



PBAC Consumer Submission for *Zilbrysq*[®] (zilucoplan) for MG patients

The Pharmaceutical Benefits Advisory Committee (PBAC) will assess a new treatment called *Zilbrysq*[®] (zilucoplan) for acetylcholine receptor autoantibody positive (AChR+) generalised Myasthenia Gravis patients at its [meeting in July 2024](#). The Myasthenia Alliance Australia (MAA) encourages MG patients and carers or families/friends to **consider making a personal submission by 29 May highlighting the lived experience**.

This PBAC meeting includes consideration of funding and prescribing criteria for zilucoplan. The MAA wants to ensure that beneficial treatments like this are available at an affordable and therefore accessible price. **The MAA will make a submission on your behalf as the organisation representing all MG patients, outlining the overall evidence of our lived experience.**

Individual and personal submissions add to this by demonstrating the diversity of our experience with MG and the importance of having different treatment options to give us the best care and quality of life. We appreciate this may mean you have to think about some tough or difficult times and experiences, so please allow yourself space to do this or talk to someone about it.

The MAA believes this is an important opportunity to **share our voice and lived experience** with national decision makers. It is also an exciting time for new treatment options for MG and we want to ensure that these are **available, accessible, and affordable**. This aligns with Priority 2.4 of the [National Strategic Action Plan for Rare Diseases](#): Enable all Australians to have equitable access to the best available health technology.

Who: Myasthenia Gravis patients (and their carers or families/friends) can make a consumer submission to contribute to the PBAC evaluation of a new treatment: *Zilbrysq*[®] (zilucoplan). PBAC is the regulatory body that recommends new medicines for listing on the Pharmaceutical Benefits Scheme (PBS) based on medical conditions, clinical effectiveness, safety, and cost-effectiveness.

What: We are in the midst of an exciting time for new treatments for MG. *Zilbrysq*[®] (zilucoplan) is a complement C5 inhibitor treatment, intended as an add-on treatment for AChR+ generalised Myasthenia Gravis adult patients. (See more details below).

When: You can make a submission until **Wednesday, 29 May 2024**.

How: Complete the **online form [here](#)**. If you have issues with using the online form, you can **send an email** directly to commentsPBAC@health.gov.au. There are 5 questions to guide your response covering your experience living with MG, current treatments, and the potential advantages and disadvantages of the new treatment.



Why: Because **the patient voice matters**. Our involvement in these assessment processes “ensures that the advice provided is informed by the needs of the people living with health conditions” ([Conversations for Change Report](#), 2023, p.1). This is also taking action on our other key theme **“Nothing about us without us”**.

More about zilucoplan*

Zilucoplan is a once-daily, self-administered subcutaneous injection of a complement C5 inhibitor treatment. A subcutaneous injection is an injection into the tissue between the skin and the underlying muscle.

Please note the PBAC evaluation at this stage concerns zilucoplan as an add-on treatment **for AChR-positive generalised MG adult patients**. Zilucoplan is not yet available in Australia as it is still under evaluation by the Therapeutic Goods Administration (TGA), but it has been approved by health authorities in other countries such as USA, Europe and Japan. This is important for us all as patients because research is evolving and we have not seen new treatment options for a long time.

Zilucoplan represents a **new pathway** to treat MG in a **fast-acting** and **manageable manner**. The **daily self-administered injection can provide flexibility** for MG patients by reducing hospital visits and for planning extended travel.

What can you do? What should you include in 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, zilucoplan**.

You don't have to have had or tried using zilucoplan to make a submission. Our submissions ensure that our voice and lived experience is part of the process. In the second part you 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. Think about the outcomes that matter most to us as patients for *any* treatment and how a treatment might make a difference in our lives.

Think about **how and why living with MG might be 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 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 how do you manage them?** Are they well-managed?
- How 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 trips to the hospital, less intrusive delivery or minimal side effects? Are you seeking innovative ways to manage your MG?
- If appropriate, and guided by your doctor, how do you feel about the **potential to reduce other medications or treatments** you may be taking for MG? What impact would this have on your general health and wellbeing?

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. If you feel comfortable doing so, please send us a copy of your submission confirmation (you can send us the email copy you receive once submitted): info@mgaq.org.au

Kind regards,

Susan White (MAA Chairperson)

Natalie Windle (MAA Secretary & MGNSW President)

Carol Buchanan (MAA Board Member & MGAQ President)



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>

Please note: Where the questionnaire asks you about *PERSONAL CONFLICT OF INTEREST*, this does *NOT* detract from your submission but ensures an understanding of the context of your views as part of a fair and transparent assessment process.

***The MAA and state associations do NOT provide medical advice regarding medications or treatments for individuals.** Decisions about whether zilucoplan 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/or ongoing burden with current treatment options.