

30 January 2024

Professor Andrew Wilson
Chair, Pharmaceutical Benefits Advisory Committee (PBAC)
MDP 952, GPO Box 9848
Canberra, ACT 2601
Email: pbac@health.gov.au

Dear Professor Wilson,

Re: Change to PBS listing of MEPOLIZUMAB Nucala® for uncontrolled severe asthma

Please find below the joint submission from Allergy & Anaphylaxis Australia (A&AA) and the National Allergy Council to the Pharmaceutical Benefits Advisory Committee (PBAC) on changes requested by GlaxoSmithKline Australia Pty Ltd to the Pharmaceutical Benefits Scheme listing of mepolizumab (Nucala®) for uncontrolled severe asthma.

We support the requested changes for:

- initial treatment to change from Authority Required (Written) to Authority Required (Telephone/Online),
- continuing treatment to change from Authority Required (Written) to Authority Required (STREAMLINED) for the treatment of uncontrolled severe asthma.
- the current requirement for treating with oral corticosteroids (either daily oral corticosteroids for at least 6 weeks, OR a cumulative dose of oral corticosteroids of at least 500 mg prednisolone equivalent in the previous 12 months, unless contraindicated or not tolerated) as part of optimised asthma therapy for the initial treatment of uncontrolled severe asthma.

It is known that oral corticosteroids can have severe long term health effects which are related to dose. Both our organisations have the patient's wellbeing as our focus, which is why we support the application for mepolizumab to be prescribed without the requirement for such a large preceding dose of oral corticosteroids. Mepolizumab has a proven efficacy and safety record, and we support patients having access to this in a timely manner without first taking large doses of a medication which is known to have the potential for harm.

People with uncontrolled severe asthma have a reduced quality of life¹. Mepolizumab has the ability to improve this and therefore any reduction in barriers to access is welcome. The proposed changes to the process of acquiring both an initial and a continuing authority prescription should help with this.

The proposed change to initiate authority and then ongoing treatment with mepolizumab will enable people with severe uncontrolled asthma access to optimal treatment for a potentially life-threatening condition in a timely manner.

¹ Hossny, E., Caraballo, L., Casale, T., El-Gamal, Y., & Rosenwasser, L. (2017). Severe asthma and quality of life. *The World Allergy Organization Journal*, 10(1), 28–28. <https://doi.org/10.1186/s40413-017-0159-y>

We acknowledge the challenges of the Australian government and the many health conditions needing urgent attention and funding, however, we cannot ignore the severe impact of uncontrolled severe asthma in Australians with allergic disease.

Background

[Allergy & Anaphylaxis Australia](#) (A&AA) is a charitable, non-profit organisation established in 1993 to support those affected by allergic disease including allergic asthma. A&AA is dedicated to assisting individuals, their caregivers and all in the community in the management of allergic conditions. A&AA's aim is to enable individuals and their families to enjoy an optimal quality of life whilst minimising risk to their health and wellbeing.

A&AA strives to raise awareness of allergic disease in the community and provides evidence-based information, resources and services to support children and adults living with allergic disease and those who care for them. A&AA has members across all states and territories of Australia. We have a Medical Advisory Board that consists of clinical immunology/allergy specialists who are also members of Australia's peak medical body, ASCIA (Australasian Society of Clinical Immunology and Allergy).

The [National Allergy Council](#) is a partnership between the Australasian Society of Clinical Immunology and Allergy (ASCIA) and A&AA, the peak medical and patient support organisations. The National Allergy Council implements the National Allergy Strategy. As part of these projects, we deliver a wide range of educational resources and training programs. Through implementation of the National Allergy Strategy, we aim to improve the health and wellbeing of Australians with allergic diseases, and minimise the burden of allergic diseases on individuals, their carers, healthcare services and the community.