



Rare diseases imatinib mesylate PBS authority application

For **initial** 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 starting initial 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)

Acknowledgements

The patient's and the prescriber's acknowledgements must be signed 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 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 **initial** PBS subsidised treatment of patients with:

- Dermatofibrosarcoma protuberans
- Hypereosinophilic syndrome or chronic eosinophilic leukaemia
- PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder
- 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

Acknowledgements

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

Patient's acknowledgement

4 I acknowledge that Pharmaceutical Benefits Scheme (PBS) subsidised treatment with imatinib mesylate for rare diseases will stop if:

- subsequent testing demonstrates that I have failed to achieve or sustain a response to treatment as detailed in the criteria.

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

5 Prescriber number

6 Family name

First given name

Phone

Fax

Prescriber's acknowledgement

7 I have explained:

- the circumstances governing PBS subsidised treatment with imatinib mesylate for rare diseases
- the nature of the ongoing monitoring and testing required to demonstrate an adequate and sustained response to therapy.

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 and criteria

Tick where applicable

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

The patient:

has signed the patient's acknowledgement

and has either

dermatofibrosarcoma protuberans

Go to 10

or

hypereosinophilic syndrome or chronic eosinophilic leukaemia requiring treatment

Go to 11

or

PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder

Go to 12

or

aggressive systemic mastocytosis with eosinophilia.

Go to 13

- 10 Dermatofibrosarcoma protuberans patients

The patient has either:

unresectable dermatofibrosarcoma protuberans (written evidence must be provided)

or

locally recurrent dermatofibrosarcoma protuberans.

Provide details of the site of the local recurrence

or

metastatic dermatofibrosarcoma protuberans.

Provide details of the site(s) of metastatic disease



Attach written evidence, if relevant, and a completed authority prescription form.

Go to 14

- 11 Hypereosinophilic syndrome or chronic eosinophilic leukaemia patients

The patient has:

confirmed presence of the Fip 1-Like 1-Platelet-Derived Growth Factor Receptor Alfa chain (FIP1L1-PDGFRB) fusion gene

and

had a recent full blood examination confirming the presence of eosinophilia.

Provide details of organs involved which require treatment:

heart

gastrointestinal tract

lung

skin

neurological

other, please specify



Attach:

- a copy of the pathology report confirming FIP1L1-PDGFRB fusion gene
- a copy of the recent full blood examination report confirming the presence of eosinophilia
- a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology report(s) providing details of organs involved
- a completed authority prescription form.

Go to 14

- 12 PDGFRB fusion gene-positive myelodysplastic or myeloproliferative disorder

The patient:

has myelodysplastic or myeloproliferative disorder confirmed by bone marrow biopsy

with

confirmed evidence of a PDGFR gene re-arrangement by either:

standard karyotyping

or

Fluorescence In Situ Hybridisation (FISH)

or

PDGFRB fusion gene transcript

and

has previously failed an adequate trial of one or more of the following conventional therapy. Provide treatment details and the response cytarabine

from to

best response and duration

or

etoposide

from to

best response and duration

or

hydroxyurea

from / / to / /

best response and duration



Attach:

- a copy of the pathology report confirming the PDGFR gene re-arrangement
- a copy of the bone marrow biopsy report which demonstrates the presence of a myelodysplastic or myeloproliferative disorder
- a completed authority prescription form.

Go to 14

13 Aggressive systemic mastocytosis with eosinophilia patients

The patient:

has confirmed presence of the FIP1L1-PDGFR fusion gene

and

has had the diagnosis of aggressive systemic mastocytosis confirmed by a bone marrow report and/or other tissue biopsy

and

has eosinophilia

and

has previously failed an adequate trial of one or more of the following conventional therapy. Provide treatment details and the response corticosteroids

name of corticosteroid

from / / to / /

best response and duration

or

hydroxyurea

from / / to / /

best response and duration

Provide details of symptomatic organs involved which require treatment:

- heart
- lung
- neurological
- gastrointestinal tract
- skin
- other, please specify



Attach:

- a copy of the pathology report confirming FIP1L1-PDGFR fusion gene
- a copy of the bone marrow biopsy report and/or other tissue biopsy report confirming the diagnosis of aggressive systemic mastocytosis
- a copy of the full blood examination report demonstrating eosinophilia
- a copy of the radiology, nuclear medicine, respiratory function or anatomical pathology report(s) providing details of symptomatic organ involvement
- a completed authority prescription form.

Prescriber's declaration

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

Signature of prescriber

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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.