

# Acute lymphoblastic leukaemia – ponatinib – initial authority application

## Online PBS Authorities



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

For more information and how to access the **Online PBS Authorities** system, go to [servicesaustralia.gov.au/hppbsauthorities](https://servicesaustralia.gov.au/hppbsauthorities)

## When to use this form

Use this form to apply for **initial** PBS-subsidised ponatinib for acute lymphoblastic leukaemia.

## Important information

**Initial** applications to start PBS-subsidised treatment can be made 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 acute lymphoblastic leukaemia **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.

## For more information

Go to [servicesaustralia.gov.au/healthprofessionals](https://servicesaustralia.gov.au/healthprofessionals)



- 10** The condition:
- is expressing the T315I mutation ▶ **Go to 11**
  - or**
  - is expressing the Philadelphia chromosome ▶ **Go to 14**
  - or**
  - has the transcript BCR-ABL ▶ **Go to 14**

**11** Provide the date of the pathology report demonstrating evidence of the T315I mutation (DD MM YYYY)

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- 12** 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).

- 13** Failure of treatment is evidenced 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 16**

- 14** The patient:
- has developed intolerance to PBS-subsidised dasatinib of a severity requiring treatment withdrawal ▶ **Go to 16**
  - or**
  - failed prior treatment with PBS-subsidised dasatinib for this condition.

- 15** Failure of treatment with dasatinib is evidenced 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

- 16**  The relevant attachments need to be provided with this form.
- Details of the proposed prescription(s).
  - Pathology report demonstrating that the patient has active acute lymphoblastic leukaemia, either 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

**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/privacypolicy](https://servicesaustralia.gov.au/privacypolicy)

## Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at [servicesaustralia.gov.au/hpos](https://servicesaustralia.gov.au/hpos)

### 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 provided details of the proposed prescription(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.

I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

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Prescriber's signature (**only** required if returning by post)


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## Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at [servicesaustralia.gov.au/hpos](https://servicesaustralia.gov.au/hpos)
- by post (signature required) to  
Services Australia  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001