Australian Government
Department of Health, Disability and Ageing
Therapeutic Goods Administration

Australian Public Assessment Report for OMLYCLO

Active ingredient: Omalizumab

Sponsor: Celltrion Healthcare Australia Pty Ltd

July 2025

About the Therapeutic Goods Administration (TGA)

- The Therapeutic Goods Administration (TGA) is part of the Australian Government Department of Health, Disability and Ageing and is responsible for regulating therapeutic goods, including medicines, medical devices, and biologicals.
- The TGA administers the *Therapeutic Goods Act 1989* (the Act), applying a risk management approach designed to ensure therapeutic goods supplied in Australia meet acceptable standards of quality, safety, and efficacy.
- The work of the TGA is based on applying scientific and clinical expertise to decision-making, to ensure that the benefits to the Australian public outweigh any risks associated with the use of therapeutic goods.
- The TGA relies on the public, healthcare professionals and industry to report problems with therapeutic goods. The TGA investigates reports received to determine any necessary regulatory action.
- To report a problem with a therapeutic good, please see the information on the TGA website.

About AusPARs

- The Australian Public Assessment Report (AusPAR) provides information about the evaluation of a prescription medicine and the considerations that led the TGA to approve or not approve a prescription medicine submission. Further information can be found in Australian Public Assessment Report (AusPAR) guidance.
- AusPARs are prepared and published by the TGA.
- AusPARs are static documents that provide information that relates to a submission at a particular point in time. The publication of an AusPAR is an important part of the transparency of the TGA's decision-making process.
- A new AusPAR may be provided to reflect changes to indications or major variations to a prescription medicine subject to evaluation by the TGA.

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List of abbreviations

Abbreviation	Meaning
ARTG	Australian Register of Therapeutic goods
ASA	Australia-Specific Annex
CRSwNP	Chronic rhinosinusitis with nasal polyps
CSU	Chronic spontaneous urticaria
EMA	European Medicines Agency
PD	pharmacodynamic(s)
PI	Product Information
PK	pharmacokinetic(s)
RMP	Risk Management Plan
SC	Subcutaneous
SE	Standard error
TGA	Therapeutic Goods Administration

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OMLYCLO (omalizumab) submission

Type of submission:	New biosimilar
Product name::	OMLYCLO
Active ingredient:	Omalizumab
Decision:	Approved
Date of decision:	21 November 2024
Approved therapeutic use for the current submission:	**Allergic Asthma** *Children 6 to < 12 years of age:* In children aged 6 to <12 years, OMLYCLO is indicated as add-on therapy to improve asthma control in patients with severe allergic asthma who have documented exacerbations despite daily high dose inhaled corticosteroids, and who have immunoglobulin E levels corresponding to the recommended dose range (see Table 1 in Section 4.2 DOSE AND METHOD OF ADMINISTRATION). *Adults and adolescents ≥ 12 years of age:* OMLYCLO is indicated for the management of adult and adolescent patients with moderate to severe allergic asthma, who are already being treated with inhaled steroids, and who have serum immunoglobulin E levels corresponding to the recommended dose range. **Chronic rhinosinusitis with nasal polyps (CRSwNP)** OMLYCLO is indicated as add-on treatment in adult patients (18 years of age and above) for the treatment of severe CRSwNP with inadequate response to intranasal corticosteroids. Recommended dosing is determined by serum immunoglobulin E levels and body weight corresponding to the recommended dose range in the Product Information (see Section 4.2 DOSE AND METHOD OF ADMINISTRATION) . **Chronic Spontaneous Urticaria (CSU)** OMLYCLO is indicated for adults and adolescents (12 years of age and above) with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment.
Date of entry onto ARTG:	26 November 2024
ARTG numbers:	427224, 427223
, *Black Triangle Scheme:*	No
Sponsor's name and address:	Celltrion Healthcare Australia Pty Ltd Suite 13-03 31 Market Street, Sydney NSW 2000

Dose form:	Solution for injection
Strength:	150 mg/mL, 75 mg / 0.5 mL
Container:	Pre-filled syringe comprising a type I glass syringe barrel with staked needle (stainless steel), rubber plunger stopper, and rigid needle shield composed of a rubber needle shield covered by a rigid shell. Each pre-filled syringe is mounted with a plastic safety device (needle guard) to prevent from needle stick injury.
Pack size:	1, 6 or 10 pre-filled syringes with needle guard.
Route of administration:	Subcutaneous (SC)
Dosage:	For information regarding dosage refer to the Product Information.
Pregnancy category:	Category B1 Drugs which have been taken by only a limited number of pregnant women and women of childbearing age, without an increase in the frequency of malformation or other direct or indirect harmful effects on the human fetus having been observed. The use of any medicine during pregnancy requires careful consideration of both risks and benefits by the treating health professional. The pregnancy database must not be used as the sole basis of decision making in the use of medicines during pregnancy. The TGA does not provide advice on the use of medicines in pregnancy for specific cases. More information is available from obstetric drug information services in your state or territory.

Proposed indication

This AusPAR describes the submission by Celltrion Healthcare Australia Pty Ltd (the Sponsor)[1] to register OMLYCLO (omalizumab), a biosimilar to XOLAIR, for the following proposed indications:

> ***Allergic Asthma***
> *Children 6 to < 12 years of age:*
> *In children aged 6 to <12 years, OMLYCLO is indicated as add-on therapy to improve asthma control in patients with severe allergic asthma who have documented exacerbations despite daily high dose inhaled corticosteroids, and who have immunoglobulin E levels corresponding to the recommended dose range.*
>
> *Adults and adolescents ≥ 12 years of age:*
> *OMLYCLO is indicated for the management of adult and adolescent patients with moderate to severe allergic asthma, who are already being treated with inhaled steroids, and who have serum immunoglobulin E levels corresponding to the recommended dose range.*

[1] A sponsor is a person or company who does one or more of the following: a) exports therapeutic goods from Australia, b) imports therapeutic goods into Australia, c) manufactures therapeutic goods for supply in Australia or d) elsewhere arranges for another party to import, export or manufacture therapeutic goods

Chronic rhinosinusitis with nasal polyps (CRSwNP)
OMLYCLO is indicated as add-on treatment in adult patients (18 years of age and above) for the treatment of severe CRSwNP with inadequate response to intranasal corticosteroids. Recommended dosing is determined by serum immunoglobulin E levels and body weight corresponding to the recommended dose range in the Product Information.

Chronic Spontaneous Urticaria (CSU)
OMLYCLO is indicated for adults and adolescents (12 years of age and above) with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment.

The conditions

Allergic asthma, chronic rhinosinusitis with nasal polyps and chronic spontaneous urticaria are IgE mediated allergic/atopic conditions.

Allergic asthma

Asthma is a chronic respiratory disease and is defined by the presence of both excessive variation in lung function confirmed via respiratory functions tests and variable respiratory symptoms such as wheeze, shortness of breath, cough and chest tightness. In young children where lung function is difficult to measure, asthma is determined by the presence of variable respiratory symptoms.[2]

Asthma is not a single disease, there are multiple phenotypes and different aetiologies, genetic and environmental risk factors. Allergic asthma is more likely when the person also has allergy and a family history of asthma. Common allergens include dust mites, moulds, furry animals, cockroaches, and pollens. Allergy tests can be helpful to confirm sensitivity to suspected allergic triggers and guide on-going management.

Chronic rhinosinusitis with nasal polyps

Chronic rhinosinusitis is an inflammation of the paranasal sinuses lasting 12 weeks or longer. CRSwNP is present in 2-4% of the adult population.

There are multiple aetiologies of CRSwNP. Patients with allergic aetiology often have an earlier onset (<20 years) and may have other signs of atopy including asthma.

Common symptoms include nasal obstruction or congestion (95% of patients), anterior or posterior postnasal drip (89%), reduction or loss of sense of smell (58%) due to occlusion of the olfactory nerve endings, and facial pain (60%).[3]

Chronic spontaneous urticaria

CSU is defined by the presence of recurrent urticaria (hives/wheals) for 6 weeks or longer. Urticaria involves transient raised pruritic lesions caused by mast cell degranulation in the superficial dermis. CSU refers to wheals arising spontaneously on most days of the week for six weeks or more and there is a lifetime prevalence of about 1.8% in the adult population.

[2] National Asthma Council. Australian Asthma Handbook: The National Guidelines for Health Professionals. 2024; Available from: https://www.asthmahandbook.org.au/

[3] Australian Society of Clinical Immunology and Allergy. Chronic Rhinosinusitis with Nasal Polyps (CRSwNP): Position Paper. 2021; Available from: https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Position_Paper_CRSwNP_2021.pdf.

Angioedema occurs with urticaria in about 40% of cases of CSU. Angioedema is a localised arising in deeper dermal layers, triggered either by mast cell-derived histamine or by bradykinin.[4]

Current treatment options

Allergic asthma

Depending on symptom severity, recommended pharmacological treatment for asthma involves a varying combination of short-acting beta agonists, long-acting beta agonists, inhaled corticosteroids and long-acting muscarinic antagonists. The Australian Asthma Handbook recommends omalizumab can be considered:[5]

- for adults and adolescents aged 12 years and over, with moderate-to-severe allergic asthma despite inhaled corticosteroid treatment, and raised IgE levels.
- for children aged 6 to 11 years with severe allergic asthma (documented exacerbations despite daily high-dose inhaled corticosteroids with or without another maintenance treatment) and raised IgE levels.

Chronic rhinosinusitis with nasal polyps

Management of CRSwNP traditionally includes saline sprays, intranasal corticosteroids and antihistamines and endoscopic sinus surgery.[6]

Chronic spontaneous urticaria

Around 80% of people with CSU go into spontaneous remission within 12 months without intervention. Symptom control includes suppression of itch and visible rash, and prevention of angioedema episodes.

Treatment options include sedating and non-sedating antihistamines, leukotriene antagonists, doxepin, omalizumab or other immunosuppressants.[7]

Clinical rationale

Regulatory status

Australian regulatory status

This product is a new biosimilar medicine for Australian regulatory purposes.

International regulatory status

At the time the TGA considered this submission, a similar submission had been considered by other regulatory agencies.

[4] Australian Society of Clinical Immunology and Allergy. Position Paper - Chronic Spontaneous Urticaria (CSU). 2020; Available from: https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Position_Paper_CSU_2020.pdf.

[5] National Asthma Council, 2024.

[6] Australian Society of Clinical Immunology and Allergy, 2021

[7] Healthdirect, Hives (urticaria), November 2023.

OMLYCLO was approved by the EMA in March 2024.[8]

On 21 March 2024, the Committee for Medicinal Products for Human Use adopted a positive opinion, recommending the granting of a marketing authorisation for the medicinal product OMLYCLO, intended for the treatment of severe persistent allergic asthma, CRSwNP and CSU.

Submissions have been made in the following jurisdictions in addition to Australia: Brazil, Switzerland, Canada, Turkey, United States, United Kingdom.

Registration timeline

Table 1 captures the key steps and dates for this submission.

This submission was evaluated under the standard prescription medicines registration process.

Table 1. Registration timeline for OMLYCLO (omalizumab)

Description	Date
Submission dossier accepted and evaluation commenced	30 November 2023
Evaluation completed	31 July 2024
Registration decision (Outcome)	21 November 2024
Registration in the ARTG completed	26 November 2024
Number of working days from submission dossier acceptance to registration decision*	251 days

*Statutory timeframe for standard submissions is 255 working days

Assessment overview

Quality evaluation summary

The Sponsor has demonstrated that OMLYCLO (is comparable to the reference product, XOLAIR, in terms of structure, species, function and degradation profile. There are no objections from a quality-perspective to the approval of OMLYCLO (omalizumab).

Nonclinical evaluation summary

The nonclinical dossier contained comparative repeat-dose toxicity study following SC dosing. The scope of the nonclinical program is adequate under the relevant TGA adopted EU guideline. The study was conducted using EU sourced XOLAIR as the reference product. No information was provided in Module 4 to verify the comparability of EU sourced and Australian-sourced XOLAIR.

No significant differences between toxicity profiles of OMLYCLO and EU-XOLAIR were observed in the comparative repeat-dose toxicity study in monkeys following SC dosing. Notable findings in the study comprised of increases in total IgE levels in monkeys following treatment with both

[8] European Medicines Agency, OMLYCLO, 2025.

OMLYCLO and XOLAIR, attributed to the pharmacological activity of omalizumab. Systemic omalizumab exposures were comparable following treatment with OMLYCLO and EU-XOLAIR.

Provided that EU-sourced XOLAIR is considered to be identical or highly comparable to the Australian product, there are no nonclinical objections to the registration of OMLYCLO.

Clinical evaluation summary

The key findings of the clinical development program include:

Efficacy: In study CT-P39 3.1, the estimate of the treatment difference 300 mg of CT-P39 and Xolair at week 12 in LS mean (SE) change from baseline in ISS7 scores was 0.70 with 90% CI [-0.22, 1.63] which was within the predefined therapeutic equivalence margins of [-2.5, 2.0]. The co-primary outcome of relative potency was unable to be evaluated.

Pharmacokinetics (PK): In study CT-P39 1.1: 90% CIs of the ratio of the geometric means for all PK primary endpoints were entirely contained within the equivalence limits of 80% to 125% across the CT-P39, EU-Xolair and US-Xolair groups.

Pharmacodynamic (PD): PD parameters were similar between the study and reference drugs under the conditions tested in the studies.

Safety/immunogenicity: There were no clinically important differences in the safety or immunogenicity profile between CT-P39 and Xolair in either healthy people or people with CSU.

Approval for OMLYCLO is recommended.

Risk management plan evaluation summary

The EU risk management plan (RMP) version 1.0 (date 02 April 2024; DLP 20 February 2023) & ASA version 1.1 (date 17 June 2024) for omalizumab (OMLYCLO) were submitted.

The updated RMP and the ASA provided are satisfactory.

The summary of safety concerns is outlined in Table 2:

Table 2. Summary of safety concerns

Summary of safety concerns	
Important identified risks	Anaphylaxis/anaphylactoid reactions
	Churg Strauss syndrome (CSS)/hypereosinophilic syndrome (HES)
Important potential risks	Arterial thromboembolic events (ATEs)
	Malignant neoplasms in adults and adolescents ≥ 12 years of age Malignant neoplasms (children 6 to less than 12 years old)
Missing information	None

Risk-benefit analysis

The therapeutic equivalence and PK equivalence have been satisfactorily demonstrated for OMLYCLO with acceptable PD and safety comparison. The overall benefit-risk profile for the omalizumab biosimilar OMLYCLO is positive.

Assessment outcome

Based on a review of quality, safety, and efficacy, the TGA decided to register OMLYCLO (omalizumab) for the following indications:

Allergic Asthma
Children 6 to < 12 years of age:
In children aged 6 to <12 years, OMLYCLO is indicated as add-on therapy to improve asthma control in patients with severe allergic asthma who have documented exacerbations despite daily high dose inhaled corticosteroids, and who have immunoglobulin E levels corresponding to the recommended dose range (see Table 1 in Section 4.2 DOSE AND METHOD OF ADMINISTRATION).

Adults and adolescents ≥ 12 years of age
OMLYCLO is indicated for the management of adult and adolescent patients with moderate to severe allergic asthma, who are already being treated with inhaled steroids, and who have serum immunoglobulin E levels corresponding to the recommended dose range (see Table 1 in Section 4.2 DOSE AND METHOD OF ADMINISTRATION).

Chronic rhinosinusitis with nasal polyps (CRSwNP)
OMLYCLO is indicated as add-on treatment in adult patients (18 years of age and above) for the treatment of severe CRSwNP with inadequate response to intranasal corticosteroids. Recommended dosing is determined by serum immunoglobulin E levels and body weight corresponding to the recommended dose range in the Product Information (see Section 4.2 DOSE AND METHOD OF ADMINISTRATION) .

Chronic Spontaneous Urticaria (CSU)
OMLYCLO is indicated for adults and adolescents (12 years of age and above) with chronic spontaneous urticaria who remain symptomatic despite H1 antihistamine treatment.

Product Information and Consumer Medicines Information

For the most recent Product Information (PI) and Consumer Medicines Information (CMI), please refer to the TGA PI/CMI search facility.

Therapeutic Goods Administration

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