Australian Government
Services Australia

medicare

PBS

Atypical haemolytic uraemic syndrome (aHUS) – eculizumab or ravulizumab – initial or switching authority application

Online PBS Authorities

You do not need to complete this form if you use the **Online PBS Authorities** system.

For more information and how to access the **Online PBS Authorities** system, go to **servicesaustralia.gov.au/hppbsauthorities**

When to use this form

Use this form to apply for **initial** PBS-subsidised eculizumab or ravulizumab for patients with atypical haemolytic uraemic syndrome (aHUS) who are:

- new patients receiving induction doses
- switching to ravulizumab from eculizumab
- switching to eculizumab from ravulizumab
- balance of supply – initial treatment.

Important information

Initial applications to start PBS-subsidised treatment can be made using the **Online PBS Authorities** system or in writing, and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for aHUS **initial** authority applications.

Complement 5 (C5) inhibitors are defined as eculizumab or ravulizumab.

Serial haematological results (every 3 months while the patient is receiving treatment) must be provided with every subsequent application for treatment.

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

Continuing treatment

This form is ONLY for **initial** treatment.

For continuing PBS-subsidised treatment, the patient must qualify under **continuing** treatment criteria.

Section 100 arrangements for eculizumab and ravulizumab

These items are available to a patient who is attending:

- an approved private hospital, **or**
- a public hospital

and is a:

- day admitted patient
- non-admitted patient, **or**
- patient on discharge.

Ravulizumab is not available as a PBS benefit for in-patients of a public hospital but **eculizumab** is.

The hospital name and provider number must be included in this authority form.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

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Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

kg

Prescriber's details

5 Prescriber number

6 Family name

First given name

7 Business phone number (including area code)

Mobile phone number

Hospital details

8 Hospital name

This hospital is a:

- ☐ public hospital
- ☐ private hospital

9 Hospital provider number

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

10 The patient is being treated by a:

- ☐ haematologist
- ☐ nephrologist
- ☐ medical practitioner in consultation with a haematologist or nephrologist

11 This application is for:

- ☐ eculizumab
- ☐ ravulizumab

12 Is this treatment in combination with another Complement 5 (C5) inhibitor?

- Yes ☐
- No ☐

MCA0PB119 2603

13 The patient has:

- ☐ **not** received prior treatment with this drug for this condition

or

- ☐ previously received PBS-subsidised eculizumab for this condition in the most recent treatment phase under the following restriction:
  - ☐ initial treatment
  - ☐ continuing treatment
  - ☐ extended continuing treatment
  - ☐ recommencement of treatment
  - ☐ continuing recommencement of treatment

or

- ☐ previously received PBS-subsidised ravulizumab for this condition in the most recent treatment phase under the following restriction:
  - ☐ initial treatment
  - ☐ continuing treatment
  - ☐ extended continuing treatment
  - ☐ recommencement of treatment
  - ☐ continuing recommencement of treatment
  - ☐ grandfather

14 This application is for:

- ☐ initial treatment with eculizumab (maximum 4 weeks treatment) [no ADAMTS-13 result available]

  ▶ ***Go to 18***

or

- ☐ initial treatment with eculizumab (maximum 24 weeks) [ADAMTS-13 result supplied with this application]

  ▶ ***Go to 18***

or

- ☐ initial treatment (loading dose) with ravulizumab (maximum 2 weeks treatment) [no ADAMTS-13 result available]

  ▶ ***Go to 18***

or

- ☐ initial treatment (loading dose and balance of supply) with ravulizumab (maximum 26 weeks) [ADAMTS-13 result supplied with this application]

  ▶ ***Go to 18***

or

- ☐ balance of supply for eculizumab where patient has previously received PBS-subsidised initial loading dose of eculizumab for aHUS (maximum 20 weeks)

  ▶ ***Go to 16***

or

- ☐ balance of supply for ravulizumab where patient has previously received PBS-subsidised initial loading dose of ravulizumab for aHUS (maximum 24 weeks)

  ▶ ***Go to 16***

or

- ☐ switching treatment from PBS-subsidised eculizumab to ravulizumab (maximum 2 weeks treatment)

  ▶ ***Go to 15***

or

- ☐ switching treatment from PBS-subsidised ravulizumab to eculizumab (maximum 24 weeks of C5 inhibitor supply for this current treatment phase under this restriction).

  ▶ ***Go to 15***

15 Results of genetic testing:

- ☐ have been previously submitted
- ☐ will be submitted with this application
- ☐ are still pending and will be submitted when available

16 The patient has or had ADAMTS-13 activity of at least 10% on a blood sample, and the result:

- ☐ was submitted at the initial application, including date and time the sample was collected

  ▶ ***Go to 24***

- ☐ was measured **7-10 days following** the last plasma exchange or infusion, and submitted **within 27 days** of commencement of PBS-subsidised **eculizumab** or **within 13 days** of commencement of PBS-subsidised **ravulizumab**

  ▶ ***Go to 17***

- ☐ has been previously submitted

  ▶ ***Go to 24***

- ☐ will be submitted with this application

  ▶ ***Go to 17***

17 ADAMTS-13 result ☐☐☐ %

Date and time that the sample for the ADAMTS-13 assay was collected

Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

Time ☐☐ . ☐☐ pm Select 'am' or 'pm'

▶ ***Go to 24***

18 Does the patient have active and progressing thrombotic microangiopathy (TMA) caused by aHUS?

Yes ☐

No ☐

19 The patient's active and progressing TMA is demonstrated by:

☐ a platelet count < 150 x 10^9/L

Provide current platelet count (**within the last week**)

x 10^9/L

and

☐ evidence of **at least 2** of the following (**within the last week**):

- ☐ presence of schistocytes on blood film
- ☐ low or absent haptoglobin
- ☐ lactate dehydrogenase (LDH) above normal range

or

☐ a kidney biopsy confirming TMA in recipients of a kidney transplant for end-stage kidney disease due to aHUS.

For all patients, a recent measurement of **eGFR**, **platelets** and two of either **LDH**, **haptoglobin** or **schistocytes** of no more than 1 week old **must** be submitted with this application.

and

☐ evidence of at least one of the following clinical features of active TMA-related organ damage or impairment:

- ☐ kidney impairment as demonstrated by one or more of the following:
  - ☐ a decline in the estimated Glomerular Filtration Rate (eGFR) of > 20% in a patient who has a pre-existing kidney impairment
  - ☐ a serum creatinine (sCr) of greater than the upper limit of normal (ULN) in a patient who has no history of pre-existing kidney impairment
  - ☐ a sCr of greater than the age-appropriate ULN in paediatric patients
  - ☐ a renal biopsy consistent with aHUS
- ☐ onset of TMA-related neurological impairment
- ☐ onset of TMA-related cardiac impairment
- ☐ onset of TMA-related gastrointestinal impairment
- ☐ onset of TMA-related pulmonary impairment.

Attach written clinical evidence to support the onset of TMA.

20 The patient has:

☐ ADAMTS-13 activity of at least 10% on a blood sample taken prior to plasma exchange or infusion

Provide ADAMTS-13 result

%

Provide date and time that the sample for the ADAMTS-13 assay was collected

Date (DD MM YYYY)

Time . am/pm Select 'am' or 'pm'

or

☐ a platelet count of > 30 x 10^9/L and serum creatinine of > 150 mol/L, if ADAMTS-13 activity was not collected prior to plasma exchange or infusion

Provide platelet count

x 10^9/L

Provide serum creatinine

mol/L

Provide date and time of **last** plasma exchange or infusion undertaken in the 2 weeks prior to collection of the ADAMTS-13 assay

Date (DD MM YYYY)

Time . am/pm Select 'am' or 'pm'

and

☐ ADAMTS-13 will be taken **7–10 days following** the last plasma exchange or infusion, with result submitted to Services Australia **within 27 days** of commencement of PBS-subsidised **eculizumab** treatment or **within 13 days** of commencement of PBS-subsidised **ravulizumab** treatment.

The patient will not be eligible for further treatment unless this requirement is met.

21 The patient has:

☐ not had diarrhoea within the preceding 14 days

or

☐ had diarrhoea within the preceding 14 days.

and current confirmed Shiga toxin-producing E.Coli (STEC) result is:

☐ negative ▶ Attach confirmed negative STEC result.

☐ positive ▶ ***Ineligible***

22 Provide current eGFR details (calculated for paediatric patients) (**within the last week**):

eGFR mL/min

Date (DD MM YYYY)

Checklist - for patients who have not received prior treatment with eculizumab or ravulizumab for this condition

23 The relevant attachments need to be provided with this form.

For **all** patients, a recent measurement of **eGFR**, **platelets** and **at least 2** of either **LDH**, **haptoglobin** or **schistocytes** of **no more than 1 week old** must be included in this application. For evidence of active and progressing TMA, all tests must have been performed within 4 weeks of application.

- ☐ Details of the proposed prescription(s).
- ☐ A detailed cover letter providing all relevant clinical information.
- ☐ ADAMTS-13 (if available).
- ☐ STEC result (if relevant).
- ☐ Additional evidence of active organ damage or impairment
- ☐ eGFR (calculated for paediatric patients).
- ☐ Serum creatinine (if applicable).
- ☐ Platelets.
- ☐ LDH.
- ☐ Presence of schistocytes on blood film.
- ☐ Low or absent haptoglobin.
- ☐ Results of genetic testing (if available).

▶ *Go to 25*

Checklist - for balance of supply or patients who are switching

24 The relevant attachments need to be provided with this form.

- ☐ Details of the proposed prescription(s).
- ☐ ADAMTS-13, if not previously submitted.
- ☐ Results of genetic testing, if not previously submitted.

Privacy notice

25 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at **servicesaustralia.gov.au/privacypolicy**

Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

26 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application
- I have provided details of the proposed prescription(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction
- the information I have provided in this form is complete and correct.

I understand that:

- giving false or misleading information is a serious offence.

☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

Prescriber's signature (**only** required if returning by post or fax)

If returning by post, print and sign by hand.

Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at **servicesaustralia.gov.au/hpos**
- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001
- by fax (signature required) to 1800 785 672

Reset form