

# Atypical haemolytic uraemic syndrome (aHUS) – eculizumab or ravulizumab – continuing authority application

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



**13** The patient:

- has previously received PBS-subsidised eculizumab for this condition under the following restriction:
  - initial treatment
  - continuing treatment
  - recommencement of treatment
  - switch from ravulizumab in the initial treatment phase
  - switch from ravulizumab in the continuing treatment phase
  - switch from ravulizumab in the extended continuing treatment phase
  - switch from ravulizumab in the recommencement of treatment phase
  - switch from ravulizumab in the continuing recommencement of treatment phase

**or**

- has previously received PBS-subsidised ravulizumab for this condition under the following restriction:
  - initial treatment
  - grandfather
  - continuing treatment
  - recommencement of treatment
  - switch from eculizumab in the continuing treatment phase
  - switch from eculizumab in the extended continuing treatment phase
  - switch from eculizumab in the recommencement of treatment phase
  - switch from eculizumab in the continuing recommencement of treatment phase

**14** This application is for a patient seeking PBS-subsidised:

- continuing treatment ▶ **Go to 16**

**or**

- continuing recommencement of treatment ▶ **Go to 16**

**or**

- extended continuing treatment ▶ **Go to 15**

**15** The patient has current severe thrombotic microangiopathy (TMA) related organ damage as indicated below:



Attach evidence including a detailed cover letter providing all relevant clinical information.

- 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**

- Patient must have a high risk of aHUS recurrence in the short term in the absence of continued treatment with eculizumab or ravulizumab.

**16** The patient has demonstrated an ongoing treatment response to PBS-subsidised eculizumab or ravulizumab for this condition as defined by the following:

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

- platelet count
- haptoglobin
- lactate dehydrogenase (LDH)

**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 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.

To determine whether a patient has failed treatment, you **must** complete the following questions.

**17** Was the patient dialysis-dependent at the time of the initial application?

No

Yes

**18** Has the patient required further dialysis?

No

Yes  Give date range, including date of most recent dialysis

From (DD MM YYYY)

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To (DD MM YYYY)

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**19** Does the patient currently require dialysis?

No

Yes

**20** Did the patient have extra-renal complications at presentation (or initiation of eculizumab or ravulizumab)?

No  **Go to 22**

Yes

**21** Has the patient demonstrated significant resolution of extra-renal complications if originally present?

No

Yes  Give details, including objective test evidence where applicable.


**Read** this before answering the following questions.

Provide the following supporting information for this patient, if applicable.

**22** An identified genetic mutation

No

Yes

Details


**23** A family history of aHUS

No

Yes

Details


**24** Details of multiple episodes of aHUS before commencing eculizumab or ravulizumab treatment

No

Yes

Details


**25** Details of history of kidney transplant (especially if due to aHUS)

No

Yes

Details


**26** Details of the individual consequences of recurrent disease

No

Yes

Details


### Checklist

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

The completed authority prescription form(s).

Applications for continuing treatment and continuing recommencement of treatment eGFR, LDH, platelets and haptoglobin results must be **within 1 week** at time of application.

Applications for extended continuing treatment eGFR, LDH, platelets and haptoglobin results must be **within 4 weeks** at time of application.

eGFR.

LDH.

Platelets.

Haptoglobin.

3 monthly and cessation haematology reports.

**and**, if applicable, attach details of:

Clinical evidence of improvement of extra-renal complications, if originally present.

Results of genetic testing, if not previously submitted.

Family history of aHUS.

Multiple episodes of aHUS before commencing eculizumab or ravulizumab treatment.

History of kidney transplant (especially if due to aHUS).

Individual consequences of recurrent disease.

Evidence of current organ involvement.

## Privacy notice

**28** 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](https://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](https://servicesaustralia.gov.au/hpos)

### 29 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 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)

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


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## 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](https://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