Australian Government
Services Australia

medicare

PBS

Atypical haemolytic uraemic syndrome (aHUS) – ravulizumab – initial grandfather authority application

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

No ☐

Yes ☐ Date commenced (DD MM YYYY)

12 Is this treatment in combination with another Complement 5 (C5) inhibitor?

No ☐

Yes ☐

MCA0PB359 240117

13 Prior to commencing non-PBS-subsidised treatment with ravulizumab for this condition, the patient had active and progressing thrombotic microangiopathy (TMA) caused by aHUS as defined by the following:

☐ 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

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

and

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

- ☐ kidney impairment as demonstrated by one or more of the following:
  - ☐ a decline in the estimated Glomerular Filtration Rate (eGFR) of greater than 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.

14 Prior to commencing non-PBS-subsidised treatment with ravulizumab for this condition, the patient had:

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

Provide ADAMTS-13 result

[%]

Date and time sample was taken

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

and time [.]

15 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) and time

[ ][ ][ ][ ][ ][ ][ ][ ] [.]

[ ][ ][ ][ ][ ][ ][ ][ ] [.]

16 Prior to commencing non-PBS-subsidised treatment with ravulizumab for this condition, the patient:

☐ did not have diarrhoea within the preceding 14 days

or

☐ had diarrhoea within the preceding 14 days.

Attach confirmed negative Shiga toxin-producing E.Coli (STEC) result.

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

No ☐ ***Go to 24***

Yes ☐

18 The patient has demonstrated an ongoing treatment response to ravulizumab for this condition as defined by the following:

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

- ☐ platelet count
- ☐ haptoglobin
- ☐ LDH

and

☐ one of the following:

- ☐ an increase in eGFR of > 25% from baseline, where the baseline is the eGFR measurement immediately prior to commencing treatment with 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, you **must** complete the following questions.

19 Was the patient dialysis-dependent at the time of commencing non-PBS-subsidised treatment with ravulizumab?

No ☐

Yes ☐

20 Has the patient required further dialysis?

No ☐

Yes ☐ Give date range, including date of most recent dialysis

From (DD MM YYYY)

To (DD MM YYYY)

21 Does the patient currently require dialysis?

No ☐

Yes ☐

22 Did the patient have extra-renal complications at presentation (or initiation of non-PBS-subsidised treatment with ravulizumab)?

No ☐ ***Go to 24***

Yes ☐

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

No ☐

Yes ☐ Give details, including objective test evidence where applicable.

Checklist

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

For grandfather patients, all tests must have been performed within 4 weeks of commencement of non-PBS-subsidised ravulizumab.

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.

- ☐ The completed authority prescription form(s).
- ☐ A detailed cover letter providing all relevant clinical information.
- ☐ ADAMTS-13.
- ☐ STEC result (if relevant).
- ☐ Additional evidence of active organ damage or impairment (for example, CT scan reports, cardiac function studies, clinical summary, kidney biopsy).
- ☐ eGFR and serum creatinine.
- ☐ Platelets.

Two of the following:

- ☐ LDH.
- ☐ Low or absent haptoglobin.
- ☐ Presence of schistocytes on blood film.

Privacy notice

25 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**

26 **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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