Australian Government
Services Australia

medicare

PBS

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 or zilucoplan 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 and zilucoplan.

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 and zilucoplan

These items are 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.

These items are 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

For **ravulizumab** applications, an 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**

Australian Government
Services Australia

medicare

PBS

Generalised myasthenia gravis – treatment refractory initial authority application

Online PBS Authorities

You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to **servicesaustralia.gov.au/hppbsauthorities**

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)

Alternative phone number (including area code)

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 This application is for:

- ☐ ravulizumab ▶ ***Go to 11***
- ☐ zilucoplan ▶ ***Go to 12***

11 Does the patient require a loading dose?

- Yes ☐ ▶ Provide separate prescriptions for loading and maintenance doses
- No ☐ ▶ Provide prescription(s) for maintenance doses

12 The patient is being treated by a prescriber who is a:

- ☐ neurologist
- ☐ clinical immunologist with expertise in the treatment of myasthenia gravis
- ☐ medical practitioner in consultation with one of the above specialist types

13 The patient has a:

- ☐ diagnosis of MGFA Disease Class II to IV

and

- ☐ positive serology for acetylcholine receptor (AChR) binding autoantibodies

14 Is the patient experiencing a myasthenic crisis?

- Yes ☐
- No ☐

MCA0PB396 2604

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) immunoglobulin, (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 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)

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

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

Reset form