



Acute lymphoblastic leukaemia ponatinib initial authority application

When to use this form

Use this authority application form (this form) to apply for **initial** Pharmaceutical Benefits Scheme (PBS) subsidised ponatinib for acute lymphoblastic leukaemia.

Important information

Initial applications must be in writing and must include sufficient supporting 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 a written authority application for initial treatment has been approved, applications for **continuing** treatment can be made by phone.

Call **1800 700 270** Monday to Friday, 8 am to 5 pm, local time.

Call charges may apply.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

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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

Prescriber's details

4 Prescriber number

5 Dr Mr Mrs Miss Ms Other

Family name

First given name

6 Business phone number

Alternative phone number

Fax number

Conditions and criteria

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

7 The patient:

has active leukaemia as defined by the presence on current pathology assessments of:

morphological infiltration of:

the bone marrow (> 5% lymphoblasts)

or

cerebrospinal fluid

or

other sites

or

if in morphological remission, the presence of cells bearing the Philadelphia chromosome on cytogenetic or Fluorescence In-situ Hybridisation (FISH) analysis in the bone marrow

or

has rising levels of BCR-ABL1 transcript on 2 consecutive occasions in a patient in complete remission while being treated with PBS subsidised dasatinib for this condition.

8 The patient:

is expressing the T315i mutation

▶ **Go to 9**

or

is expressing the Philadelphia chromosome

▶ **Go to 11**

or

has the BCR-ABL transcript.

▶ **Go to 11**

9 The patient:

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

and

has failed treatment with chemotherapy, with or without another tyrosine kinase inhibitor

and

is ineligible for allogeneic haemopoietic stem cell transplantation

or

has failed allogeneic haemopoietic stem cell transplantation (where appropriate).

10 Failure of treatment is demonstrated by:

- failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with intensive chemotherapy, with or without another tyrosine kinase inhibitor

or

- morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy, with or without another tyrosine kinase inhibitor

or

- morphological or cytogenetic relapse or persistence of leukaemia after allogeneic haemopoietic stem cell transplantation.

▶ **Go to 13**

11 The patient:

- has developed intolerance to PBS subsidised dasatinib of a severity requiring treatment withdrawal

▶ **Go to 13**

or

- failed prior treatment with PBS subsidised dasatinib for this condition.

12 Failure of treatment with dasatinib is demonstrated by:

- failure to achieve a complete morphological and cytogenetic remission after a minimum of 2 months treatment with PBS subsidised dasatinib for this condition


or

- morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by PBS subsidised dasatinib for this condition

or

- rising levels of BCR-ABL1 transcript on 2 consecutive occasions in a patient in complete remission while being treated with PBS subsidised dasatinib for this condition.

Checklist

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

- The completed authority prescription form(s).
- Pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, manifest as cytogenetic evidence of the Philadelphia chromosome, or morphological evidence of acute lymphoblastic leukaemia plus qualitative RT-PCR evidence of BCR-ABL transcript (if applicable) and evidence of the T315I mutation (if applicable).
- Pathology reports documenting rising levels of BCR-ABL1 transcript on 2 consecutive occasions in a patient in complete remission while being treated with PBS subsidised dasatinib for this condition (if applicable).

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/privacy

Prescriber's declaration

15 I have explained to the patient or the parent/authorised guardian (if patient is under 18 years of age):

- the circumstances surrounding Pharmaceutical Benefits Scheme subsidised treatment with ponatinib for acute lymphoblastic leukaemia.
- the nature of the ongoing monitoring and testing required to demonstrate no progressive disease.

I believe these to be understood and accepted by the patient or the parent/authorised guardian.

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



Date

/ /

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