Australian Government
Services Australia

medicare

PBS

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

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 must be 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
- a public participating hospital (**eculizumab only**), **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 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

kg

Prescriber's details

5 Prescriber number

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

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?

No ☐

Yes ☐

MCA0PB119 2401

13 The patient:

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

or

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

or

- ☐ has previously received PBS-subsidised ravulizumab for this condition 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]

or

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

or

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

or

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

or

- ☐ switching treatment from PBS-subsidised eculizumab to ravulizumab and the patient has or has had ADAMTS-13 activity of greater than or equal to 10% on a blood sample (maximum 2 weeks treatment)

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or

- ☐ switching treatment from PBS-subsidised ravulizumab to eculizumab and the patient has or has had ADAMTS-13 activity of greater than or equal to 10% on a blood sample (maximum 24 weeks of C5 inhibitor for current treatment phase under this restriction).

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15 The patient has active and progressing thrombotic microangiopathy (TMA) caused by aHUS as defined by the following:

- ☐ 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

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

and

- ☐ evidence of at least one of the following clinical features of active TMA-related organ damage or impairment as defined below:
  - ☐ Kidney impairment as demonstrated by one or more of the following:
    - ☐ a decline in the estimated Glomerular Filtration Rate (eGFR) of greater than 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.

16 The patient has:

☐ ADAMTS-13 activity of greater than or equal to 10% on a blood sample taken prior to plasma exchange or infusion

Provide ADAMTS-13 result

%

Date and time sample was taken

Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

and time ☐☐.☐☐

or

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

Provide platelet count

x 10^9/L

Provide serum creatinine

mol/L

Provide date and time of last plasma exchange or infusion. ADAMTS-13 must be taken **7–10 days following** the last plasma exchange or infusion.

Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

and time ☐☐.☐☐

and

☐ I confirm that the ADAMTS-13 result will be 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.

17 The patient has:

☐ not had diarrhoea within the preceding 14 days

or

☐ had diarrhoea within the preceding 14 days.

Attach current confirmed negative Shiga toxin-producing E.Coli (STEC) result.

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

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

☐ The completed authority prescription form(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 (for example, CT scan reports, cardiac function studies, clinical summary, kidney biopsy).

☐ eGFR and serum creatinine (must be within 1 week at time of application).

☐ Full blood count and film (must be within 1 week at time of application).

☐ LDH (must be within 1 week at time of application).

☐ Presence of schistocytes on blood film (must be within 1 week at time of application).

☐ Low or absent haptoglobin (must be within 1 week at time of application).

☐ Results of genetic testing (if available).

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Checklist (for patients who are switching)

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

☐ The completed authority prescription form(s).

☐ ADAMTS-13.

☐ Results of genetic testing, if not previously submitted.

Privacy notice

20 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**

21 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 the completed authority prescription form(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 acknowledge that:

- I have explained to the patient the circumstances governing treatment with eculizumab and ravulizumab for aHUS.
- the PBS-subsidised treatment with eculizumab or ravulizumab will cease if treatment failure is experienced.

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)

If returning by post, print and sign by hand.

Returning this form

Return this form, the authority prescription form(s) and any relevant attachments:

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

  or

- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

  or

- by fax to 1800 785 672

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