Purpose of this form

You must lodge this form for a patient starting initial Pharmaceutical Benefits Scheme (PBS) subsidised treatment with bortezomib 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 1 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

Complete the appropriate authority prescription form and attach to this application.

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

<table>
<thead>
<tr>
<th>Bortezomib Prescription Guide</th>
<th>qty</th>
<th>repeats</th>
</tr>
</thead>
<tbody>
<tr>
<td>Newly diagnosed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>eligible for Stem Cell Transplant (SCT)</td>
<td>Body Surface Area (BSA) x 1300mcg</td>
<td>15</td>
</tr>
<tr>
<td>ineligible for high dose chemotherapy</td>
<td>BSA x 1300mcg</td>
<td>31</td>
</tr>
<tr>
<td>severe acute renal failure</td>
<td>BSA x 1300mcg</td>
<td>31</td>
</tr>
<tr>
<td>Progressive disease</td>
<td>BSA x 1300mcg</td>
<td>15</td>
</tr>
<tr>
<td>Retreatment</td>
<td>BSA x 1300mcg</td>
<td>15</td>
</tr>
</tbody>
</table>

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

Bortezomib patients

- Newly diagnosed – eligible for SCT
  - Patients are eligible to receive initial treatment with 4 cycles of bortezomib only prior to stem cell transplant. No continuing treatment is available.
- Newly diagnosed – ineligible for high dose chemotherapy
- Patients who have received an initial treatment course, who do not have progressive disease and who have not yet achieved a best confirmed response to bortezomib are eligible for a further 5 cycles. This treatment is available by phone.
- Newly diagnosed – severe acute renal failure
  - Patients who have received an initial treatment course, who remain in renal failure and who can demonstrate at least a partial response to bortezomib are eligible for a further 5 cycles. This treatment will be available by phone after faxed submission of the continuing form.
- Progressive disease and retreatment
  - Patients who have achieved at least a partial response at the completion of cycle 4 are eligible for continuing treatment. This must be submitted in writing and by mail.

For more information

For more information go to our website at humanservices.gov.au/health professionals > PBS > Specialised drugs (PBS) J-Z > Multiple myeloma or if you need assistance completing this form, or for more information call 1800 700 270 and select option 1, Monday to Friday, between 8.00 am and 5.00 pm, Australian Eastern Standard Time.

Note: Call charges apply from mobile phones.

Filling in this form

- Please use black or blue pen
- Print in BLOCK LETTERS
- Mark boxes like this ✓ or ✗

Returning your form

Send the completed authority application form, all relevant attachments and a completed appropriate authority prescription form to:

Department of Human Services
Prior written approval of Specialised Drugs
Reply Paid 9826
Hobart TAS 7001
Multiple myeloma – bortezomib
Initial PBS authority application

Patient’s details

1 Medicare/Department of Veterans’ Affairs 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 treatment with bortezomib for multiple myeloma will stop if subsequent testing demonstrates that I have failed to achieve or sustain a response to treatment as detailed in the PBS criteria.

• 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 treatment with bortezomib for multiple myeloma, and

• the nature of the ongoing monitoring and testing required to demonstrate an adequate response to treatment as detailed in the PBS criteria.

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

Bortezomib dosing details

10 Provide the patient’s Body Surface Area (BSA):

Provide the dose of bortezomib (BSA x 1300)

Conditions and prior treatment

11 To qualify for PBS authority approval, under these criteria, one of the following conditions must be met.

The patient:

☐ has newly diagnosed symptomatic multiple myeloma.  
(Note: Diagnostic bone marrow must be supplied for all patients)

and

☐ is eligible for an autologous stem cell transplant and will receive treatment with bortezomib in combination with chemotherapy
or □ is ineligible for high dose chemotherapy and will receive treatment with bortezomib in combination with a corticosteroid and melphalan or cyclophosphamide. 

 Go to Attachments

or □ has severe acute renal failure and will receive treatment with bortezomib in combination with a corticosteroid and/or cyclophosphamide and □ requires dialysis or □ is at high risk of requiring dialysis in the opinion of a nephrologist

a) Provide current eGFR report and:
b) Name of nephrologist

c) Provide date of review / / Go to 14

or □ has not received prior PBS subsidised bortezomib for progressive disease and □ has had a primary stem cell transplant Date of transplant / / Go to 12

or □ has received prior PBS subsidised bortezomib and this application is for re-treatment with bortezomib, as monotherapy, or in combination with a corticosteroid and/or cyclophosphamide 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.)

and □ has current progressive disease Go to 13

12 and □ will be treated with bortezomib, as monotherapy, or in combination with a corticosteroid and/or cyclophosphamide and □ has histological diagnosis of multiple myeloma. Note: Diagnostic bone marrow must be supplied

and □ has failed a trial of at least 4 weeks of thalidomide treatment at a dose of at least 100 mg daily;

Dose mg

From / / To / / as confirmed by:
□ disease progression during or within 6 months of discontinuing thalidomide treatment or □ severe intolerance or toxicity unresponsive to clinically appropriate dose adjustment Provide details on contraindications or intolerance including the degree of toxicity. Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Contraindication or toxicity and grade

or □ has failed to achieve at least a minimal response after 8 or more weeks of thalidomide based therapy for progressive disease as defined as:
□ less than a 25% reduction in serum or urine M protein or □ in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels

Provide details of thalidomide based therapy

From / / To / / Name and dose of drugs used

□ less than a 25% reduction in serum or urine M protein or □ in oligo-secretory and non-secretory myeloma patients only, less than a 25% reduction in the difference between involved and uninvolved serum free light chain levels

Provide details of thalidomide based therapy

From / / To / / Name and dose of drugs used
13 and has progressive disease as demonstrated by current pathology:

a) at least a 25% increase and an absolute increase of at least 5g/L in serum monoclonal protein (serum M protein).

b) at least a 25% increase in 24 hour urinary light chain M protein excretion, and an absolute increase of at least 200 mg/24 hours (Bence Jones protein).

c) oligo-secretory or non-secretory patients only, at least a 50% 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 less than 10 g/L and 24 hour BJP is less than 200mg/day.

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.

e) an increase in the size or number of lytic bone lesions (not including compression fractures).

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).

g) 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

14 Supply at least one of the following reports:

a) the level of serum M protein.

b) the results of 24 hour urinary light chain M protein excretion (Bence-Jones Protein).

c) 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 less than 10 g/L)
   - current or previous Bence-Jones protein (must be less than 200 mg/day).

d) a bone marrow aspirate or trephine.

e) if present, the size and location of lytic bone lesions (not including compression fractures).

f) 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).

g) if present, the level of hypercalcaemia, corrected for albumin concentration.

Attachments

Attach all relevant pathology, diagnostic imaging reports, clinical examination reports and the appropriate authority prescription form.

Note: It is strongly recommended that applications for newly diagnosed patients include all relevant pathology reports of disease markers documented in section 14, in order to facilitate the assessment of response, that is an essential part of subsequent applications for further prescription of PBS-subsidised bortezomib.

Prescriber’s declaration

15 I declare that:
   • the information provided in this form is complete and correct.
   • I have attached all relevant reports and forms.

Prescriber’s signature

Date

Privacy notice

Centrelink, Medicare, Child Support and CRS Australia are services within the Australian Government Department of Human Services (Human Services).

Your personal information is protected by law, including the Privacy Act 1988. Your information is collected for Social Security, Family Assistance, Medicare, Child Support and CRS purposes. This information may be required by the powers provided within each services’ legislation or voluntarily given by you when you apply for services or payments.

Your information will be used for the assessment and administration of payments and services. Your information may also be used within Human Services, where you have provided consent or it is required or authorised by law. Human Services may disclose your information to Commonwealth departments, other persons, bodies or agencies ONLY where you have provided consent or it is required or authorised by law.

You can get more information about privacy by going to our website humanservices.gov.au/privacy or requesting a copy of the full privacy policy at one of our Service Centres.