



Supporting information for Acute Lymphoblastic Leukaemia - dasatinib PBS authority application

For **initial** PBS subsidised treatment of acute lymphoblastic leukaemia with dasatinib.

Important Information

You must lodge this form for a patient starting initial PBS subsidised treatment with dasatinib for acute lymphoblastic leukaemia.

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Patients are not eligible to receive PBS subsidised dasatinib

- if receiving PBS subsidised imatinib mesylate
- if eligible for allogeneic haemopoietic stem cell transplant.

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

Assistance

If you need assistance in completing this form, or more information, call Medicare Australia on **1800 700 270**** and select option 3 (8 am to 5 pm EST Monday to Friday) or visit www.medicareaustralia.gov.au

Lodgment

Send the completed authority application form, a completed authority prescription form and all relevant attachments to:

Medicare Australia
Prior written approval of specialised drugs
Reply Paid 9826
GPO Box 9826
Hobart TAS 7001
(no stamp required if posted in Australia)

Acknowledgments

The patient's and prescriber's acknowledgments must be signed by the patient and prescriber in the presence of a witness (over 18 years of age).

Authority prescription form

A completed authority prescription form must be attached to this form.

The medical indication section of the authority prescription form does not need to be completed when submitted with this supporting information form.

Phone approvals

Under no circumstance will telephone approvals be granted for initial authority applications.

Applications for continuing treatment

All applications for continuing treatment, as monotherapy, of patients who do not have progressive disease, may be made by telephone to Medicare Australia on **1800 700 270**** and select option 3 (8 am to 5pm EST Monday to Friday).

**** Call charges apply to mobile and pay phones only**



Acute Lymphoblastic Leukaemia - dasatinib PBS authority application Supporting information form

For **initial** PBS subsidised treatment of acute lymphoblastic leukaemia with dasatinib.

Complete all parts of this application
Print neatly in BLOCK LETTERS
Tick where applicable

Patient's details

1 Medicare/DVA number

2 Family name

First given name

Date of birth

Acknowledgments

The patient's and prescriber's acknowledgments must be signed by the patient and prescriber in the presence of a witness (over 18 years of age).

Patient's acknowledgment

3 **I acknowledge that:** Pharmaceutical Benefits Scheme (PBS) subsidised treatment with dasatinib for acute lymphoblastic leukaemia will stop

- if subsequent testing demonstrates that I have progressive disease
- if I have an allogeneic haemopoietic stem cell transplant.

My prescriber has explained the nature of the ongoing monitoring and testing required in order to demonstrate an adequate response to therapy.

Signature of patient

Date

Prescriber's details

4 Prescriber number

5 Family name

First given name

6 Phone

Fax

Prescriber's acknowledgment

7 **I have explained:**

- the circumstances governing PBS subsidised treatment with dasatinib for acute lymphoblastic leukaemia
- the nature of the ongoing monitoring and testing required to demonstrate that they do not have progressive disease
- that treatment will stop if they have an allogeneic haemopoietic stem cell transplant.

I believe these to be understood and accepted by the patient.

Signature of prescriber

Date

Witness's details

8 Family name

First given name

I have witnessed the signature of **BOTH** the patient and the prescriber.

Signature of witness (over 18 years of age)

Date

Conditions, criteria and prior treatment

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

9 The patient:

- has signed the patient's acknowledgment
- will be treated with dasatinib as monotherapy
- is not appropriate for an allogeneic haemopoietic stem cell transplant

and immediately before starting treatment with dasatinib has/had

- active leukaemia as defined by presence on pathology assessment of:

either

- morphological infiltration of:
 - the bone marrow (> 5% lymphoblasts)
- or**
- cerebrospinal fluid
- or**
- other sites (other than peripheral blood)

or

- if in morphological remission the presence of cells bearing the Philadelphia chromosome on cytogenetic or FISH analysis in the bone marrow

and

- on either peripheral blood or bone marrow, a pathology report supporting the presence of:

either

- cytogenetic evidence of the Philadelphia chromosome

or

- the *BCR-ABL* transcript

and

- has failed treatment with imatinib mesylate and chemotherapy as documented by:

- failure to achieve a complete morphological and cytogenetic remission after a **minimum** of two months treatment with intensive chemotherapy and imatinib mesylate

Dates of treatment

from to

or

- morphological or cytogenetic relapse of leukaemia after achieving a complete remission induced by chemotherapy and imatinib mesylate

or

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

For patients who were treated with dasatinib before 1 December 2007.

Dates of treatment

from to



- Attach all relevant pathology reports and a completed authority prescription form.

Prescriber's declaration

I declare that: the information provided on this form is correct.

Signature of prescriber

Date

/ /

Privacy note

The information provided on this form will be used to assess applications and eligibility for the nominated patient under the PBS subsidised treatment with dasatinib for acute lymphoblastic leukaemia. The collection of this information is authorised by the *National Health Act 1953* and may be disclosed to the Department of Health and Ageing, or as authorised or required by law.