



# Idiopathic thrombocytopenic purpura

## Initial PBS authority application

### Supporting information

#### Important information

You must lodge this form for an adult patient starting **initial** PBS subsidised treatment with either eltrombopag or romiplostim for the treatment of severe chronic immune idiopathic thrombocytopenic purpura.

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

The lodgement of this application must be made within one month of the date of the full blood count.

Where the application is sought on the basis of a medical contraindication to surgery, a signed and dated letter from the clinician making this assessment, which includes the date upon which the patient was assessed for surgery and the clinical grounds upon which surgery is contraindicated, must be submitted.

Patients are able to trial either eltrombopag and/or romiplostim within the initial treatment period.

Patients who fail to demonstrate a response to treatment with either eltrombopag and/or romiplostim under the initial restriction will not be eligible to receive further PBS subsidised treatment with either of these drugs.

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

#### Section 100 arrangements

These items are only available to a patient who is attending:

- an approved private hospital
- a public participating hospital

or

- a public hospital

and is a

- day admitted patient
- non-admitted patient

or

- patient on discharge

These items are not available as a PBS benefit for in-patients of the hospital. The hospital provider number must be included on the application form.

#### 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.

At the time of the written authority application for:

- romiplostim, medical practitioners should request sufficient number of vials of appropriate strength to provide a single treatment at a dose of 1 mcg/kg/week. Up to one repeat may be requested.
- eltrombopag, medical practitioners should include a completed authority prescription for a quantity of 28 tablets and up to five repeats.

#### Phone approvals

Under no circumstance will telephone approvals be granted for complete authority applications, or for treatment that would otherwise extend the treatment period.

#### Applications for the balance of the initial period of dose titration of romiplostim

Subsequently during the initial period of dose titration, authority applications for a single dose and up to one repeat may be obtained by calling Medicare Australia on **1800 700 270** (call charges may apply) and select option 4, between 8.00 am and 5.00pm EST, Monday to Friday.

Once the patient's dose has been stable for a period of four weeks, authority approvals for up to four weeks of treatment and up to four repeats may be granted.

#### Applications for continuing treatment

The first period of PBS subsidised continuing treatment must be submitted in writing.

Second and subsequent applications for continuing treatment, for patients who are able to demonstrate an adequate response to treatment may be made by calling Medicare Australia on **1800 700 270** (call charges may apply) and select option 4 between 8.00 am and 5.00pm EST, Monday to Friday.

#### Assistance

If you need assistance completing this form, or more information, call Medicare Australia on **1800 700 270** (call charges may apply) option 4, between 8.00 am to 5.00 pm EST, Monday to Friday or visit [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) > for health professionals > PBS > Specialised drugs (PBS) A-1 > Idiopathic thrombocytopenic purpura

#### 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



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## 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  /  /
- 4** Patient's current weight  kg

## Patient's acknowledgement

- 5** I acknowledge that PBS subsidised treatment with eltrombopag or romiplostim for severe chronic immune idiopathic thrombocytopenic purpura 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.
- Patient's signature
- Date  /  /

## Prescriber's details

- 6** Prescriber number
- 7** Family name   
 First given name
- 8** Work phone number  ( )  
 Alternative phone number   
 Fax number  ( )

## Hospital details

- 9** Hospital name
- 10** Hospital provider number

## Prescriber's acknowledgement

- 11** I have explained:
- the circumstances governing PBS subsidised treatment with eltrombopag or romiplostim for severe chronic immune idiopathic thrombocytopenic purpura
  - 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.
- Prescriber's signature
- Date  /  /

## Witness's acknowledgement

- 12** I have witnessed the signatures of **BOTH** the patient and the prescriber.
- Witness's full name (over 18 years of age)
- Witness signature
- Date  /  /

## Thrombopoietin receptor agonist (TRA) details

- 13** Which TRA is this application for?
- eltrombopag  
 romiplostim

## Conditions, criteria and prior treatment

- To qualify for PBS authority approval the following conditions must be met.
- 14** The adult patient:
- has severe chronic immune idiopathic thrombocytopenic purpura (**Note:** A full blood count pathology report must be supplied.)

**and**

is splenectomised  
Provide date of splenectomy

**or**

is not splenectomised and a splenectomy is contraindicated.  
(**Note:** Supporting documentation must be supplied.)

**and**

has had an inadequate response, or is intolerant to, corticosteroid therapy for at least four to six weeks.  
Provide details.

Name of steroid

Dose

From

to

**and**

has had an inadequate response, or is intolerant to, immunoglobulin therapy

Provide date of treatment

**and**

has a platelet count of  $\leq 20 \times 10^9/L$

**or**

has a platelet count of  $20 - 30 \times 10^9/L$

**and**

is experiencing significant bleeding, or has a history of significant bleeding in this platelet range.

## Attachments



Attach full blood count pathology report, all other relevant attachments and a completed authority prescription form

## Prescriber's declaration

### 15 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 the 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.