



Rare diseases imatinib mesylate PBS authority application

For **continuing** Pharmaceutical Benefits Scheme (PBS) subsidised treatment of patients with:

- Dermatofibrosarcoma protuberans
- Hypereosinophilic syndrome or chronic eosinophilic leukaemia
- Platelet-Derived Growth Factor Receptor (PDGFR) B fusion gene-positive myelodysplastic or myeloproliferative disorder
- Aggressive systemic mastocytosis with eosinophilia.

Important information

You must lodge this form for a patient continuing PBS subsidised treatment with imatinib mesylate for rare diseases.

For each rare disease the relevant section of the application must be completed and the relevant reports provided.

The maximum dose that will be approved for:

- dermatofibrosarcoma protuberans is 800 mg/day
- hypereosinophilic syndrome or chronic eosinophilic leukaemia is 400 mg/day
- PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder is 400 mg/day
- aggressive systemic mastocytosis with eosinophilia is 400 mg/day.

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 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

Lodgement

Send the completed application form, all relevant pathology reports and a completed authority prescription form 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)

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 phone approvals be granted for complete authority applications, or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment

All applications for continuation treatment must be submitted on a written application form.

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



Rare diseases imatinib mesylate PBS authority application Supporting information form

For **continuing** PBS subsidised treatment of patients with:

- Dermatofibrosarcoma protuberans
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- Aggressive systemic mastocytosis with eosinophilia.

Complete all parts of the application

Print in BLOCK LETTERS

Patient's details

1 Medicare/DVA number

2 Family name

First given name

3 Date of birth

Conditions and criteria

Tick where applicable

4 To qualify for PBS authority approval, under this criterion, one of the following conditions must be met. The patient has previously received PBS subsidised treatment with imatinib mesylate for:

either

dermatofibrosarcoma protuberans
Go to 5

or

hypereosinophilic syndrome or chronic eosinophilic leukaemia
Go to 6

or

PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder
Go to 7

or

aggressive systemic mastocytosis with eosinophilia.
Go to 8

5 Dermatofibrosarcoma protuberans patients

the patient has demonstrated a response to imatinib mesylate treatment

and

the disease remains unresectable **and** ongoing therapy is clinically indicated.

Go to 9

6 Hypereosinophilic syndrome or chronic eosinophilic leukaemia patients

the patient has achieved and maintained a complete haematological response, with a normal eosinophil count as demonstrated by the attached copy of the full blood examination

and

the disease has not progressed on imatinib mesylate treatment.

Go to attachments

7 PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder

the patient has achieved and maintained a complete haematological response as demonstrated by the attached copy of the full blood examination

and

the disease has not progressed on imatinib mesylate treatment.

Go to attachments

8 Aggressive systemic mastocytosis with eosinophilia patients

the patient has achieved and maintained a complete haematological response as demonstrated by the attached copy of the full blood examination

and

the disease has not progressed on imatinib mesylate treatment.

Go to attachments

Attachments

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

Prescriber's details

9 Prescriber number

10 Family name

First given name

Phone

Fax

Prescriber's declaration

11 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 restrictions for PBS subsidised treatment for dermatofibrosarcoma protuberans, hypereosinophilic syndrome or eosinophilic leukaemia, PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder or aggressive systemic mastocytosis with eosinophilia. 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.