Australian Government
Department of Human Services

medicare

PBS

Acute lymphoblastic leukaemia – Ponatinib Initial grandfather PBS authority application

Supporting information

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, for patients who have received non-PBS subsidised treatment with ponatinib prior to **1 September 2018**.

Important information

Initial **grandfather** applications to start PBS subsidised treatment must be 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 acute lymphoblastic leukaemia **initial** grandfather authority applications.

The prescriber's declaration must be completed and signed before this form is submitted.

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

Continuing treatment

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

For continuing PBS subsidised treatment, a grandfathered patient must qualify under the continuing treatment criteria. After a written authority application for initial grandfather treatment has been approved, applications for continuing treatment can be made by phone. Call **1800 700 270** Monday to Friday, between 8.00 am and 5.00 pm, Australian Eastern Standard Time.
Note: Call charges may apply.

Treatment specifics

A patient may qualify for PBS subsidised treatment under this restriction once only.

For more information

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

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Filling in this form

- **Please use black or blue pen**.
- Print in BLOCK LETTERS.
- Where you see a box like this ☐ ▶ ***Go to 5*** skip to the question number shown. You do not need to answer the questions in between.

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 previously received non-PBS subsidised therapy with this drug for this condition prior to **1 September 2018**

and

☐ will receive treatment with ponatinib as a sole PBS subsidised therapy for this condition.

8 The patient:

☐ has the Philadelphia chromosome

or

☐ has the transcript BCR-ABL.

9 While on dasatinib treatment for this condition, the patient had:

☐ 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**
- ☐ the presence of cells bearing the Philadelphia chromosome on cytogenetic or Fluorescence In-situ Hybridisation (FISH) analysis in the bone marrow, if in morphological remission
- **or**
- ☐ rising levels of BCR-ABL1 transcript on 2 consecutive occasions in a patient in complete remission.

10 The patient:

☐ had developed intolerance to PBS subsidised dasatinib of a severity requiring treatment withdrawal

▶ ***Go to 12***

or

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

11 Failure of treatment with dasatinib was 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

Date of treatment

From / / to / /

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

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

☐ The completed authority prescription form(s).

☐ Pathology report demonstrating that the patient had 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 at the time of ponatinib initiation.

☐ 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

13 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by the Australian Government Department of Human Services for the purposes of assessing and processing this authority application.

Personal information may be used by the department, 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 the department manages personal information, including our privacy policy, can be found at **humanservices.gov.au/privacy**

Prescriber's declaration

14 I have explained to the patient:

- the circumstances governing 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.

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 the Australian Government Department of Human Services 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 / /

Reset form Print form

Returning your form

You can 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 **humanservices.gov.au/hpos**
- **By mail**, send this form, the authority prescription form(s) and any relevant attachments to:

  Department of Human Services
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001