

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: New PBS listing of Omlyclo® (omalizumab)

On behalf of the Australasian Society of Clinical Immunology and Allergy (ASCIA) we are writing in support of the request by Celltrion Healthcare Australia Pty Ltd for the Pharmaceutical Benefits Scheme (PBS) listing of Omlyclo® (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

Omlyclo[®]

CELLTRION HEALTHCARE AUSTRALIA PTY LTD

(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 an omalizumab biosimilar for the treatment of uncontrolled severe asthma, uncontrolled severe allergic asthma, and severe chronic spontaneous urticaria, under the same conditions as its reference biologic.

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 brands and 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 Jill Smith
ASCIA President ASCIA CEO

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