



Gastrointestinal stromal tumour - metastatic or unresectable

Initial PBS authority application

Supporting information

Important information

You must lodge this form for a patient starting **initial** PBS subsidised treatment with imatinib mesylate for metastatic or unresectable malignant gastrointestinal stromal tumour.

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

For all initial applications supply:

- a copy of the pathology report supporting diagnosis of a gastrointestinal stromal tumour and confirming the presence of CD117 on immunohistochemical staining
- a copy of the most recent (within two months of application), computer tomography (CT) scan, magnetic resonance imaging (MRI) or ultrasound assessment of the tumour(s) including whether or not there is evidence of metastatic disease
- written evidence to support an application which is being made on the basis of an unresectable tumour.

All patients must start treatment at a dose of imatinib mesylate not exceeding 400 mg per day for three months. Authority prescriptions for a higher dose will not be approved during this initial treatment period.

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.

Applications for continuing treatment

Patients who achieve a response to treatment at an imatinib mesylate dose of 400 mg per day should be continued at this dose and assessed for response at regular intervals.

A response to treatment is defined as a decrease from baseline in the sum of the products of the perpendicular diameters of all measurable lesions of 50 per cent or greater (response definition based on the Southwest Oncology Group standard criteria, see Demetri et al. N Engl J Med 2002; 347: 472-80).

Patients who fail to achieve a response to 400 mg per day after a minimum of three months treatment, may have their dose increased to 600 mg per day. Authority applications for doses higher than 600 mg per day will not be approved.

All applications for continuing treatment may be made by calling **1800 700 270** (call charges may apply) option 3, between 8.00 am and 5.00 pm EST, Monday to Friday.

Assistance

If you need assistance completing this form, or more information call Medicare on **1800 700 270** (call charges may apply) 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 > Gastrointestinal stromal tumour (GIST) imatinib mesylate > Gastrointestinal stromal tumour (GIST), metastatic or unresectable – imatinib mesylate**

Lodgement

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

Medicare Australia
Prior written approval of specialised drugs
Reply Paid 9826
Hobart TAS 7001

(No stamp required if posted in Australia)

Print in **BLOCK LETTERS**

Tick where applicable

