Australian Government
Services Australia

medicare

PBS

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

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 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 **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
- 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 for a patient previously treated with PBS-subsidised eculizumab for aHUS (maximum 24 weeks)

or

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

or

☐ ravulizumab for a patient previously treated with a PBS-subsidised Complement 5 (C5) inhibitor for aHUS (maximum 26 weeks)

or

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

▶ *Go to 26*

or

☐ balance of supply for ravulizumab where patient has received PBS-subsidised recommencement supply of ravulizumab for aHUS (maximum 24 weeks)

▶ *Go to 26*

MCA0PB176 2401

12 Is this treatment in combination with another C5 inhibitor?

No ☐
Yes ☐

13 This application is for a patient who has demonstrated a 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 eculizumab or ravulizumab

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 at the time of treatment cessation, you **must** complete the following questions.

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

No ☐
Yes ☐

15 Did the patient require further dialysis?

No ☐
Yes ☐ Give date range, including date of most recent dialysis

From (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

To (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

16 Did the patient require dialysis at the time of treatment cessation?

No ☐
Yes ☐

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

No ☐ ***Go to 19***
Yes ☐

18 Did the patient demonstrate significant resolution of extra-renal complications if originally present?

No ☐
Yes ☐ Give details, including objective test evidence where applicable.

19 At the time of this application, the patient has the following clinical conditions:

☐ significant haemolysis as measured within 1 week of time 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 either a 25% decline from patient baseline

Provide baseline platelet count

x 10^9/L

Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

Provide current platelet count (within 1 week at time of application)

x 10^9/L

or

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

Provide current platelet count (within 1 week at time of application)

x 10^9/L

or

☐ TMA-related organ impairment including on recent biopsy

Provide supporting evidence.

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

20 An identified genetic mutation

No ☐
Yes ☐

Details

21 A family history of aHUS

No ☐
Yes ☐

Details

22 Details of multiple episodes of aHUS before commencing eculizumab or ravulizumab treatment

No ☐
Yes ☐

Details

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

No ☐
Yes ☐

Details

24 Details of the individual consequences of recurrent disease

No ☐
Yes ☐

Details

Checklist (for recommencement treatment)

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

- ☐ The completed authority prescription form(s).
- ☐ eGFR (must be within 1 week at time of application).
- ☐ Evidence that the patient has had a treatment response to their previous treatment with eculizumab or ravulizumab (include pathology reports).
- ☐ LDH (must be within 1 week at time of application).
- ☐ Platelets (must be within 1 week at time of application).
- ☐ Low or absent haptoglobin (must be within 1 week at time of application).
- ☐ 3 monthly and cessation haematology reports, if applicable.

and, if applicable, provide details of:

- ☐ Recent biopsy evidence.
- ☐ Supporting statement with clinical evidence of TMA-related organ damage.
- ☐ Results of genetic testing, if not previously submitted.
- ☐ Family history of aHUS.
- ☐ Multiple episodes of aHUS following the treatment break.
- ☐ History of kidney transplant (especially if due to aHUS).
- ☐ Individual consequences of recurrent disease.

▶ *Go to 27*

Checklist (for balance of supply of recommencement treatment)

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

- ☐ The completed authority prescription form.

Privacy notice

27 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**

28 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)

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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