australasian society of clinical immunology and allergy

23 January 2025

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

Dear PBAC Chair,

Re: PBS listing of a new strength of Xolair® (omalizumab)

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 the Pharmaceutical Benefits Scheme (PBS) listing of a new strength of Xolair® (omalizumab), as outlined in the table below, for review at the March 2025 PBAC meeting.

OMALIZUMAB Injection 75 mg in 0.5 mL single dose pre-filled syringe Injection 150 mg in 1 mL single dose pre-filled syringe Injection 300 mg in 2 mL single dose pre-filled syringe Injection 75 mg in 0.5 mL single dose pre-filled pen Injection 150 mg in 1 mL single dose pre-filled pen Injection 300 mg in 2 mL single dose pre-filled pen Xolair® NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED (New PBS listing)	Uncontrolled severe asthma Uncontrolled severe allergic asthma Severe chronic spontaneous urticaria	To request Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new strength and new forms of omalizumab for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria.

ASCIA supports this request for the following reasons:

- The use of omalizumab for the treatment of chronic spontaneous urticaria (CSU) has been one of the most effective treatments for clinical immunology/allergy specialists to prescribe.
- Omalizumab is also an effective treatment of uncontrolled severe asthma and uncontrolled severe allergic asthma.
- Having multiple strengths of omalizumab available on the PBS mitigates against the risk of supply issues and provides more flexibility in dosing.

Yours sincerely,

Dr Michael O'Sullivan
ASCIA President

Jill Smith
ASCIA CEO

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