

Generalised myasthenia gravis – bridging therapy 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, rozanolixizumab or zilucoplan as **bridging therapy** for patients with generalised myasthenia gravis (gMG).

Important information

Authority applications for PBS-subsidised **bridging therapy** 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 **bridging therapy** for gMG authority applications.

Where the term 'gMG biological agent' is referenced, it refers to ravulizumab, rozanolixizumab 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 **bridging therapy**.

After an authority application for **bridging therapy** has been approved, applications for **continuous therapy** 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, rozanolixizumab 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.

Patient must **not** receive **more than 6 months** of bridging treatment with any gMG biological agent under this restriction.

For more information

Go to servicesaustralia.gov.au/healthprofessionals



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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

rozanolixizumab

▶ Go to 12

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

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 an oral corticosteroid?

Yes

No

17 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



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18 The patient has undergone 2 of the following 3 remission inducing treatments with:

NS-IST for 3 months

Tick one only

- azathioprine
- ciclosporin
- cyclophosphamide
- methotrexate
- mycophenolate
- tacrolimus

Dose

From (DD MM YYYY)

To (DD MM YYYY)

and/or

oral corticosteroids for 3 months

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

MG-ADL score

Date of assessment (DD MM YYYY)

and

MGC score of at least 10

MGC score

Date of assessment (DD MM YYYY)


A retrospective assessment for one of the MGC score or MG-ADL score can be accepted in cases where it was not conducted after completing 3 months of remission inducing treatments.

20 Will the patient receive more than 6 months of bridging treatment with any gMG biological agent under PBS-subsidised bridging therapy for 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)



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