

29 January 2025

Chair, Pharmaceutical Benefits Advisory Committee (PBAC)
Department of Health and Ageing
GPO Box 9848 Canberra ACT 2601

Dear PBAC Chair,

RE: New PBS listing of Omlyclo® (omalizumab)

We are writing on behalf of the National Allergy Council and Allergy & Anaphylaxis Australia, in support of the request by Celltrion Healthcare Australia Pty Ltd for the Pharmaceutical Benefits Scheme (PBS) listing of Omlyclo® (omalizumab) as follows:

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 for: Omalizumab (Omlyclo®) Injection 75 mg in 0.5 mL single dose pre-filled syringe; Injection 150 mg in 1 mL single dose pre-filled syringe, for: Uncontrolled severe asthma; Uncontrolled severe allergic asthma; Severe chronic spontaneous urticaria.

We support this request to ensure equitable access to Omlyclo®, a medication which is one of the most effective treatments for Chronic Spontaneous Urticaria (CSU), in addition to uncontrolled severe asthma and uncontrolled severe allergic asthma. Multiple dose availability supports appropriate dosing and can help reduce supply issues.

Kind regards,

Ms Maria Said AM
CEO
Allergy & Anaphylaxis Australia

Dr Sandra Vale
CEO
National Allergy Council