



australasian society of clinical immunology and allergy

10 March 2025

Chair, Pharmaceutical Benefits Advisory Committee (PBAC)
Department of Health and Aged Care
GPO Box 9848 Canberra ACT 2601
Email: pbac@health.gov.au

Dear PBAC Chair,

Re: PBS listing of Xolair® (omalizumab) for chronic rhinosinusitis with nasal polyps

On behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA) we are writing in support of the request by Novartis Pharmaceuticals Australia Pty Ltd for Pharmaceutical Benefits Scheme (PBS) listing of Xolair® (omalizumab) for chronic rhinosinusitis with nasal polyps (CRSwNP), as outlined in the table below, for review at the May 2025 PBAC meeting.

Table with 3 columns: Product details (OMALIZUMAB, various injection and pen formulations, Novartis Pharmaceuticals Australia Pty Limited), Indication (Chronic rhinosinusitis with nasal polyps (CRSwNP)), and Request details (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 CRSwNP).

Chronic rhinosinusitis (CRS) is defined as an inflammation of the paranasal sinuses for more than 12 weeks, localised or diffuse. It is one of the most common chronic conditions worldwide, present in 2-4% of the adult population, increasing with age and other co-morbidities. CRS with Nasal Polyps (CRSwNP) is one of the main subgroups of CRS.

ASCIA supports this request for PBS listing of Xolair® for CRSwNP for the following reasons:

- CRSwNP has a significant impact on quality of life especially when atopic diseases, asthma or other comorbidities are present.
• Many patients with CRSwNP remain sub-optimally controlled and require surgical management.
• PBS listing of Xolair® (omalizumab), a targeted biologic therapy for CRSwNP with acceptable safety profiles, is likely to be steroid-sparing and reduce the number of surgical procedures for patients.

- PBS listing of Xolair® (omalizumab) for CRSwNP would enable patients to change to another biologic therapy if they have a sub-optimal response to other treatments.

Omalizumab is already used to treat other conditions (chronic spontaneous urticaria and uncontrolled severe asthma), and has been one of the most effective treatments for clinical immunology/allergy specialists to prescribe.

To provide guidance to prescribers regarding appropriate use of targeted biologic therapies for CRSwNP, such as Xolair® (omalizumab), ASCIA has developed a [CRSwNP Position Paper](#) (including a treatment algorithm) which is available open access on the ASCIA website

Please email jill@allergy.org.au if you require additional information.

Yours sincerely,

Dr Michael O'Sullivan
ASCIA President

Jill Smith
ASCIA CEO