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5.18 OMALIZUMAB, Injection 75 mg in 0.5 mL single dose pre-filled pen, Injection 150 mg in 1 mL single dose pre-filled pen, Omlyclo®, Celltrion Healthcare Australia Pty Ltd

1 Purpose of Submission

1.1 The Category 4 submission requested to list omalizumab (Omlyclo®) 75 mg in 0.5 mL and 150 mg in 1.0 mL single dose pre-filled pen (PFP) form under the same circumstances as the PBS-listed omalizumab biosimilar (Omlyclo®) 75 mg in 0.5 mL and 150 mg in 1.0 mL in the single dose pre-filled syringe (PFS) presentation 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 the basis of a cost minimisation approach so that the PFP presentation will be the same approved ex-manufacturer price (AEMP) at the time of listing as the equivalent current presentations (PFS).

2 Background

2.1 Omalizumab is currently listed on the PBS as an Authority Required listing for uncontrolled severe allergic asthma (USAA) (≥6 years), uncontrolled severe asthma (≥12 years), and severe chronic spontaneous urticaria (CSU), under the Highly Specialised Drugs program.

2.2 The PBAC has previously acknowledged the TGA delegate's overview and 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 (para 2.2 omalizumab Public Summary Document [PSD] March 2025 PBAC meeting).

2.3 **Error! Reference source not found.** presents the key components of the current PBS listings for the originator omalizumab (Xolair®) and the requested listings in the submission for Omlyclo®.

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Table 1: Current PBS listings of Xolair PFP 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 PFP	Initial treatment	14904K 14949T	*Authority Required (Written)*	75 mg/0.5 mL PFP	Initial treatment	14904K (add brand) 14949T (add brand)	*Authority Required (Written)*
150 mg/mL PFP		14884J 14923K		150 mg/mL PFP		14884J (add brand) 14923K (add brand)	
75 mg/0.5 mL PFP	Continuing treatment	14921H 14950W	*Authority Required (Telephone/Online)*	75 mg/0.5 mL PFP	Continuing treatment	14921H 14950W *New PBS item*	*Authority Required (STREAMLINED)*
150 mg/mL PFP		14922J 14928Q		150 mg/mL PFP		14919F *New PBS item* 14947Q *New PBS item*	
75 mg/0.5 mL PFP	Balance of supply	14905L 14939G	*Authority Required (Telephone/Online)*	75 mg/0.5 mL PFP	Balance of supply	14905L (add brand) 14939G (add brand)	*Authority Required Telephone/ Online)*
150 mg/mL PFP		14883H 14929R		150 mg/mL PFP		14883H (add brand) 14929R (add brand)	
Severe chronic spontaneous urticaria							
150 mg/mL PFP	Initial Treatment	14903J 14945N	*Authority Required (Written)*	150 mg/mL PFP	Initial Treatment	14903J (add brand) 14945N (add brand)	*Authority Required (Written)*
	Continuing treatment	14937E 14938F	*Authority Required (Telephone/ Online)*		Continuing treatment	*New PBS Item (Public)* *New PBS item(Private)*	*Authority Required (STREAMLINED)*

Source: Table 1 6 of the submission
Abbreviations: PFP= pre-filled pen; PFS = pre-filled syringe

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Registration status

2.4 Omlyclo® 75 mg/0.5 mL and 150 mg/1.0 mL PFP were registered on the Australian Register of Therapeutic Goods (ARTG) on 4 August 2025 and approved for allergic asthma (children 6 to < 12 years of age, adults and adolescents ≥ 12 years of age), chronic spontaneous urticaria (adults and adolescents ≥ 12 years of age) and chronic rhinosinusitis with nasal polyps (CRSwNP) (adults ≥ 18 years of age).

Previous PBAC consideration

2.5 Omalizumab (Xolair®) was first considered by the PBAC in November 2009, for uncontrolled severe allergic asthma (≥12 years) but was not recommended due to concerns primarily with cost-effectiveness

2.6 Omalizumab (Xolair®) was then recommended by the PBAC at its November 2010 meeting. The resubmission sought PBS listing under Section 100 Highly Specialised Drugs (HSD) for uncontrolled severe allergic asthma in patients aged 12 and older. Subsequently following the September 2017 PBAC meeting, PBS listing for omalizumab was expanded to include CSU.

2.7 At its March 2025 meeting the PBAC recommended Section 100 HSD 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 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).

3 Requested listing

3.1 The submission requested PBS listings for Omlyclo® 75 mg/0.5 mL and 150 mg/1.0 mL PFP to be identical to those of omalizumab 75 mg/0.5 mL and 150 mg/1.0 mL available in PFS presentation for Omlyclo® and both PFS and PFP presentations for Xolair®. The PBS listing being sought with this submission is identical to that of omalizumab PFS with the exception that the Sponsor is seeking STREAMLINED authority for continuing supply.

3.2 The requested listings are consistent with those for the current PBS listing of omalizumab available as Omlyclo and Xolair, which have an Authority Required listing for initial supply. The submission requested STREAMLINED authority for continuing and balance of supply treatment. There is no change proposed to the requested maximum quantities or packs.

3.3 The submission requested that Omlyclo 75 mg/0.5 mL and 150 mg/1.0 mL PFP device be 'a' flagged against Xolair and biosimilar omalizumab items of the same mg dose and form (i.e. omalizumab 75 mg/0.5 mL and 150 mg/1.0 mL PFP device).

3.4 The submission requested Section 100 (Highly Specialised Drugs Program) Authority Required listings of Omlyclo under the same clinical criteria as the PBS-listed reference

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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:

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 pen device	*14904K/ Public*	1	1	7	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	*14949T/ Private*	1	1	7	
Omalizumab 150 mg/mL injection, 1 mL pen device	*14884J/ Public*	1	1	7	
Omalizumab 150 mg/mL injection, 1 mL pen device	*14923K/ Private*	1	1	7	

		Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (in writing only via post/HPOS upload)
Prescribing rule level		**Administrative Advice:** **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.
		Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).
		Indication: Uncontrolled severe asthma
		Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)
		Indication: Uncontrolled severe asthma
		Treatment Phase: Initial treatment - Initial 2 (Change of treatment)

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 pen device	*New/Public*	1	1	5	Omlyclo (PFS)
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	*New/Private*	1	1	5	
Omalizumab 150 mg/mL injection, 1 mL pen device	*New/Public*	1	1	5	
Omalizumab 150 mg/mL injection, 1 mL pen device	*New/Private*	1	1	5	

		Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (Streamlined)
Prescribing rule level		**Administrative Advice:** **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.
		Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).
		Indication: Uncontrolled severe asthma
		Treatment Phase: Continuing treatment

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 pen device	14905L/Public	1	1	0	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	14939G/ Private	1	1	0	
omalizumab 150 mg/mL injection, 1 mL pen device	14883H / Public	1	1	0	
omalizumab 150 mg/mL injection, 1 mL pen device	14929R / Private	1	1	0	

		Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (telephone/online PBS Authorities system~~)~~
		Administrative Advice: **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.
		Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).
		Indication: Uncontrolled severe asthma
		Treatment Phase: Balance of supply

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
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	14903J/Public	2	2	2	Xolair
omalizumab 150 mg/mL injection, 1 mL pen device	14945N/Private	2	2	2	

		Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
		Prescriber type: ☒Medical Practitioners
		Restriction type: ☒Authority Required (in writing only via post/HPOS upload)
		Administrative Advice: **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.
		Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).
		Indication: Severe chronic spontaneous urticaria
		Treatment Phase: Initial treatment

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 pen device	*New/Public*	2	2	5	Omlyclo (PFS)
omalizumab 150 mg/mL injection, 1 mL pen device	*New/Private*	2	2	5	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (Streamlined)				
	Administrative Advice: **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).				
	Indication: Severe chronic spontaneous urticaria				
	Treatment Phase: Continuing treatment				

3.5 The submission requested that Omlyclo PFP be considered equivalent (a-flagged) to Xolair PFP and PFS, for the purpose of substitution for the existing listings and indications previously approved at PBAC.

3.6 The submission also requested implementation of biosimilar uptake drivers be applied to Omlyclo.

4 Comparator

4.1 The submission proposed a biosimilar of omalizumab PFP, and compared this to the currently listed originator brand Xolair 75 mg/0.5 mL PFP and 150 mg/mL PFP. As such a comparator was not nominated.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer input

5.2 The PBAC noted and welcomed the input from organisations (2) and an individual consumer (1) via the Office of Health Technology Assessment Consultation Hub.

5.3 The following organisations provided inputs: the National Allergy Council, Allergy & Anaphylaxis Australia (A&AA), Australasian Society of Clinical Immunology and Allergy (ASCIA).

5.4 Each of the inputs supported the listing of the PFP presentation of Omlyclo, citing ease of use as a key consideration. The inputs indicated that the PFP was considered straightforward and more convenient for patients to administer.

5.5 The PBAC noted that ASCIA supported the submission for several reasons. ASCIA advised that omalizumab is one of the most effective treatments available to clinical immunology and allergy specialists for the management of chronic spontaneous urticaria (CSU). ASCIA further noted that omalizumab is also an established treatment for patients with uncontrolled severe asthma, including uncontrolled severe allergic asthma. ASCIA considered that the availability of biosimilar products in the same strengths and dosage forms on the PBS would reduce the risk of supply disruptions and increase prescribing flexibility.

Clinical evidence

5.6 At its March 2025 meeting the PBAC noted that the TGA confirmed Omlyclo to be a biosimilar medicinal product to Xolair based on the presented clinical data. (para 5.2 omalizumab [Omlyclo], PSD March 2025 PBAC meeting).

5.7 The submission claimed that the Sponsor developed Omlyclo in the PFP presentation without conducting any additional clinical studies with the justification that bioequivalence and clinical usability demonstrated with the PFS presentation is not expected to change between the two devices.

Economic analysis

5.8 As a Category 4 submission, the economic analysis has not been independently evaluated.

5.9 The submission presented a cost-minimisation approach of Omlyclo compared with Xolair. The equi-effective doses were proposed based on the clinical claim in the submission "*on a mg for mg basis the omalizumab (pre-filled pen) is therapeutically equivalent to the omalizumab syringe (or prefilled syringe) in terms of both clinical efficacy and safety. This is true for both reference omalizumab and other biosimilars.*"

5.10 In the submission, the Sponsor proposed listing of Omlyclo PFP at the same approved ex-manufacturer price (AEMP) as the equivalent PFS presentations at the time of submission (November 2025). The proposed AEMP price of Omlyclo PFP 75 mg is therefore $104.54 and for the 150 mg is $209.07 (respectively).

5.11 The submission claimed that Omlyclo PFP device presentations are not expected to grow the market and since the price is cost-minimised, any increase or decrease in the rate of uptake should have no impact on the financial estimates

5.12 The submission estimated that 600,000 to < 700,000 scripts for omalizumab 75 mg and 150 mg for all forms would be supplied over the first six years of listing (90,000 to < 100,000 in Year 1 to 100,000 to < 200,000 in Year 6).

5.13 The submission stated that the estimated financial cost to the PBS/RPBS for all forms of omalizumab 75 mg and 150 mg is $30 million to < $40 million over six years (Year 1 $0 to < $10 million to Year 6 $0 to < $10 million).

5.14 The submission estimated nil net financial implications to the PBS/RPBS for listing Omlyclo.

5.15 Table 2: Estimated net cost to the PBS/RPBS for the Omlyclo 75 mg and 150 mg PFP devices – Published PricesTable 2 presents the estimated extent of use, cost of omalizumab 75 mg and 150 mg PFP device to the PBS/RPBS and the net financial implications to the PBS/RPBS.

Table 2: Estimated net cost to the PBS/RPBS for the Omlyclo 75 mg and 150 mg PFP devices – Published Prices

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
PBS						
omalizumab PFP ($)	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
omalizumab other presentations ($)	-[redacted][2]	-[redacted][2]	-[redacted][2]	-[redacted][2]	-[redacted][2]	-[redacted][2]
Net cost to PBS	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
RPBS						
omalizumab PFP ($)	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
omalizumab other presentations ($)	-[redacted][2]	-[redacted][2]	-[redacted][2]	-[redacted][2]	-[redacted][2]	[redacted][2]
Net cost to RPBS ($)	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Net cost PBS / RPBS ($)	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; PFP= pre-filled pen
Source: Table 4.9, p23 of the submission
The redacted values correspond to the following values
[1] *$0 to < $10 million*
[2] *net cost saving*

Quality use of medicines

5.16 The submission states that the Omlyclo PFP device packaging will contain specific instructions on how to use the device.

6 PBAC Outcome

6.1 The PBAC recommended the Section 100 (Highly Specialised Drugs Program) Authority Required listings of omalizumab (Omlyclo®) 75 mg/0.5 mL and 150 mg/1.0 mL PFP form for subcutaneous (SC) injection under the same circumstances as the PBS-listed omalizumab (Omlyclo®) 75 mg/0.5 mL and 150 mg/1.0 mL PFS.

6.2 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.

6.3 The PBAC recommended that Omlyclo 75 mg/0.5 mL and 150 mg/1.0 mL PFP device be 'a' flagged against Xolair and biosimilar omalizumab items of the same mg dose and form (i.e. omalizumab 75 mg/0.5 mL and 150 mg/1.0 mL PFP device).

6.4 The PBAC noted that omalizumab is currently PBS-listed for USAA in patients aged 6 to less than 12 years only in the PFS form. In this circumstance, the PBAC recommended that it would not be appropriate to 'a' flag the PFP form to the existing PFS presentations for the treatment of USAA in the paediatric population.

6.5 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.

6.6 The PBAC considered that the listing of Omlyclo would not result in a net cost to the PBS and RPBS as it would likely substitute for Xolair and existing Omlyclo presentations and not increase the overall market utilisation.

6.7 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.

6.8 The PBAC recalled that the TGA has confirmed that, in equal dose, Omlyclo PFS is the same as Xolair PFS (TGA delegate's overview).

6.9 The PBAC noted this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:
Recommended

7 Recommended listing

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

Uncontrolled severe asthma

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 pen device	*14904K/ Public*	1	1	7	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	*14949T/ Private*	1	1	7	
Omalizumab 150 mg/mL injection, 1 mL pen device	*14884J/ Public*	1	1	7	
Omalizumab 150 mg/mL injection, 1 mL pen device	*14923K/ Private*	1	1	7	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (in writing only via post/HPOS upload)				
	Administrative Advice: **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).				
	Indication: Uncontrolled severe asthma				
	Treatment Phase: Initial treatment - Initial 1 (New patients; or Recommencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)				
	Indication: Uncontrolled severe asthma				
	Treatment Phase: Initial treatment - Initial 2 (Change of treatment)				

Add new item codes:

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 pen device	*New/Public*	1	1	5	Omlyclo (PFS)
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	*New/Private*	1	1	5	
Omalizumab 150 mg/mL injection, 1 mL pen device	*New/Public*	1	1	5	
Omalizumab 150 mg/mL injection, 1 mL pen device	*New/Private*	1	1	5	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (Streamlined)				
	Administrative Advice: **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).				
	Indication: Uncontrolled severe asthma				
	Treatment Phase: Continuing treatment				

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 pen device	14905L/Public	1	1	0	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	14939G/ Private	1	1	0	
omalizumab 150 mg/mL injection, 1 mL pen device	14883H / Public	1	1	0	
omalizumab 150 mg/mL injection, 1 mL pen device	14929R / Private	1	1	0	

	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: ☒Medical Practitioners
	Restriction type: ☒Authority Required (telephone/online PBS Authorities system)
	Administrative Advice: **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.
	Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).
	Indication: Uncontrolled severe asthma
	Treatment Phase: Balance of supply

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
OMALIZUMAB					
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	14903J/Public	2	2	2	Xolair
omalizumab 150 mg/mL injection, 1 mL pen device	14945N/Private	2	2	2	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (in writing only via post/HPOS upload)				
	Administrative Advice: **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).				
	Indication: Severe chronic spontaneous urticaria				
	Treatment Phase: Initial treatment				

Add new item codes:

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 pen device	*New/Public*	2	2	5	Omlyclo (PFS)
omalizumab 150 mg/mL injection, 1 mL pen device	*New/Private*	2	2	5	
	Category / Program: ☒ Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (Streamlined)				
	Administrative Advice: **Biosimilar prescribing policy** Prescribing of the biosimilar brand is encouraged for treatment naive patients.				
	Administrative Advice: 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 (www.health.gov.au/health-topics/medicines).				
	Indication: Severe chronic spontaneous urticaria				
	Treatment Phase: Continuing treatment				

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

8 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.

9 Sponsor's Comment

The sponsor had no comment.