



Imatinib mesylate, chronic phase Chronic myeloid leukaemia PBS authority application Supporting information

Important information

You must lodge this form for a patient **continuing** PBS subsidised treatment with imatinib mesylate for chronic phase of chronic myeloid leukaemia expressing the Philadelphia chromosome or the transcript *BCR-ABL* tyrosine kinase.

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

A copy of a pathology cytogenetic report or quantitative PCR report conducted on bone marrow or peripheral blood supporting the response to treatment must be provided.

Assessments of response to treatment, as detailed in the criteria, must be submitted as follows:

- i) between 10 and 12 months of the commencement of treatment with imatinib mesylate, at which time patients in whom a response has been demonstrated may receive authorisation for a further 12 months of treatment; or
- ii) patients who failed to demonstrate a response to treatment at between 10 and 12 months, but have been able to demonstrate a response within the initial 18 months may also receive authorisation for a further 12 months of treatment; and
- iii) at no greater than 12 month intervals thereafter.

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

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 form.

Phone approvals

Under no circumstance will phone approvals be granted for initial authority applications or for treatment that would otherwise extend the treatment period.

Assistance

If you need assistance completing this form or need more information call **1800 700 270** (call charges may apply) and select option 3, between 8.00 am and 5.00 pm EST, Monday to Friday, or go to **www.medicareaustralia.gov.au > For health professionals > PBS > Specialised drugs (PBS) A-I > Chronic myeloid leukaemia (CML) – imatinib mesylate**

Lodgement

Send the completed authority application form, the relevant pathology reports and a completed authority prescription form to:

Medicare Australia

Prior written approval of specialised drugs

Reply Paid 9826

Hobart TAS 7001

Print in **BLOCK LETTERS**

Tick where applicable



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For **continuation** of PBS subsidised treatment with imatinib mesylate of patients with chronic phase, chronic myeloid leukaemia.

Patient's details

1 Medicare/DVA card number

- - Ref no.

2 Mr Mrs Miss Ms Other

Family name

First given name

3 Date of birth

/ /

Prescriber's details

4 Prescriber number

5 Family name

First given name

6 Work phone number

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Alternative phone number

Fax number

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Conditions and criteria

7 To qualify for PBS authority approval the following condition must be met.

The patient can demonstrate an adequate response to treatment by either:

standard karyotyping which indicates the number of Philadelphia positive cells in the bone marrow

where standard karyotyping is not informative for technical reasons: Fluorescence in situ hybridisation (FISH) with *BCR-ABL* specific probe

quantitative PCR indicating the relative level of *BCR-ABL* transcript in the peripheral blood using the International Scale

Pathology details


8 Provide the following details from the pathology report

Name of approved pathology authority (APA)

Date of report

/ /

Attachments

 Attach a copy of the supporting pathology report and a completed authority prescription form.

Prescriber's declaration

9 I declare that:

- the information on this form is correct.

Prescriber's signature

Date

/ /

Privacy note

The information provided on this form will be used to assess eligibility of a nominated person to receive PBS subsidised treatment. The collection of this information is authorised by the *National Health Act 1953*. This information may be disclosed to the Department of Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.