

Generalised myasthenia gravis – treatment refractory initial authority application

Online PBS Authorities



Requesting PBS Authorities online provides an immediate assessment in real time.

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 PBS-subsidised ravulizumab for initial treatment of treatment refractory generalised myasthenia gravis (gMG) patients.

Important information

Initial applications to start PBS-subsidised treatment for treatment refractory gMG can be made in real time 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 treatment refractory gMG **initial** authority applications.

Where the term 'gMG biological agent' is referenced, it refers to ravulizumab.

The term 'MGFA' refers to Myasthenia Gravis Foundation of America, 'MGC' refers to Myasthenia Gravis Composite and 'MG-ADL' refers to Myasthenia Gravis-Activities of Daily Living.

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** treatment of treatment refractory gMG.

After an authority application for **initial** treatment has been approved, applications for **continuing treatment** for treatment refractory gMG can be made in real time 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.

The following are settings and time limits where a gMG biological agent is PBS-subsidised:

1. 3 months of acute treatment - 'acute severe gMG'
2. 6 months of bridging therapy - 'bridging therapy for gMG'
3. Continuous therapy - 'treatment refractory gMG'

A patient may transition sequentially from one phase to another where all criteria are met (for example, **1** to **2** to **3**) but cannot return to an earlier treatment setting.

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.

Treatment specifics

Appropriate number of vials should be requested based on the patient's weight, according to the specified dosage in the Therapeutic Goods Administration (TGA) approved Product Information (PI). Dose and dosing frequency must not exceed that specified in the TGA-approved PI. An appropriate amount of drug (maximum quantity in units) may require prescribing both strengths. A separate authority prescription form must be completed for each strength requested.

This treatment must provide **no more than 6 months** of therapy per initial authority application under this restriction.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

15 The patient:

is receiving concomitant treatment with a non-steroidal immunosuppressant (NS-IST)

or

has had a thymectomy

16 Is the patient receiving concomitant treatment with any of the following: (i) another gMG biological agent, (ii) intravenous immunoglobulin (IVIg), (iii) plasma exchange (PLEX), (iv) rituximab for this condition?

Yes

No

17 The patient:

has not received treatment with a gMG biologic within 3 months prior to the first authority application for gMG in treatment refractory setting

and

has undergone **2** of the following 3 remission inducing treatments with:

NS-IST for **at least 12 months**

and/or

oral corticosteroids for **at least 12 months**

and/or

a thymectomy

or

is considered by the treating clinician to have deteriorating gMG disease during a treatment break with a gMG biological agent

and

has undergone **2** of the following 3 remission inducing treatments with:

NS-IST for **at least 9 months**

and/or

oral corticosteroids for **at least 9 months**

and/or

a thymectomy

18 Provide details of remission inducing treatments with:

NS-IST

Tick one only

azathioprine

ciclosporin

cyclophosphamide

methotrexate

mycophenolate

tacrolimus

Dose

From (DD MM YYYY)

To (DD MM YYYY)

and/or

oral corticosteroids

Name of steroid

Dose

From (DD MM YYYY)

To (DD MM YYYY)

and/or

a thymectomy

Date (DD MM YYYY)

19 Despite having undergone 2 remission-inducing treatments, the patient has a:

MG-ADL score of at least 6

Baseline MG-ADL score

Date of assessment (DD MM YYYY)

and

MGC score of at least 10

Baseline MGC score

Date of assessment (DD MM YYYY)

20 Will the treatment provide more than 6 months of therapy per initial authority application (including loading and maintenance doses) under treatment refractory gMG?

Yes

No

Checklist

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

Details of the proposed prescription(s).

Privacy notice

22 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

23 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)

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



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