

# Atypical haemolytic uraemic syndrome (aHUS) – eculizumab or ravulizumab – continuing 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](https://servicesaustralia.gov.au/hppbsauthorities)

## When to use this form

Use this form to apply for **continuing** PBS-subsidised eculizumab or ravulizumab for patients with atypical haemolytic uraemic syndrome (aHUS).

## Important information

**Continuing** 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 **continuing** 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 **continuing** treatment.

## 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](https://servicesaustralia.gov.au/healthprofessionals)



- 13** Receiving no more than 24 weeks of treatment per continuing treatment course, the patient is seeking PBS-subsidised:
- continuing** treatment  
**and** will receive
- no more than 80 weeks** of **eculizumab** treatment in total under this restriction
- or**
- no more than 72 weeks** of **ravulizumab** treatment in total under this restriction
- or**
- no more than 104 weeks** supply of a **C5 inhibitor** under the initial and continuing treatment restrictions if C5 inhibitors were switched during that course.

▶ **Go to 15**

- or**
- continuing recommencement** of treatment after responding to the recommencement of treatment with a C5 inhibitor

▶ **Go to 15**

- or**
- extended continuing** treatment

▶ **Go to 14**

- 14** The patient has:
- a TMA-related cardiomyopathy as evidenced by left ventricular ejection fraction < 40% on current objective measurement
- or**
- severe TMA-related neurological impairment
- or**
- severe TMA-related gastrointestinal impairment
- or**
- severe TMA-related pulmonary impairment on current objective measurement
- or**
- grade 4 or 5 chronic kidney disease (eGFR of less than 30 mL/min)
- or**
- a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab or ravulizumab.



Attach evidence, including a supporting statement with clinical evidence.

- 15** The patient has demonstrated ongoing treatment response with PBS-subsidised eculizumab or ravulizumab for this condition, evidenced by:
- normalisation of haematology as demonstrated by **at least 2** of the following:
- platelet count
  - haptoglobin
  - lactate dehydrogenase (LDH)

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

- and** one of the following:
- 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

- 16** Provide eGFR details (calculated for paediatric patients)

Baseline eGFR  mL/min

Current eGFR  mL/min

Date of current eGFR (DD MM YYYY)

- 17** Has the patient experienced treatment failure with eculizumab or ravulizumab for this condition in the most recent treatment phase?

Yes  **Ineligible**

No  **Go to 18**

- 18** Does the patient require dialysis?

Yes  **Go to 19**

No  **Go to 22**

- 19** The patient is:

dialysis-dependent at the time of application

**or**

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

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

Yes

No  **Ineligible**

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

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 before commencing or recommencing eculizumab or ravulizumab treatment

- 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

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

For **continuing** treatment and **continuing recommencement** of treatment, eGFR, LDH, platelets and haptoglobin results must be **no more than 1 week old** at the time of application.

For **extended continuing** treatment, eGFR, LDH, platelets and haptoglobin results must be **no more than 4 weeks old** at time of application.

- Details of the proposed prescription(s).
- eGFR (calculated for paediatric patients).
- LDH.
- Platelets.
- Haptoglobin.
- 3-monthly serial haematological results (required).
- Clinical evidence of severe TMA-related cardiomyopathy (including current LVEF result), neurological impairment, gastrointestinal impairment or pulmonary impairment.
- Clinical evidence of improvement of extra-renal complications, if originally present.

### Privacy notice

24 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 [servicessaustralia.gov.au/privacypolicy](https://servicessaustralia.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 [servicessaustralia.gov.au/hpos](https://servicessaustralia.gov.au/hpos)

25 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)



### Returning this form

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

- **online** (no signature required), upload through HPOS at [servicessaustralia.gov.au/hpos](https://servicessaustralia.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