Australian Government
Services Australia

medicare

PBS

# Atypical Haemolytic Uraemic Syndrome (aHUS) – eculizumab Initial authority application

## Purpose of this form

This form must be completed by one of the following specialists or prescribed in consultation with one of the following:

- paediatric nephrologist
- nephrologist
- paediatric haematologist
- haematologist.

You must lodge this form for a patient applying for **initial** Pharmaceutical Benefits Scheme (PBS) subsidised treatment with eculizumab.

The information in this form is correct at the time of publishing and is subject to change.

## Important information

All applications must be in writing and must include a detailed cover letter providing all relevant clinical information as well as sufficient supporting information to determine the patient's eligibility according to the PBS criteria.

Serial haematological results must be provided every 3 months while the patient is receiving PBS subsidised treatment with eculizumab. The patient must have received a meningococcal vaccine before commencing treatment with PBS subsidised eculizumab.

Where genetic testing has been performed, a copy of these test results should be provided with the application.

At the time of completing the authority application form for the first 4 weeks of treatment, medical practitioners should request the appropriate number of vials to provide sufficient drug for the 4 weeks. The authority prescription form for the balance of initial treatment should be written for a quantity to provide sufficient drug for 4 weeks of treatment and up to 4 repeats, according to the specified dosage in the approved Product Information (PI) for the treatment of atypical Haemolytic Uraemic Syndrome (aHUS).

Applications for treatment with eculizumab, where the dose and dosing frequency exceeds that specified in the approved PI, will not be approved.

## Section 100 arrangements

This item is only available to a patient who is attending:

- an approved private hospital
- a public participating hospital

**or**

- a public hospital.

## Authority prescription form

A completed authority prescription form and all supporting documentation including a detailed cover letter must be attached to this form.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

## Applications for extended initial treatment

An **Atypical Haemolytic Uraemic Syndrome (aHUS) – eculizumab Extended initial PBS authority application (PB175)** form must be completed and submitted to Services Australia with all relevant supporting documentation (test results) and a detailed cover letter providing all relevant clinical information from the patient's medical file.

## Filling in this form

- **Please use black or blue pen**
- Print in BLOCK LETTERS
- Mark boxes like this ☐ with a ✓ or ✗

## Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

  **or**

- by post, send this form, the authority prescription form(s) and any relevant attachments to:

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

  **or**

- by fax, **1800 785 672**

## For more information

Go to **servicesaustralia.gov.au/healthprofessionals** or call **1800 700 270** Monday to Friday, 8 am to 5 pm, Australian Eastern Standard Time.

Call charges may apply.

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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 / /

**4** Patient's weight kg

## Patient's or parent/guardian's acknowledgement and consent

**5** **I acknowledge that**:

- my prescriber has explained the nature of the ongoing monitoring and testing required to demonstrate an adequate response to therapy.
- PBS subsidised treatment with eculizumab will cease if treatment failure as defined in the PBS restriction is experienced.

**I consent to**:

- my prescriber providing Services Australia and the Department of Health with any personal or sensitive information (in addition to information required to be provided with this form, including my health records) which is required for the purposes of administering the PBS, including verifying my eligibility to receive eculizumab for atypical Haemolytic Uraemic Syndrome (aHUS).

Patient's name (or parent/guardian's name if patient is under 18 years of age)

Patient's signature (or parent/guardian's signature if patient is under 18 years of age)

Date

/ /

## Prescriber's details

**6** Prescriber number

**7** Prescriber's specialty

**Tick ALL that apply**

- ☐ Paediatric nephrologist
- ☐ Nephrologist
- ☐ Paediatric haematologist
- ☐ Haematologist

**or** in consultation with:

- ☐ Paediatric nephrologist
- ☐ Nephrologist
- ☐ Paediatric haematologist
- ☐ Haematologist

**8** Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

**9** Business phone number

( )

Alternative phone number

Fax number

( )

## Hospital details

**10** Hospital name

**11** Hospital provider number

## Conditions and criteria

**12** This application is for:

☐ initial treatment (max 4 weeks treatment) [no ADAMTS-13 result available]

or

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

**13 The patient has**:

☐ active and progressing TMA caused by aHUS as defined by the following:

(1) A platelet count < 150 x $10^9$/L

Provide current platelet count (**within the last week**)

x $10^9$/L

**and**

evidence of 2 of the following (**within the last week**).

**Tick ALL that apply**

(i) ☐ presence of schistocytes on blood film

(ii) ☐ low or absent haptoglobin

(iii) ☐ lactate dehydrogenase (LDH) above normal range

**OR**

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

**AND**

(3) evidence of at least one of the following clinical features of active TMA related organ damage or impairment as defined below:

(a) ☐ Kidney impairment as demonstrated by one or more of the following:

(i) ☐ a decline in the estimated Glomerular Filtration Rate (eGFR) of greater than 20 per cent in a patient who has a pre-existing kidney impairment

(ii) ☐ 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

(iii) ☐ a sCr of greater than the age-appropriate ULN in paediatric patients

(iv) ☐ renal biopsy consistent with aHUS

(b) ☐ onset of TMA-related neurological impairment

(c) ☐ onset of TMA-related cardiac impairment

(d) ☐ onset of TMA-related gastrointestinal impairment

(e) ☐ onset of TMA-related pulmonary impairment.

Attach written clinical evidence to support the onset of TMA.

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

Provide ADAMTS-13 result

%

Date and time sample was taken

Date / / 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 150mol/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 **1–2 weeks following** the last plasma exchange or infusion.

Date / / 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.

The patient will not be eligible for further treatment unless this requirement is met.

**15 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.

**16 The patient has**:

☐ received the meningococcal vaccine

Attach a copy of the current Certificate of Vaccination or a statement that vaccination has or will be administered and appropriate antibiotic prophylaxis has been prescribed.

If the patient has not received the meningococcal vaccine, provide details

## Attachments

**17** Attach the following documents from the patient's medical file to support this application:

- ☐ A detailed cover letter providing all relevant clinical information
- ☐ ADAMTS-13 (if available)
- ☐ Copy of current vaccination certificate
- ☐ STEC result (if relevant)
- ☐ Additional evidence of active organ damage or impairment (e.g. CT scan reports, cardiac function studies, clinical summary, kidney biopsy, etc.)
- ☐ eGFR and serum creatinine (must be recent measurement)
- ☐ 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)

## Privacy notice

**18** 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/privacy**

## Prescriber's acknowledgement and declaration

**19** **I declare that:**

- the information I have provided in this form is complete and correct.
- I have attached the completed authority prescription form, all relevant test results and documentation, including a cover letter providing all relevant clinical information.

**I understand that:**

- giving false or misleading information is a serious offence.

**I acknowledge that**:

- I have explained to the patient the circumstances governing treatment with eculizumab for atypical Haemolytic Uraemic Syndrome (aHUS).
- the PBS subsidised treatment with eculizumab will cease if treatment failure is experienced.

I believe these to be understood and accepted by the patient.

Prescriber's signature

✍

Date

/ /

Reset form Print form