Australian Government
Services Australia

medicare

PBS

Chronic myeloid leukaemia – asciminib or ponatinib – 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 ponatinib for patients with chronic myeloid leukaemia (CML), or
- **initial** PBS-subsidised asciminib for CML patients with T315I mutation.

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 CML **initial** authority applications.

Tyrosine Kinase Inhibitors (TKI) are defined as asciminib, dasatinib, imatinib, nilotinib and ponatinib.

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.

For continuing PBS-subsidised treatment with **ponatinib**, the patient must qualify under the **first continuing** treatment criteria.

After an authority application for **first continuing** treatment has been approved, applications for **subsequent continuing** treatment with ponatinib 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.

For continuing PBS-subsidised treatment with **asciminib** for patients with T315I mutation, applications 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.

For more information

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

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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)

Conditions and criteria

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

7 The patient has active chronic myeloid leukaemia (CML) confirmed by:

a bone marrow biopsy pathology report demonstrating cytogenetic evidence of the Philadelphia chromosome

or

a bone marrow biopsy/peripheral blood pathology report demonstrating a RT-PCR level of BCR-ABL transcript > 0.1% on the international scale

Provide details of the pathology report confirming the patient's active CML

Date of pathology report (DD MM YYYY)

Unique identifying number/code or provider number

and

is expressing the T315I mutation

Provide details of the bone marrow biopsy pathology report confirming the T315I mutation

Date of pathology report (DD MM YYYY)

Unique identifying number/code or provider number

Go to 9

or

is not expressing the T315I mutation (for **ponatinib** only).

MCA0PB171 2309

8 The patient:

☐ will receive treatment with ponatinib as the sole PBS-subsidised therapy for this condition

and

☐ this request will not exceed a total of 18 months of initial treatment

and

☐ has failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority

Where there has been a loss of response to dasatinib, provide the following details

Date of pathology report (DD MM YYYY)

Unique identifying number/code or provider number

Date of pathology report (DD MM YYYY)

Unique identifying number/code or provider number

or

In the case of progressive splenomegaly or extramedullary involvement, provide dates of assessment (DD MM YYYY)

or

☐ has developed intolerance to dasatinib of a severity necessitating permanent treatment withdrawal

and

☐ has failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority

Where there has been a loss of response to nilotinib, provide the following details

Date of pathology report (DD MM YYYY)

Unique identifying number/code or provider number

Date of pathology report (DD MM YYYY)

Unique identifying number/code or provider number

or

In the case of progressive splenomegaly or extramedullary involvement, provide dates of assessment (DD MM YYYY)

or

☐ has developed intolerance to nilotinib of a severity necessitating permanent treatment withdrawal

or

☐ is not eligible for PBS-subsidised treatment with nilotinib because the patient has a blast crisis.

▶ *Go to 13*

9 This application is for:

☐ asciminib ▶ *Go to 10*

or

☐ ponatinib ▶ *Go to 11*

10 The patient:

☐ will receive treatment with asciminib as the sole PBS-subsidised therapy for this condition

and

☐ is not in the blast phase of the condition

and

☐ has failed an adequate trial of at least one TKI confirmed through a pathology report from an Approved Pathology Authority

▶ *Go to 12*

or

☐ has experienced intolerance to at least one TKI

▶ *Go to 13*

11 The patient:

☐ will receive treatment with ponatinib as the sole PBS-subsidised therapy for this condition

and

☐ this request will not exceed a total of 18 months of initial treatment

and

☐ has failed an adequate trial of imatinib confirmed through a pathology report from an Approved Pathology Authority

or

☐ has failed an adequate trial of dasatinib confirmed through a pathology report from an Approved Pathology Authority

or

☐ has failed an adequate trial of nilotinib confirmed through a pathology report from an Approved Pathology Authority

12 Where there has been a loss of response to at least one TKI, provide the following details

Date of pathology report (DD MM YYYY)

Unique identifying number/code or provider number

Date of pathology report (DD MM YYYY)

Unique identifying number/code or provider number

or

In the case of progressive splenomegaly or extramedullary involvement, provide dates of assessment (DD MM YYYY)

Checklist

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

☐ The completed authority prescription form(s).

Privacy notice

14 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/privacypolicy**

Prescriber's declaration

15 **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

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