

## **5.27 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<sup>®</sup>,**

**Celltrion Healthcare Australia Pty Ltd**

### **1. Purpose of Submission**

- 1.1. The Category 3 submission requested the listing of a new biosimilar brand of omalizumab (Omlyclo<sup>®</sup>) in the forms of 75 mg in 0.5 mL and 150 mg in 1 mL pre-filled syringe (PFS) under the same clinical criteria as the PBS-listed reference biologic, Xolair<sup>®</sup> in the forms of 75 mg in 0.5 mL and 150 mg in 1 mL PFS for the treatment of uncontrolled severe asthma (USA), uncontrolled severe allergic asthma (USAA), and severe chronic spontaneous urticaria (CSU). The submission requested that biosimilar uptake drivers (lower authority restrictions) be applied to Omlyclo.
- 1.2. Listing was requested on a cost-minimisation basis to Xolair.

### **2. Background**

- 2.1. Omlyclo, in the forms of 75 mg in 0.5 mL and 150 mg in 1 mL PFS, was TGA approved on 26 November 2024 for the treatment of allergic asthma (patients aged 6 to <12 and ≥12 years), CSU, and chronic rhinosinusitis with nasal polyps (CRSwNP).
- 2.2. The TGA document (page 2 of TGA delegate's overview) stated that Omlyclo is a biosimilar medicinal product to Xolair and satisfactory therapeutic and pharmacokinetic (PK) bioequivalence for Omlyclo compared to Xolair was demonstrated in clinical evidence, with comparable pharmacodynamics (PD) and safety.
- 2.3. Table 1 presents the key components of the current PBS listings for Xolair and the requested listings in the submission.

**Table 1: Current PBS listings of Xolair versus requested listings for Omlyclo:**

Xolair				Omlyclo				
Uncontrolled severe asthma								
Form(s)	Treatment Phase	PBS item code	Restriction level	Form(s)	Treatment Phase	PBS item code	Restriction level	
75 mg/0.5 mL PFS	Initial treatment	10118M	Authority Required (Written)	75 mg/0.5 mL PFS	Initial treatment	10118M	Authority Required (Written)	
150 mg/mL PFS		10110D		10109C		10110D		10109C
		10122R		10122R		10122R		
75 mg/0.5 mL PFS	Continuing treatment	11835X	Authority Required (Telephone/Online)	75 mg/0.5 mL PFS	Continuing treatment	<i>New/ Public</i>	Authority Required (STREAMLINED)	
150 mg/mL PFS		11840E		<i>New/ Private</i>				
		11824H		<i>New/ Public</i>				
		11864K				<i>New/ Private</i>		
75 mg/0.5 mL PFS	Balance of supply	11846L	Authority Required (Telephone/Online)	75 mg/0.5 mL PFS	Balance of supply	11846L	Authority Required (Telephone/Online)	
150 mg/mL PFS		11826K		11828M		11826K		11828M
		11828M		11825J		11825J		11825J
		11825J				11825J		
Uncontrolled severe allergic asthma in patients aged 6 to 12 years								
75 mg/0.5 mL PFS	Initial treatment	10967F	Authority Required (Written)	75 mg/0.5 mL PFS	Initial treatment	10967F	Authority Required (Written)	
150 mg/mL PFS		10956P		10973M		10956P		10973M
		10968G		10968G		10968G		
75 mg/0.5 mL PFS	Continuing treatment	11946R	Authority Required (Telephone/Online)	75 mg/0.5 mL PFS	Continuing treatment	<i>New/ Public</i>	Authority Required (STREAMLINED)	
150 mg/mL PFS		11952C		<i>New/ Private</i>				
		11945Q		<i>New/ Public</i>				
		11953D				<i>New/ Private</i>		
75 mg/0.5 mL PFS	Balance of supply	11962N	Authority Required (Telephone/Online)	75 mg/0.5 mL PFS	Balance of supply	11962N	Authority Required (Telephone/Online)	
150 mg/mL PFS		11958J		11950Y		11958J		11950Y
		11950Y		11932B		11932B		11932B
		11932B				11932B		
Severe chronic spontaneous urticaria								
150 mg/mL PFS	Initial Treatment	11176F	Authority Required (Written)	150 mg/mL PFS	Initial Treatment	11176F	Authority Required (Written)	
		11175E		11175E				
	Continuing treatment	11168T	Authority Required (Telephone/Online)		Continuing treatment	<i>New/ Public</i>	Authority Required (STREAMLINED)	
		11163M		<i>New/ Private</i>				

Source: Table 1 6 of the submission

Abbreviations: PFS = pre-filled syringe

2.4. Omlyclo is the first biosimilar brand for omalizumab to request PBS listing and has not previously been considered by the PBAC.

### 3. Requested listing

3.1. The submission requested Section 100 (Highly Specialised Drugs Program) Authority Required listings of Omlyclo under the same clinical criteria as the PBS-listed reference biologic, Xolair. As the submission requested the same restrictions as the reference brand, an abridged version of the requested listings is presented below. The submission requested that biosimilar uptake drivers (lower authority restrictions) be applied to Omlyclo.

#### Uncontrolled severe asthma

*Add brand to existing items:*

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MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
OMALIZUMAB						
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe		10110D/ Public	1	1	7	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe		10118M/ Private	1	1	7	
omalizumab 150 mg/mL injection, 1 mL syringe		10109C/ Public	1	1	7	
omalizumab 150 mg/mL injection, 1 mL syringe		10122R/ Private	1	1	7	
<b>Restriction Summary 15845/ Treatment of Concept: 15846</b>						
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners					
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand is encouraged for treatment naive patients.</i>					
	<b>Administrative Advice:</b> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i>					
<b>Indication:</b> Uncontrolled severe asthma						
<b>Treatment Phase:</b> Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)						
<b>Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required</b>						
<b>Indication:</b> Uncontrolled severe asthma						
<b>Treatment Phase:</b> Initial treatment - Initial 2 (Change of treatment)						

Add new items:

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
OMALIZUMAB						
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe		<i>New/ Public</i>	1	1	5	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe		<i>New/ Private</i>	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe		<i>New/ Public</i>	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe		<i>New/ Private</i>	1	1	5	
<b>Restriction Summary 15379/ Treatment of Concept: 15347</b>						
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners					
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system) <input checked="" type="checkbox"/> Authority Required (Streamlined)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand is encouraged for treatment naive patients.</i>					
	<b>Administrative Advice:</b>					

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	<p><i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i></p>
	<p><b>Indication:</b> Uncontrolled severe asthma</p>
	<p><b>Treatment Phase:</b> Continuing treatment</p>
	<p><b>Administrative Advice:</b> For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or <a href="mailto:medinfo.phauno@novartis.com">medinfo.phauno@novartis.com</a></p>
	<p><b>Administrative Advice:</b> Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a>) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</p>
	<p><b>Prescribing Instructions:</b> <del>All applications for For second and subsequent continuing treatments with this drug, must include a measurement of response to the prior course of therapy must be documented in the patient's medical records. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated. The assessment should, where possible, be completed by the same physician who initiated treatment with this drug. Where a response assessment is not undertaken and provided at the time of application, the patient will be deemed to have failed to respond to treatment with this drug.</del></p>
	<p><b>Prescribing Instructions:</b> The following information <del>must be provided at the time of application</del> and must be documented in the patient's medical records: (a) Asthma Control Questionnaire (ACQ-5) score; and (b) If applicable, maintenance oral corticosteroid dose; and (c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced. The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.</p>

Add brand to existing items:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11846L/ Public	1	1	0	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11826K/ Private	1	1	0	
omalizumab 150 mg/mL injection, 1 mL syringe	11828M/ Public	1	1	0	
omalizumab 150 mg/mL injection, 1 mL syringe	11825J/ Private	1	1	0	
<b>Restriction Summary 15349/ Treatment of Concept: 15376</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
Prescriber nauno	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand is encouraged for treatment naive patients.</i>				

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	<b>Administrative Advice:</b> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i>
	<b>Indication:</b> Uncontrolled severe asthma
	<b>Treatment Phase:</b> Balance of supply

Uncontrolled severe allergic asthma

*Add brand to existing items:*

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	10967F/ Public	1	1	6	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	10956P/ Private	1	1	6	
omalizumab 150 mg/mL injection, 1 mL syringe	10973M/ Public	1	1	6	
omalizumab 150 mg/mL injection, 1 mL syringe	10968G/ Private	1	1	6	
<b>Restriction Summary 15351/ Treatment of Concept: 15350</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand is encouraged for treatment naive patients.</i>				
	<b>Administrative Advice:</b> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i>				
<b>Indication:</b> Uncontrolled severe allergic asthma					
<b>Treatment Phase:</b> Initial treatment					

*Add new items:*

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	<i>New/ Public</i>	1	1	5	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	<i>New/ Private</i>	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	<i>New/ Public</i>	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	<i>New/ Private</i>	1	1	5	
<b>Restriction Summary 15382/ Treatment of Concept: 15352</b>					
	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				

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<b>Concept ID</b> (for internal Dept. use)	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system) <input checked="" type="checkbox"/> Authority Required (Streamlined)
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand Omlyclo is encouraged for treatment naive patients.</i>
	<b>Administrative Advice:</b> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i>
	<b>Indication:</b> Uncontrolled severe allergic asthma
	<b>Treatment Phase:</b> Continuing treatment
	<b>Administrative Advice:</b> <del>Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a>) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).</del>

Add brand to existing items:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11962N/ Public	1	1	0	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11958J/ Private	1	1	0	
omalizumab 150 mg/mL injection, 1 mL syringe	11950Y/ Public	1	1	0	
omalizumab 150 mg/mL injection, 1 mL syringe	11932B/ Private	1	1	0	

Restriction Summary 15381/ Treatment of Concept: 15403

<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand is encouraged for treatment naive patients.</i>
	<b>Administrative Advice:</b> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i>
	<b>Indication:</b> Uncontrolled severe allergic asthma
	<b>Treatment Phase:</b> Balance of supply in a patient aged 6 to 12 years

Severe chronic spontaneous urticaria

Add brand to existing items:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
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OMALIZUMAB						
omalizumab 150 mg/mL injection, 1 mL syringe		11176F/ Public	2	2	2	Omlyclo
omalizumab 150 mg/mL injection, 1 mL syringe		11175E/ Private	2	2	2	
<b>Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required</b>						
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners					
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand is encouraged for treatment naive patients.</i>					
	<b>Administrative Advice:</b> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i>					
<b>Indication:</b> Severe chronic spontaneous urticaria						
<b>Treatment Phase:</b> Initial treatment						

Add new items:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
OMALIZUMAB					
omalizumab 150 mg/mL injection, 1 mL syringe	<i>New/ Public</i>	2	2	5	Omlyclo
omalizumab 150 mg/mL injection, 1 mL syringe	<i>New/ Private</i>	2	2	5	
<b>Restriction Summary 10734/ Treatment of Concept:7046</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system) <input checked="" type="checkbox"/> Authority Required (Streamlined)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> <i>Prescribing of the biosimilar brand is encouraged for treatment naive patients.</i>				
	<b>Administrative Advice:</b> <i>Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage (<a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a>).</i>				
<b>Indication:</b> Severe chronic spontaneous urticaria					
<b>Treatment Phase:</b> Continuing treatment					
<b>Administrative Advice:</b> <del>Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see <a href="http://www.servicesaustralia.gov.au/HPOS">www.servicesaustralia.gov.au/HPOS</a>) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).</del>					

3.2. The submission requested that Omlyclo be considered equivalent (a-flagged) to Xolair for the purpose of substitution.

- The submission supported the implementation of biosimilar uptake drivers and requested that this be applied to Omlyclo.

## 4. Consideration of the evidence

### *Sponsor hearing*

4.1. There was no hearing for this item.

### *Consumer comments*

4.2. The PBAC noted and welcomed the input from the Australasian Society of Clinical Immunology and Allergy (ASCIA), Asthma Australia, and the National Allergy Council (NAC) and Allergy & Anaphylaxis Australia (A&AA) via the Consumer Comments facility on the PBS website. These organisations supported the PBS listing of Omlyclo with ASCIA stating that omalizumab has been one of the most effective treatments for clinical immunology/allergy specialists to prescribe. Asthma Australia noted that the availability of Omlyclo may increase patient choice for those who prefer one pre-filled syringe device over the other, and NAC and A&AA considered that multiple dose availability supports appropriate dosing and can help to reduce supply issues.

### *Clinical evidence*

4.3. The TGA has confirmed that, in equal dose, Omlyclo is the same as Xolair (TGA delegate’s overview).

### *Estimated PBS usage and financial implications*

4.4. Listing the biosimilar brand Omlyclo does not change the overall utilisation omalizumab. The submission provided the following economic and financial analyses (see Table 2 and The submission estimated nil net financial implications to the PBS/RPBS for listing Omlyclo. The PBAC is asked to advise if this is appropriate.

4.5. Table 3).

**Table 2: Current price for Xolair and proposed price for Omlyclo**

	<b>Xolair</b>	<b>Omlyclo</b>
<b>Forms</b>	<b>AEMP</b>	<b>AEMP</b>
<b>75 mg/0.5 mL PFS</b>	\$107.60	\$107.60
<b>150 mg/mL PFS</b>	\$215.19	\$215.19

Abbreviations: AEMP = approved ex-manufacturer price; PFS = pre-filled syringe

Source: Table 3 2 of the submission

### **Committee-In-Confidence information**



**End Committee-In-Confidence information**

4.6. The submission estimated nil net financial implications to the PBS/RPBS for listing Omlyclo. The PBAC is asked to advise if this is appropriate.

**Table 3: Estimated use and financial implications**

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
<b>Estimated extent of use</b>						
Number of scripts dispensed	<sup>1</sup>	<sup>2</sup>	<sup>3</sup>	<sup>3</sup>	<sup>4</sup>	<sup>4</sup>
<b>Estimated financial implications of Omlyclo</b>						
Cost to PBS/RPBS less co-payment	<sup>5</sup>	<sup>5</sup>	<sup>5</sup>		<sup>5</sup>	<sup>5</sup>
<b>Estimated financial implications of Xolair</b>						
Cost to PBS/RPBS less co-payment	<sup>6</sup>	<sup>6</sup>	<sup>6</sup>	<sup>6</sup>	<sup>6</sup>	<sup>6</sup>
<b>Net financial implications</b>						
Net cost to PBS/RPBS <sup>a</sup>	<sup>5</sup>	<sup>5</sup>	<sup>5</sup>	<sup>5</sup>	<sup>5</sup>	<sup>5</sup>

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.

Source: Financial Estimates workbook

The redacted values correspond to the following ranges:

<sup>1</sup> 500 to < 5,000

<sup>2</sup> 5,000 to < 10,000

<sup>3</sup> 10,000 to < 20,000

<sup>4</sup> 20,000 to < 30,000

<sup>5</sup> \$0 to < \$10 million

<sup>6</sup> net cost saving

**5. PBAC Outcome**

- 5.1. The PBAC recommended Section 100 (Highly Specialised Drugs Program) Authority Required listings of a new biosimilar brand of omalizumab (Omlyclo®) in the forms of 75 mg in 0.5 mL and 150 mg in 1 mL pre-filled syringe (PFS) on a cost-minimisation basis and under the same circumstances as the PBS-listed reference biologic, Xolair®, for the treatment of uncontrolled severe asthma (USA), uncontrolled severe allergic asthma (USAA), and severe chronic spontaneous urticaria (CSU).
- 5.2. The PBAC noted that the TGA has confirmed biosimilarity between Omlyclo and the reference product Xolair.
- 5.3. The PBAC noted the submission requested that biosimilar uptake drivers be applied to Omlyclo, that is, to have an Authority Required (STREAMLINED) requirement for the subsequent continuing treatment listings and the inclusion of an administrative note across all Omlyclo listings encouraging use of the biosimilar brand for treatment naïve patients. The PBAC considered that the application of biosimilar uptake drivers to Omlyclo would be clinically appropriate and would not impact cost-effectiveness.
- 5.4. The PBAC noted that omalizumab is currently PBS-listed for USAA in patients aged 6 to less than 12 years. The PBAC considered it would be clinically appropriate to lower the restriction level of the current PBS listing to Authority Required (STREAMLINED) for continuing treatment in the paediatric population, in line with biosimilar uptake drivers.

- 5.5. The PBAC advised that, under Section 101(4AACD) of the National Health Act 1953, Xolair and Omlyclo should be considered equivalent for substitution on the Schedule of Pharmaceutical Benefits.
- 5.6. The PBAC considered that the listing of Omlyclo would not result in a net cost to the PBS as it would likely substitute for Xolair and not increase the overall market utilisation.
- 5.7. The PBAC noted its recommendation was on a cost-minimisation basis and advised that, because Omlyclo is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity over Xolair, or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 5.8. The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

**Outcome:**

Recommended

## 6. Recommended listing

- 6.1. As the submission requested the same restrictions as the reference brand, the full restrictions have not been reproduced here.

Uncontrolled severe asthma

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	10110D/ Public	1	1	7	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	10118M/ Private	1	1	7	
omalizumab 150 mg/mL injection, 1 mL syringe	10109C/ Public	1	1	7	
omalizumab 150 mg/mL injection, 1 mL syringe	10122R/ Private	1	1	7	
<b>Restriction Summary 15845/ Treatment of Concept: 15846</b>					
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	<b>Administrative Advice:</b> Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ( <a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a> ).				

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	<b>Indication:</b> Uncontrolled severe asthma
	<b>Treatment Phase:</b> Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)
<b>Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required</b>	
	<b>Indication:</b> Uncontrolled severe asthma
	<b>Treatment Phase:</b> Initial treatment - Initial 2 (Change of treatment)

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
<b>OMALIZUMAB</b>					
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	New/ Public	1	1	5	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	New/ Private	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	New/ Public	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	New/ Private	1	1	5	
<b>Restriction Summary 15379/ Treatment of Concept: 15347</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	<b>Administrative Advice:</b> Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ( <a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a> ).				
<b>Indication:</b> Uncontrolled severe asthma					
<b>Treatment Phase:</b> Continuing treatment					
<b>Prescribing Instructions:</b> For second and subsequent continuing treatments with this drug, a measurement of response to the prior course of therapy must be documented in the patient's medical records. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to the prior course of treatment, the assessment of oral corticosteroid dose or the assessment of time adjusted exacerbation rate should be made from 20 weeks after the first PBS-subsidised dose of this drug under this restriction so that there is adequate time for a response to be demonstrated.					
<b>Prescribing Instructions:</b> The following information must be documented in the patient's medical records: (a) Asthma Control Questionnaire (ACQ-5) score; and (b) If applicable, maintenance oral corticosteroid dose; and (c) For patients transitioned from the paediatric to the adolescent/adult restrictions, confirmation that the time-adjusted exacerbation rate has reduced. The most recent Asthma Control Questionnaire (ACQ-5) score must be no more than 4 weeks old at the time of application.					

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MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
OMALIZUMAB						
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe		11846L/ Public	1	1	0	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe		11826K/ Private	1	1	0	
omalizumab 150 mg/mL injection, 1 mL syringe		11828M/ Public	1	1	0	
omalizumab 150 mg/mL injection, 1 mL syringe		11825J/ Private	1	1	0	
<b>Restriction Summary 15349/ Treatment of Concept: 15376</b>						
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners					
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> Prescribing of the biosimilar brand is encouraged for treatment naive patients.					
	<b>Administrative Advice:</b> Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ( <a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a> ).					
<b>Indication:</b> Uncontrolled severe asthma						
<b>Treatment Phase:</b> Balance of supply						

Uncontrolled severe allergic asthma

MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
OMALIZUMAB						
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe		10967F/ Public	1	1	6	Omlyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe		10956P/ Private	1	1	6	
omalizumab 150 mg/mL injection, 1 mL syringe		10973M/ Public	1	1	6	
omalizumab 150 mg/mL injection, 1 mL syringe		10968G/ Private	1	1	6	
<b>Restriction Summary 15351/ Treatment of Concept: 15350</b>						
Concept ID (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners					
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> Prescribing of the biosimilar brand is encouraged for treatment naive patients.					
	<b>Administrative Advice:</b> Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ( <a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a> ).					
<b>Indication:</b> Uncontrolled severe allergic asthma						

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<b>Treatment Phase:</b> Initial treatment
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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	New/ Public	1	1	5	Omyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	New/ Private	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	New/ Public	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	New/ Private	1	1	5	
<b>Restriction Summary 15382/ Treatment of Concept: 15352</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> Prescribing of the biosimilar brand Omyclo is encouraged for treatment naive patients.				
	<b>Administrative Advice:</b> Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ( <a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a> ).				
<b>Indication:</b> Uncontrolled severe allergic asthma					
<b>Treatment Phase:</b> Continuing treatment					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11962N/ Public	1	1	0	Omyclo
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11958J/ Private	1	1	0	
omalizumab 150 mg/mL injection, 1 mL syringe	11950Y/ Public	1	1	0	
omalizumab 150 mg/mL injection, 1 mL syringe	11932B/ Private	1	1	0	
<b>Restriction Summary 15381/ Treatment of Concept: 15403</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)					
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	<b>Administrative Advice:</b>				

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	Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ( <a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a> ).
	<b>Indication:</b> Uncontrolled severe allergic asthma
	<b>Treatment Phase:</b> Balance of supply in a patient aged 6 to 12 years

Severe chronic spontaneous urticaria

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
OMALIZUMAB					
omalizumab 150 mg/mL injection, 1 mL syringe	11176F/ Public	2	2	2	Omlyclo
omalizumab 150 mg/mL injection, 1 mL syringe	11175E/ Private	2	2	2	
<b>Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	<b>Administrative Advice:</b> Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ( <a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a> ).				
<b>Indication:</b> Severe chronic spontaneous urticaria					
<b>Treatment Phase:</b> Initial treatment					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
OMALIZUMAB					
omalizumab 150 mg/mL injection, 1 mL syringe	New/ Public	2	2	5	Omlyclo
omalizumab 150 mg/mL injection, 1 mL syringe	New/ Private	2	2	5	
<b>Restriction Summary 10734/ Treatment of Concept:7046</b>					
<b>Concept ID</b> (for internal Dept. use)	<b>Category / Program:</b> <input checked="" type="checkbox"/> Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	<b>Prescriber type:</b> <input checked="" type="checkbox"/> Medical Practitioners				
	<b>Restriction type:</b> <input checked="" type="checkbox"/> Authority Required (Streamlined)				
Prescribing rule level	<b>Administrative Advice:</b> <b>Biosimilar prescribing policy</b> Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	<b>Administrative Advice:</b>				

	Encouraging biosimilar prescribing for treatment naive patients is Government policy. A viable biosimilar market is expected to result in reduced costs for biological medicines, allowing the Government to reinvest in new treatments. Further information can be found on the Medicines webpage ( <a href="http://www.health.gov.au/health-topics/medicines">www.health.gov.au/health-topics/medicines</a> ).
	<b>Indication:</b> Severe chronic spontaneous urticaria
	<b>Treatment Phase:</b> Continuing treatment

***These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.***

## **7. Context for Decision**

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

## **8. Sponsor’s Comment**

The sponsor had no comment.