Australian Government
Services Australia

medicare

PBS

Atypical haemolytic uraemic syndrome (aHUS) – ravulizumab – initial grandfather 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 **initial grandfather** PBS-subsidised ravulizumab for patients with atypical haemolytic uraemic syndrome (aHUS) who have received non-PBS-subsidised treatment with ravulizumab for the same condition.

Important information

Initial grandfather applications to start PBS-subsidised treatment 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 **initial grandfather** 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 **initial grandfather** treatment.

For continuing PBS-subsidised treatment, the patient must qualify under **continuing** treatment criteria.

Section 100 arrangements for ravulizumab

This item is 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.

This item is not available as a PBS benefit for in-patients of a public hospital.

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 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 Has the patient previously received non-PBS-subsidised therapy with ravulizumab for this condition?

- Yes ☐
- No ☐

12 Commencement date of non-PBS-subsidised ravulizumab (DD MM YYYY)

Commencement date of non-PBS-subsidised Complement 5 (C5) inhibitor, if different from the above (DD MM YYYY)

13 Is this treatment in combination with another C5 inhibitor?

- Yes ☐
- No ☐

14 Prior to commencing non-PBS-subsidised treatment with a C5 inhibitor for this condition, did the patient have active and progressing thrombotic microangiopathy (TMA) caused by aHUS?

- Yes ☐
- No ☐

MCA0PB359 2603

15 The patient's active and progressing TMA was demonstrated by:

☐ a platelet count < 150 x 10^9/L

Provide platelet count [x 10^9/L]

and

☐ evidence of **at least 2** of the following:

- ☐ presence of schistocytes on blood film
- ☐ low or absent haptoglobin
- ☐ lactate dehydrogenase (LDH) above normal range

or

☐ a kidney biopsy confirming TMA in recipients of a kidney transplant for end-stage kidney disease due to aHUS

and

☐ evidence of at least one of the following clinical features of active TMA-related organ damage or impairment:

- ☐ kidney impairment as demonstrated by:
  - ☐ a decline in the estimated Glomerular Filtration Rate (eGFR) of > 20% in a patient who has a pre-existing kidney impairment
  - ☐ 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
  - ☐ a sCr of greater than the age-appropriate ULN in paediatric patients
  - ☐ a renal biopsy consistent with aHUS
- ☐ onset of TMA-related neurological impairment
- ☐ onset of TMA-related cardiac impairment
- ☐ onset of TMA-related gastrointestinal impairment
- ☐ onset of TMA-related pulmonary impairment.

📎 Attach written clinical evidence to support the onset of TMA.

16 Prior to commencing non-PBS-subsidised treatment with a C5 inhibitor for this condition, the patient had ADAMTS-13 activity of at least 10% on a blood sample:

☐ not confounded by any plasma exchange or infusion

Provide ADAMTS-13 result [%]

Provide 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 17***

or

☐ without any plasma exchange or infusion

Provide ADAMTS-13 result [%]

▶ ***Go to 18***

17 Provide the dates and times of any plasma exchanges or infusions that were undertaken in the two weeks prior to the collection of the ADAMTS-13 assay

Date (DD MM YYYY) [ ] [ ] [ ]

Time [. pm] Select 'am' or 'pm'

18 Provide eGFR details (calculated for paediatric patients)

Baseline eGFR [mL/min]

Date (DD MM YYYY) [ ] [ ] [ ]

19 In the preceding 14 days of commencing non-PBS-subsidised treatment with a C5 inhibitor for this condition, the patient:

☐ did not have diarrhoea

or

☐ had diarrhoea

and confirmed Shiga toxin-producing E.Coli (STEC) result is:

☐ negative ▶ 📎 Attach confirmed negative STEC result.

☐ positive ▶ ***Ineligible***

20 Has the patient received at least 26 weeks of initial non-PBS-subsidised ravulizumab for this condition?

Yes ☐ ▶ ***Go to 21***

No ☐ ▶ ***Go to 23***

For patients who have received at least 26 weeks of non-PBS-subsidised ravulizumab treatment, a recent measurement of **eGFR**, **platelets** and two of either **LDH**, **haptoglobin** or **schistocytes** of no more than 1 week old **must** be submitted with this application.

21 The patient:

☐ has demonstrated on-going treatment response with ravulizumab for this condition

and

☐ has not experienced treatment failure with ravulizumab for this condition.

22 Current eGFR [mL/min]

Date (no more than 1 week old) (DD MM YYYY) [ ] [ ] [ ]

Checklist

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

For evidence of active and progressing TMA, all tests must have been performed within 4 weeks of commencement of non-PBS-subsidised C5 inhibitor.

For patients who have received at least 26 weeks of non-PBS-subsidised ravulizumab treatment, results for eGFR, platelets and two of either LDH, haptoglobin or schistocytes must be within 1 week at time of application.

- ☐ Details of the proposed prescription(s).
- ☐ A detailed cover letter providing all relevant clinical information.
- ☐ ADAMTS-13.
- ☐ STEC result (if relevant).
- ☐ Additional evidence of active organ damage or impairment.
- ☐ eGFR (calculated for paediatric patients).
- ☐ Serum creatinine (if applicable).
- ☐ Platelets.
- ☐ LDH.
- ☐ Low or absent haptoglobin.
- ☐ Presence of schistocytes on blood film.
- ☐ Results of genetic testing (if available).

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 **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**

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)

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