Australian Government
Services Australia

medicare

PBS

Multiple myeloma progressive disease – lenalidomide – initial authority application

Online services

Requesting PBS Authorities online provides an immediate assessment in real time.

For more information and how to access the **Online PBS Authorities** system, go to **servicesaustralia.gov.au/hppbsauthorities**

When to use this form

Use this form to apply for **initial** PBS-subsidised lenalidomide for patients with progressive multiple myeloma.

Important information

Initial applications to start PBS-subsidised treatment can be made in real time using the **Online PBS Authorities** system or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for **initial** authority applications.

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

Continuing treatment

This form is ONLY for **initial** treatment.

After an authority application for initial treatment has been approved, applications for **continuing** treatment can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm local time.

Call charges may apply.

Section 100 arrangements for lenalidomide

This item is available to a patient who is attending:

- an approved private hospital
- a public participating hospital, **or**
- a public hospital

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

This item is not available as a PBS benefit for in-patients of a public hospital.

The hospital name and provider number must be included in this authority form.

Treatment specifics

Patients receiving lenalidomide under the PBS listing must be registered in the risk management program relevant for the brand of lenalidomide being prescribed and dispensed.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

Australian Government
Services Australia

medicare

PBS

Multiple myeloma progressive disease – lenalidomide – initial authority application

Online services

You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to **servicesaustralia.gov.au/hppbsauthorities**

Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

6 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

7 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

8 Hospital provider number

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

9 Does the patient have multiple myeloma confirmed by a histological diagnosis?

No ☐

Yes ☐

10 Provide details of the histological report

Date of report (DD MM YYYY)

Unique identifying number/code or provider number

11 The patient:

☐ has undergone a primary stem cell transplant.

Date of report (DD MM YYYY)

or

☐ is ineligible for a primary stem cell transplant.

12 Is the treatment monotherapy or form part of dual combination therapy limited to this drug and dexamethasone?

No ☐

Yes ☐

MCA0PB158 2302

13 The patient:

☐ has progressive disease after at least one prior therapy

Name(s) of prior therapies

Dates of most recent treatment cycle

From (DD MM YYYY)

To (DD MM YYYY)

14 Progressive disease can be demonstrated by:

Tick ALL that apply

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

☐ at least a 25% increase in 24-hour urinary light chain M protein excretion, and an absolute increase of at least 200mg/24 hours

☐ in oligo-secretory and non-secretory myeloma patients only, at least a 50% increase in the difference between involved free light chain and uninvolved free light chain. Oligo-secretory and non-secretory patients are defined as having active disease with less than 10g/L serum M protein

☐ at least a 25% relative increase and at least a 10% 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% 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 2.65mmol/L not attributable to any other cause).

Current diagnostic reports

15 Nomination of which disease activity parameters will be used to assess response:

Results for (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) evidence should be provided.

a) ☐ the level of serum M protein

Provide the current level of serum M protein

Date of current diagnostic report (DD MM YYYY)

Unique identifying number/code or provider number

b) ☐ Bence-Jones proteinuria

Provide the current results of 24-hour urinary light chain M protein excretion

Date of current diagnostic report (DD MM YYYY)

Unique identifying number/code or provider number

c) ☐ the serum level of free kappa and lambda light chains

Provide the current results of the serum level

Date of current diagnostic report (DD MM YYYY)

Unique identifying number/code or provider number

d) ☐ a bone marrow aspirate or trephine

Provide the current percentage of plasma cells in a bone marrow aspirate or on biopsy

Date of current diagnostic report (DD MM YYYY)

Unique identifying number/code or provider number

e) ☐ if present, the size and location of lytic bone lesions

Provide details

f) ☐ if present, the size and location of all soft tissue plasmacytomas by clinical or radiographic examination (that is, MRI or CT-scan)

Provide details

If applicable, provide the date of current radiographic report (DD MM YYYY)

Unique identifying number/code or provider number

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

Provide the current calcium corrected for albumin concentration

Date of current diagnostic report (DD MM YYYY)

Unique identifying number/code or provider number

Checklist

16 The relevant attachments need to be provided with this form.

☐ The completed authority prescription form(s).

Privacy notice

17 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at **servicesaustralia.gov.au/privacy**

Prescriber's declaration

18 **I declare that**:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine.
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application.
- I have attached the completed authority prescription form(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction.
- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

Prescriber's signature

On completion, print and sign by hand.

Date (DD MM YYYY)

Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

  or

- by post, send this form, the authority prescription form(s) and any relevant attachments to:

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

Reset form Print form