



## **PBAC Consumer Submission for Ultomiris® Ravulizumab for MG patients** **There is still time to make your submission!**

The Pharmaceutical Benefits Advisory Committee (PBAC) will assess a new treatment called *Ultomiris*® (Ravulizumab) for generalised Myasthenia Gravis patients at its [meeting in March 2024](#). This evaluation considers how Ravulizumab can be both accessible and affordable for all MG patients in Australia.

This document provides more information about Ravulizumab and more guidance for your personal submission. It follows information from the Myasthenia Alliance Australia (MAA) to the Australian MG community in December 2023. Please read through this earlier information in addition to the below.

You can make your submission to PBAC by **Wednesday, 31 January 2024** through the **online form [here](#)**. If you have any technical issues with completing the form, **send an email** directly to [commentsPBAC@health.gov.au](mailto:commentsPBAC@health.gov.au).

### **More about Ravulizumab\*\***

Ultomiris® Ravulizumab is a **long-acting complement C-5 inhibitor treatment** that is being proposed as an **add-on to standard therapy** (including immunosuppressants like corticosteroids, methotrexate, mycophenolate, and azathioprine). Please note the evaluation at this stage concerns Ravulizumab **for AChR-positive MG patients**. This remains important and exciting for us all as patients because we have not seen a new treatment for a long time.

Ravulizumab represents a **new pathway** in treating MG in a **safe and fast-acting** manner as demonstrated by its clinical trial. It is also a **manageable option** for MG patients; generally an **8-weekly treatment cycle of 45-minute infusions**.

For more information, please see the **attached Consumer Medicine Information**, a TGA-approved document, and the following Australian Government links:

<https://www.tga.gov.au/resources/auspmd/ultomiris> (approval for another condition);  
<https://www.healthdirect.gov.au/medicines/brand/amt,1405341000168107/ultomiris>

### **What is important and useful for your submission?**

Your submission to PBAC can be broken down into two parts:

1. In the first part, you **tell your story** about living with MG and the current treatments you take/receive.
2. In the second part, you focus on the **advantages and disadvantages of the treatment, Ravulizumab**.

Remember - you don't have to have had or tried using Ravulizumab to make a submission. This second part can talk about your **unmet needs** with current treatments and the **desired**



**benefits** of this treatment... if you can imagine any treatment providing you with better management of your symptoms and better quality of life, this is where you can talk about it!

Your submission does *not* need to go into technical or scientific detail about the treatment. What you can do is **share the patient experience of living with MG** and what you feel are the best future outcomes for managing your symptoms and side effects as well as improving, or maintaining, your quality of life.

It is useful for you to think about **how and why living with MG is a burden for you, or how it prevents you from doing things** including work, study, or daily activities. **Provide specific examples of these where you can.** We also encourage you to **describe what “not well-controlled” MG looks like from the patient perspective** especially as this can vary amongst us.

Some questions to think about (you don't have to answer them all!):

- Has the pathway to your diagnosis or does your current treatment come with a **high burden** and what does this look like?
- What are your **symptoms and do you manage them well?**
- Does your MG **impact your ability** to go to work or school, or have a social life? Are you isolated at home, unable to prepare meals or do housework, or did a family member have to give up work to care for you? How long does it take you to get ready to go out? How many days do you take off work for medical appointments?
- What **adjustments** have you had to make in your life since you were diagnosed with MG? Does having MG and your current treatment regime impact your ability to travel or take holidays away from home?
- Is your MG **fluctuating**, making you feel **uncertain**, or do you feel you do not have control of your MG?
- Are you seeking a **more manageable treatment option** in terms of less frequent and less intrusive delivery or minimal side effects?

Also see the below tips, thanks to the Patient Voice Initiative (PVI):

1. **Do share what you know** (don't cut and paste)
2. **Be specific** (don't give general information)
3. **Do explain the difficulties of having a rare disease** (don't give number of cases, unless you disagree with the number given)
4. **Do explain the reality of living with the condition** (don't explain the condition)
5. **Do explain the reality of having (or not having) treatment** (don't explain the treatment)
6. **Do submit what happens in the real world** (don't submit clinical data)
7. **Do submit the numbers that matter to you** (don't submit published literature and statistics)

A reminder that **the MAA will make a submission as the national organisation** representing and advocating for MG patients. **Your individual submission adds to this** by presenting your



unique experiences and concerns living with MG. Also, please send us a copy of your submission confirmation if you feel comfortable doing so: [info@mgaq.org.au](mailto:info@mgaq.org.au)

Kind regards,  
Susan White (MAA Chairperson)  
Natalie Windle (MAA Secretary & MGNSW President)  
Carol Buchanan (MGAQ President)

***\*\*Please note the MAA and state associations do NOT provide medical advice regarding medications or treatments for individuals. Decisions about whether Ravulizumab will be suitable for you as a patient must be discussed with your doctor or health professional. The focus of these submissions to PBAC is to describe our patient perspective of living with MG and where/how/why we feel we have unmet needs, uncertainty, and ongoing burden with current treatment options.***

***More information and tips*** about making a PBAC submission can be found through the Rare Voices Australia (RVA) and Patient Voice Initiative (PVI) websites:

<https://rarevoices.org.au>

<https://www.patientvoiceinitiative.org> and

<https://www.patientvoicehub.org/training/index.cfm?event=page.login>