Supply at least one of the following reports:

- the level of serum M protein.
- the results of 24 hour urinary light chain M protein excretion (Bence-Jones Protein).
- the serum level of free kappa and lambda light chains.
Provide evidence of oligo-secretory or non-secretory multiple myeloma
 - current or previous serum M (must be < 10 g/L)
 - current or previous Bence-Jones protein (must be < 200 mg/day).
- a bone marrow aspirate or trephine.
- if present, the size and location of lytic bone lesions (not including compression fractures).
- If present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination (Magnetic Resonance Imaging (MRI) or Computer Tomography (CT) scan).
- if present, the level of hypercalcaemia, corrected for albumin concentration.

Attachments



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

Prescriber's declaration

12 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.