Australian Government
Services Australia

medicare

PBS

# Atypical haemolytic uraemic syndrome (aHUS) – eculizumab or ravulizumab – recommencement 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 **recommencing** PBS-subsidised eculizumab or ravulizumab for patients with atypical haemolytic uraemic syndrome (aHUS).

## Important information

Authority applications 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 **recommencement** 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 **recommencing** treatment.

For continuing PBS-subsidised treatment, the patient must qualify under the **continuing recommencement of 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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## Online PBS Authorities

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

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

- Yes ☐
- No ☐

**12** This application is for:

- ☐ eculizumab for a patient demonstrating treatment response to previous treatment with PBS-subsidised eculizumab for aHUS (maximum 24 weeks)

***Go to 14***

**or**

- ☐ eculizumab for a patient treated with PBS-subsidised eculizumab under the switch from ravulizumab in the recommencement treatment phase (maximum 24 weeks)

***Go to 14***

**or**

- ☐ ravulizumab for a patient demonstrating treatment response to previous treatment with a PBS-subsidised C5 inhibitor for aHUS (maximum 26 weeks)

***Go to 14***

**or**

- ☐ balance of supply for eculizumab where patient has received PBS-subsidised recommencement supply of eculizumab for aHUS (maximum 20 weeks)

***Go to 24***

**or**

- ☐ balance of supply for ravulizumab where patient has received PBS-subsidised loading dose of ravulizumab with insufficient therapy to complete the maximum allowable treatment under their specified treatment phase for aHUS (maximum 24 weeks)

***Go to 13***

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

☐ has been previously submitted

**or**

☐ will be submitted with this application

ADAMTS-13 result ____ %

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

Date (DD MM YYYY)

__ __ __ __ __ __ __ __

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

▶ ***Go to 24***

**14** The patient has had a treatment response to their previous treatment with eculizumab or ravulizumab, evidenced by:

☐ normalisation of haematology as demonstrated by **at least 2** of the following:

- ☐ platelet count
- ☐ haptoglobin
- ☐ lactate dehydrogenase (LDH)

**and**

☐ an increase in estimated Glomerular Filtration Rate (eGFR) of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with a C5 inhibitor

**or**

☐ an eGFR within +/- 25% from baseline

**or**

☐ an avoidance of dialysis-dependence but worsening of kidney function with a reduction in eGFR > 25% from baseline.

**15** Provide eGFR details (calculated for paediatric patients)

Baseline eGFR ____ mL/min

Response eGFR ____ mL/min

Date of response eGFR (DD MM YYYY)

__ __ __ __ __ __ __ __

**16** Did the patient experience treatment failure with eculizumab or ravulizumab for this condition in the most recent treatment phase?

Yes ☐ ▶ ***Ineligible***

No ☐ ▶ ***Go to 17***

**17** Did the patient require dialysis in the most recent treatment phase?

Yes ☐ ▶ ***Go to 18***

No ☐ ▶ ***Go to 21***

**18** The patient was:

☐ dialysis-dependent at the time treatment was ceased

**or**

☐ on dialysis and had been on dialysis for 4 months of the previous 6 months while receiving a PBS-subsidised C5 inhibitor

**19** Was the indication for continuing eculizumab or ravulizumab to treat severe extra-renal complications that have significantly improved?

Yes ☐

No ☐ ▶ ***Ineligible***

**20** Provide a supporting statement that any initial extra-renal complications of TMA have significantly improved, with clinical evidence attached with this application, if applicable

**21** The patient currently has the following clinical conditions:

☐ significant haemolysis as measured within 1 week of application by:

- ☐ low or absent haptoglobin

**or**

- ☐ presence of schistocytes on the blood film

**or**

- ☐ LDH above normal range

**and**

☐ platelet consumption as measured by:

- ☐ 25% decline from patient baseline

Baseline platelet count

____ x $10^9$/L

Current platelet count

____ x $10^9$/L

Date of current platelet count (within 1 week of application) (DD MM YYYY)

__ __ __ __ __ __ __ __

**or**

- ☐ thrombocytopenia (platelet count < 150 x $10^9$/L)

Current platelet count

____ x $10^9$/L

Date (within 1 week of application) (DD MM YYYY)

__ __ __ __ __ __ __ __

**or**

☐ TMA-related organ impairment including on recent biopsy

Provide supporting evidence.

**22** Provide the following supporting information, if applicable:

- ☐ Results of genetic testing, if not previously submitted
- ☐ A family history of aHUS
- ☐ A history of multiple episodes of aHUS following the treatment break
- ☐ A history of kidney transplant (especially if required due to aHUS)
- ☐ An inclusion of the individual consequences of recurrent disease

**or**

☐ Above relevant information has been previously submitted

**or**

☐ None of the above is applicable to the patient

## Checklist - for recommencement treatment

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

- ☐ Details of the proposed prescription(s).
- ☐ eGFR (calculated for paediatric patients).
- ☐ Platelet count.
- ☐ Haptoglobin
- ☐ LDH.
- ☐ Clinical evidence of TMA-related organ impairment including on recent biopsy.
- ☐ Clinical evidence of improvement of extra-renal complications, if originally present

▶ *Go to 25*

## Checklist - for balance of supply of recommencement treatment

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

- ☐ Details of the proposed prescription(s).
- ☐ ADAMTS-13, if not previously submitted (applicable to **ravulizumab** only)

## 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