



12 March 2025

Pharmaceutical Benefits Advisory Committee (PBAC)

Dear PBAC,

Re – Omalizumab (Xolair®) - a Novartis Pharmaceuticals Australia Pty Ltd product

Novartis Pharmaceuticals have applied to request a Section 100 (Highly Specialised Drugs Program) Authority Required (Written) listing for the initial treatment and an Authority Required (Telephone/Online) listing for the continuing treatment of patients with chronic rhinosinusitis with nasal polyps (CRSwNP).

Allergy & Anaphylaxis Australia (A&AA) and the National Allergy Council welcome the opportunity to lodge our comments in support of this submission for Omalizumab (Xolair®) which is on the May 2025 Pharmaceutical Benefits Advisory Committee (PBAC) meeting agenda.

A&AA is a registered charity, established in 1993, to inform and support those affected by allergy and anaphylaxis. 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 the Australasian Society of Clinical Immunology and Allergy (ASCIA). The National Allergy Council is a partnership between ASCIA and A&AA as the peak medical and patient support organisations in Australia and funded by the Australian Government Department of Health and Aged Care to implement the National Allergy Strategy.

Chronic rhinosinusitis with nasal polyps is a condition that can greatly impact quality of life. There are treatments available for this condition but for some, the treatments are ineffective or only short lived. The listing of Omalizumab on the Pharmaceutical Benefits Scheme (PBS) would offer these patients hope for an improvement in their debilitating condition.

Patients with chronic rhinosinusitis with nasal polyps have often endured years of different treatments including nasal sprays, oral medication, and even nasal polyp surgery, only to have the polyps regrow and the symptoms recur. The signs and symptoms include a runny nose, persistent congestion, postnasal drip, reduced sense of smell and taste, headache, toothache, facial pain, bad breath and/or bad taste in the mouth, snoring, and nosebleeds. Potential complications include obstructive sleep apnoea, asthma flares and recurrent sinus infections. It can result in poor sleep, reduced productivity at work or school, reduced mood, and self-esteem issues.

Often this condition is associated with allergic conditions and these patients may be under the care of both a specialist clinical immunologist/allergist as well as an Ear Nose and Throat (ENT) surgeon. Many have endured repeated nasal polyp removal surgeries. The requirement for

repeated surgery is associated with the risk of complications that is present for any surgical procedure, as well as the monetary cost of the surgery and the recovery time off work. Many patients have also tried multiple different costly medical therapies. These patients have a reduced quality of life due to their condition, and they also have the added financial burden of using these less successful medical therapies. Until recently, the medical therapies have mainly consisted of intranasal and oral corticosteroids, allergen immunotherapy and antibiotics. There are well documented risks associated with long term oral corticosteroid and antibiotic use.

In 2022 Mepolizumab was approved for use in this condition and for many this drug has resulted in a significant improvement in their symptoms and quality of life. Whilst Omalizumab is a similar type of drug to Mepolizumab, there are differences which mean that Omalizumab could be prescribed to people for whom Mepolizumab is unsuitable.

Omalizumab has been well researched and is already listed on the PBS for other conditions, including chronic spontaneous urticaria and asthma where it has been successful in improving patients' quality of life. We ask that those patients with chronic rhinosinusitis with nasal polyps are given the same opportunity to access this medication if their treating clinical immunology/allergy specialist, ENT surgeon or respiratory physician thinks it may offer them some relief. As Omalizumab 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. 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.

Allergy & Anaphylaxis Australia and the National Allergy Council support the PBS listing of Omalizumab so that people with chronic rhinosinusitis with nasal polyps can, together with their treating medical specialist and surgeon, decide on the most appropriate treatment for them. It is important we consider the burden on the person with the chronic condition and the healthcare system when broadening the scope of trusted medicines that have been proven to improve health and wellbeing.

Yours sincerely,

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