

20 May 2025

Pharmaceutical Benefits Advisory Committee (PBAC)

Dear PBAC,

Re – Nemolizumab (Nemluvio®) - a Galderma Australia Pty Ltd product

On behalf of Allergy & Anaphylaxis Australia (A&AA), the Australasian Society of Clinical Immunology and Allergy (ASCIA) and the National Allergy Council, we write in support of the application from Galderma, for Pharmaceutical Benefits Scheme (PBS) listing of nemolizumab (Nemluvio®) as outlined in the table below, for review at the July 2025 PBAC meeting:

<p>NEMOLIZUMAB Powder for injection containing nemolizumab 30 mg with diluent in pre-filled dual-chamber pen Nemluvio® GALDERMA AUSTRALIA PTY LTD (New PBS listing)</p>	<p>Atopic dermatitis</p>	<p>To request a General Schedule Authority Required (Telephone/Online) listing for the treatment of patients with severe atopic dermatitis affecting the whole body, face, and/or hands.</p>
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We welcome the opportunity to provide our comments in support of this application, for the following reasons:

- Severe atopic dermatitis is a devastating disease that has profound effects on both physical and mental health. It can impact an individual's ability to work and often results in social isolation with poor sleep and low self-esteem contributing to a poor quality of life. Itch is often cited as a major debilitating component of atopic dermatitis, greatly affecting sleep and resulting in broken painful skin and an increased risk of infection.
- People with severe atopic dermatitis should be able to have equitable access to the most appropriate treatments for them. It is important we consider the burden on the person with the chronic condition, their family and the healthcare system when considering registration and PBS listing of medications proven to improve health and wellbeing.
- A&AA have been contacted by many patients with severe atopic dermatitis for whom the 2021 PBS listing of dupilumab has been life changing. Dupilumab is a monoclonal antibody blocking interleukin 4 and interleukin 13 receptor signalling.
- Nemolizumab is a monoclonal antibody that acts as an interleukin 31 antagonist. Clinical trials have shown that nemolizumab effectively disrupts the itch-scratch cycle in chronic pruritic skin conditions. Therefore, whilst both dupilumab and nemolizumab are monoclonal antibodies, their method of action is different. As nemolizumab has a different method of action than any other currently available treatment for this condition, it may assist with improved management and therefore, improve quality of life, for some people with severe atopic dermatitis, including those who have tried other treatments. There are also differing dosing schedules as well as apparent differences with side effect profile that may be beneficial for some people with severe atopic dermatitis.

- It is important that patients and their treating doctors have a choice of treatments that best suit the disease state and the person taking it.

We thank the PBAC for the opportunity to provide our comments, and hope that the PBAC will give due consideration to this letter of support for the application from Galderma for PBS funding of **Nemolizumab (Nemluvio®)** for the treatment of severe atopic dermatitis.

Please contact us if you require additional information.

Yours sincerely,

Ms Maria Said AM
CEO
Allergy & Anaphylaxis
Australia

Dr Sandra Vale
CEO
National Allergy
Council

Ms Jill Smith
CEO
ASCIA

About our organisations

Allergy & Anaphylaxis Australia (A&AA) is a registered charity, established in 1993, to inform and support those affected by allergic disease including atopic dermatitis, commonly known as eczema. 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. We are a part of an international alliance of like-minded organisations and work closely with peak medical bodies including ASCIA.

The **Australasian Society of Clinical Immunology and Allergy (ASCIA)** was established in 1990 as the peak professional body for clinical immunology and allergy in Australia and New Zealand. ASCIA's purpose is to advance the science and practice of allergy and clinical immunology, by promoting the highest standard of medical practice, training, education and research.

The **National Allergy Council** is a partnership between ASCIA and A&AA as the peak medical and patient support organisations in Australia and is funded by the Australian Government Department of Health and Aged Care to implement the National Allergy Strategy. The National Allergy Council aims to deliver public health initiatives so that people with allergic conditions can live safe and inclusive lives.