

5.28 OMALIZUMAB,

Injection 75 mg in 0.5 mL single dose pre-filled syringe,

Injection 150 mg in 1 mL single dose pre-filled syringe,

Injection 300 mg in 2 mL single dose pre-filled syringe,

Injection 75 mg in 0.5 mL single dose pre-filled pen,

Injection 150 mg in 1 mL single dose pre-filled pen,

Injection 300 mg in 2 mL single dose pre-filled pen,

Xolair[®],

NOVARTIS PHARMACEUTICALS AUSTRALIA PTY LIMITED

1 Purpose of Submission

1.1 The Category 4 submission requested Section 100 (Highly Specialised Drugs Program) Authority Required listings for the following new forms of omalizumab (Xolair[®]):

- A new strength of 300 mg/2 mL injection
- New pre-filled pen (PFP) forms in 75 mg/0.5 mL, 150 mg/mL, and 300 mg/2 mL strengths
- New pre-filled syringe (PFS) forms with a new safety device in 75 mg/0.5 mL, 150 mg/mL, and 300 mg/2 mL strengths to replace the currently PBS-listed PFS forms.

1.2 The submission requested listing the new 75 mg/0.5 mL, 150 mg/mL, 300 mg/2 mL PFP and PFS forms under the same circumstances as the existing listings for the treatment of:

- Uncontrolled severe asthma (USA) in patients aged 12 years or older
- Uncontrolled severe allergic asthma (USAA) in patients aged 6 to 12 years
- Severe chronic spontaneous urticaria (CSU)

However, the 300 mg/2 mL PFS and all strengths of PFP were not requested for listing in USAA, as these forms are not intended for use in patients under 12 years of age.

- 1.3 Listing was requested on the basis of a cost-minimisation approach versus the existing 150 mg/mL PFS of omalizumab.

2 Background

- 2.1 Omalizumab 75 mg/0.5 mL PFS is currently listed on the PBS for the initial treatment of USA and USAA as Section 100 (Highly Specialised Drugs Program) Authority Required (Written), and for continuing treatment and balance of supply as Authority Required (Telephone/Online).
- 2.2 Omalizumab 150 mg/mL PFS is listed on the PBS for the initial treatment of USA and USAA as Section 100 (Highly Specialised Drugs Program) Authority Required (Written), and for continuing treatment and balance of supply as Authority Required (Telephone/Online). Additionally, 150 mg/mL PFS is listed for the initial and continuing treatment of severe CSU as Authority Required (Written) and Authority Required (Telephone/Online), respectively.

Registration status

- 2.3 The new PFS and PFP forms, including the 300 mg/2 mL strength, were registered on the Australian Register of Therapeutic Goods (ARTG) on 4 September 2024.
- 2.4 Omalizumab is TGA-approved for the following indications:
- Allergic asthma (6 to < 12 years): add-on therapy for severe allergic asthma with documented exacerbations despite daily high-dose inhaled corticosteroids and corresponding immunoglobulin E (IgE) levels to the recommended dose range in the TGA approved Production Information (PI).
 - Allergic asthma (≥12 years): management of moderate to severe allergic asthma in patients already on inhaled corticosteroids with corresponding IgE levels to the recommended dose range in the PI.
 - Chronic rhinosinusitis with nasal polyps (CRSwNP): add-on therapy for severe CRSwNP in adults (≥18 years) with inadequate response to intranasal corticosteroids.
 - CSU: for adults and adolescents (≥12 years) who remain symptomatic despite H1 antihistamine treatment.
- 2.5 The recommended doses for asthma indications are determined based on body weight (kg) and baseline IgE levels (IU/mL), ranging from 75 mg to 750 mg, to be administered subcutaneously every two or four weeks. The recommended dose for CSU is 150 mg or 300 mg by subcutaneous injection every four weeks.

Previous PBAC consideration

- 2.6 The 300 mg strength and PFP forms of omalizumab have not been considered by the PBAC previously.

- 2.7 Omalizumab was initially recommended by the PBAC for the treatment of severe allergic asthma in patients aged 12 years and older at its November 2010 meeting. Subsequently, the PBAC recommended omalizumab for paediatric patients (6 to < 12 years) on a cost-effectiveness basis compared to placebo plus optimised asthma therapy in July 2016 (paragraph 7.1, USAA Public Summary Document (PSD), July 2016 PBAC meeting).
- 2.8 The treatment for uncontrolled chronic idiopathic urticaria (now referred to as CSU) was recommended on a cost-minimisation basis to ciclosporin at the November 2015 PBAC meeting, and the equi-effective doses were revised to omalizumab 300 mg and ciclosporin 4 mg/kg at the November 2016 PBAC Meeting (paragraph 5.1, CSU PSD, November 2016 PBAC meeting).
- 2.9 At its March 2014 meeting, the PBAC recommended listing the 75 mg/0.5 mL and 150 mg/mL PFS forms of omalizumab under Section 100 (Highly Specialised Drugs Program) Authority Required listings for USAA, in addition to the existing 150 mg powder for subcutaneous injection, which was delisted on 1 December 2014.
- 2.10 A separate Category 2 submission to request a Section 100 (Highly Specialised Drugs Program) Authority Required listing of omalizumab (Xolair®) for the treatment of patients with CRSwNP will be considered at the May 2025 PBAC meeting. The requested listing for the CRSwNP indication includes the new strength of 300 mg/2 mL and the new PFS and PFP forms.

3 Requested listing

3.1 Table 1 provides a summary of the requested listings for each form and strength of omalizumab in the submission for the current PBS indications and treatment phases.

Table 1: Summary of the requested listings for each form of omalizumab

Indication	Treatment phase	75 mg/0.5 mL		150 mg/mL		300 mg/2 mL	
		PFS	PFP	PFS	PFP	PFS	PFP
Uncontrolled Severe Asthma	Initial	Written	Written	Written	Written	Written	Written
	Continuing	Telephone/ Online	Telephone/ Online	Telephone/ Online	Telephone/ Online	Telephone/ Online	Telephone/ Online
	Balance of supply	Telephone/ Online	Telephone/ Online	Telephone/ Online	Telephone/ Online	Telephone/ Online	Telephone/ Online
Uncontrolled severe allergic asthma	Initial	Written	NR	Written	NR	NR	NR
	Continuing	Telephone/ Online	NR	Telephone/ Online	NR	NR	NR
	Balance of supply	Telephone/ Online	NR	Telephone/ Online	NR	NR	NR
Chronic severe spontaneous urticaria	Initial	NR	NR	Written	Written	Written	Written
	Continuing	NR	NR	Telephone/ Online	Telephone/ Online	Telephone/ Online	Telephone/ Online

Source: compiled by the Secretariat during evaluation

Abbreviations; PFS = pre-filled syringe; PFP = pre-filled pen; NR = not requested in the submission

3.2 As the submission requested the same restrictions as the current listings for the existing PFS form, except for the maximum quantity of the 300 mg/2 mL strength for CSU, the full restrictions have not been reproduced. An abridged version of the requested listings is presented below:

Add new medicinal product pack as follows:

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	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	10118M/ Private	1	1	7	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW/ Public	1	1	7	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW/ 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	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Public	1	1	7	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Private	1	1	7	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	7	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	7	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	7	

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omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	7	
Restriction Summary 15845/ Treatment of Concept: 15846					
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
27327	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)				
Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required					
27327	Indication: Uncontrolled severe asthma				
	Treatment Phase: Initial treatment - Initial 2 (Change of treatment)				
Administrative Advice [New] ¹	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringes and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen devices are equivalent for the purposes of substitution.				
Administrative Advice [New] ²	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.				
Administrative Advice [New] ³	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.				

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	11835X/ Public	1	1	5	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11840E/ Private	1	1	5	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	5	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	11824H/ Public	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	11864K/ 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	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	5	

Restriction Summary 15379/ Treatment of Concept: 15347					
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				

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	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
27327	Indication: Uncontrolled severe asthma
	Treatment Phase: Continuing treatment
Administrative Advice [New] ¹	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringes and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen devices are equivalent for the purposes of substitution.
Administrative Advice [New] ²	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.
Administrative Advice [New] ³	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.

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	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11826K/ Private	1	1	0	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW	1	1	0	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW	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	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Public	1	1	0	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Private	1	1	0	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	0	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	0	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	0	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	0	

Restriction Summary 15349/ Treatment of Concept: 15376	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
27327	Indication: Uncontrolled severe asthma
	Treatment Phase: Balance of supply
Administrative Advice [New] ¹	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringes and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen devices are equivalent for the purposes of substitution.

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Administrative Advice [New] ²	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.
Administrative Advice [New] ³	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.

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	Xolair
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	
Restriction Summary 15351/ Treatment of Concept: 15350					
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
11873	Indication: Uncontrolled severe allergic asthma				
	Treatment Phase: Initial treatment				
Caution ¹ [New]	The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.				
Caution ² [New]	The 300 mg/2 mL omalizumab syringe device is not intended for use in children under 12 years of age for this indication.				

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	11946R/ Public	1	1	5	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11952C/ Private	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	11945Q/ Public	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	11953D/ Private	1	1	5	
Restriction Summary 15382/ Treatment of Concept: 15352					

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Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
11873	Indication: Uncontrolled severe allergic asthma
	Treatment Phase: Continuing treatment
Caution ¹ [New]	The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.
Caution ² [New]	The 300mg/2mL omalizumab syringe device is not intended for use in children under 12 years of age for this indication.

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	Xolair
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

Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
11873	Indication: Uncontrolled severe allergic asthma
	Treatment Phase: Balance of supply in a patient aged 6 to 12 years
Caution ¹ [New]	The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.
Caution ² [New]	The 300 mg/2 mL omalizumab syringe device is not intended for use in children under 12 years of age for this indication.

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	Xolair
omalizumab 150 mg/mL injection, 1 mL syringe	11175E/ Private	2	2	2	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Public	2	2	2	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Private	2	2	2	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	2	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	2	

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omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	2	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	2	

Restriction Summary 7055/ Treatment of Concept:7055

Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)

Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required

17467	Indication: Severe chronic spontaneous urticaria
	Treatment Phase: Initial treatment
Administrative Advice [New] ²	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.
Administrative Advice [New] ³	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.

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	11168T/ Public	2	2	5	Xolair
omalizumab 150 mg/mL injection, 1 mL syringe	11163M/ Private	2	2	5	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Public	2	2	5	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Private	2	2	5	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	5	

Restriction Summary 10734/ Treatment of Concept:7046

Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
17467	Indication: Severe chronic spontaneous urticaria
	Treatment Phase: Continuing treatment
Administrative Advice [New] ²	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.
Administrative Advice [New] ³	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.

- 3.3 The submission noted that the new 75 mg/0.5 mL and 150 mg/mL PFS forms with BD UltraSafe Plus™ safety device retained the same ARTG numbers as the existing 75 mg/0.5 mL and 150 mg/mL PFS forms with BD UltraSafe Passive™. As such, the submission proposed that new PBS item codes for the new PFS forms would not be required, as the new PFS forms are intended to replace the currently PBS-listed PFS forms without any changes to the existing restrictions.
- 3.4 The submission stated that the bioequivalence of the PFS and PFP forms has been demonstrated (see paragraph 5.4) and proposed that omalizumab PFP should be considered equivalent to omalizumab PFS for the same strength for the purposes of substitution (i.e., ‘a’-flagged to each other in the Schedule), with a note stating that the PBS listing of one form is equivalent to the PBS listing of the other form for substitution purposes.
- 3.5 As per the PI, the 300 mg/2 mL PFS and all strengths of PFP are not intended for patients under 12 years of age. Therefore, these forms were excluded from the USAA listings. The submission proposed that an administrative note be included, stating that the 300 mg/2 mL pre-filled syringe and all strengths of the pen device are not intended for use in children under 12 years of age.
- 3.6 The submission requested the same maximum quantities and number of repeats for the PFP form as the existing listings for the PFS form, with the exception of a maximum quantity of 1 for the 300 mg PFP and PFS forms for severe CSU, to align with the TGA-recommended dose of 300 mg every four weeks (see paragraph 2.5).

4 Comparator

- 4.1 The submission nominated the currently PBS-listed omalizumab 150 mg/mL PFS as the main comparator. This was appropriate.
- 4.2 Alternative medicines listed on the PBS for USA and CSU on a cost-minimisation basis are summarised in Table 2. Mepolizumab and benralizumab would be considered appropriate comparators in USA, and ciclosporin in CSU.

Table 2: Alternative medicines listed on the PBS for uncontrolled severe asthma and chronic spontaneous urticaria

Uncontrolled severe asthma		Chronic spontaneous urticaria	
Drug Name	Equi-effective doses	Drug Name	Equi-effective doses
Mepolizumab (≥12 years)	omalizumab 398 mg = mepolizumab 100 mg	Ciclosporin	omalizumab 300 mg = ciclosporin 4 mg/kg
Benralizumab	benralizumab 30 mg every four weeks for the first three doses, then every eight weeks (7.5 doses over one year) = mepolizumab 100 mg every four weeks (13 doses over one year).		

Source: compiled by the Secretariat during evaluation using [Therapeutic Relativity Sheets](#) accessed on 5 February 2025

- 4.3 The Pre-PBAC response (pp. 1-2) argued that the alternative comparators listed in Table 2 are not appropriate, as the primary population for the new forms of omalizumab consists of patients stabilised on omalizumab treatment, with no clinical rationale to switch to an alternative biological agent or immunosuppressant unless there is treatment failure or an incomplete response. The Pre-PBAC response stated that the criteria for mepolizumab and benralizumab under initial treatment - initial 2

(change of treatment) for the USA indication necessitate a reassessment of treatment response to qualify for a change in therapy. Additionally, ciclosporin is no longer recommended for CSU unless a patient fails treatment with omalizumab (ASCIA 2020 guidelines¹).

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted and welcomed the input from organisations (3) via the Consumer Comments facility on the PBS website. The PBAC acknowledged the support for listing the new forms of Xolair from the Australasian Society of Clinical Immunology and Allergy (ASCIA), Asthma Australia, and the National Allergy Council and Allergy & Anaphylaxis Australia.

5.3 The organisations highlighted that having multiple strengths and forms of omalizumab available on the PBS may mitigate the risk of supply issues and provide dosing flexibility. Specifically, the 300 mg strength will reduce the number of concurrent injections, lower out-of-pocket expenses, and improve convenience and treatment compliance for those who require higher doses. Asthma Australia further noted that Xolair PFS and PFP with a safety device will increase consumer choice, potentially improving comfort and convenience with smaller needles and ease of use for self-administration. This may result in improved acceptance and treatment compliance, as well as fewer consultations. Asthma Australia emphasized that the 300 mg strength and the PFP form are not approved for use in children aged 6-11 years. It proposed that the relevant devices and strengths be clearly labelled and identifiable as for use in adults and adolescents only, to reduce the possibility of medication errors in this younger population.

Clinical trials

5.4 The submission was based on a Phase I bioequivalence study, CIGE025K12101 (referred to as Study K12101), which demonstrated the bioequivalence of the new 300 mg/2 mL PFP and 300 mg/2 mL PFS with two doses of the existing 150 mg/mL PFS of omalizumab (TGA Clinical Evaluation Report).

¹ ASCIA (2020) Position Paper - Chronic Spontaneous Urticaria (CSU). Accessed on 25 March 2025 at: https://www.allergy.org.au/images/stories/pospapers/ASCIA_HP_Position_Paper_CSU_2020.pdf

Table 3: Clinical study report presented in the submission

Study ID	Protocol title	Purpose of the study
CIGE025K12101 (referred to as Study K12101)	An open-label, randomized, single-dose, 3-parallel-group, bioequivalence study of omalizumab administered by a proposed prefilled syringe system in an autoinjector configuration and with a needle safety device configuration, both compared against the registered prefilled syringe product in healthy participants.	To demonstrate bioequivalence of omalizumab between: <ul style="list-style-type: none"> • 300 mg/2 mL proposed PFS- autoinjector (AI) and 2 x (150 mg/mL) current PFS-needle safety device (NSD) in healthy volunteers. • 300 mg/2 mL proposed PFS-NSD and 2 x (150 mg/1 mL) current PFS-NSD in healthy volunteers.

Source: Study ID CIGE025K12101 Full Clinical Study Report (Attachment 4 of the submission).

5.5 The submission noted that the most recent Periodic Safety Update Report (PSUR, 31 December 2022), which included an analysis of safety data from Study K12101, supported that the safety of omalizumab remained consistent with previous experience and that its benefit-risk profile remained positive.

5.6 As a Category 4 submission, no evaluation of the clinical evidence was undertaken.

Clinical claim

5.7 The submission claimed non-inferior comparative effectiveness and safety of the proposed new strength and PFS and PFP forms of omalizumab compared with the currently PBS-listed strengths and PFS form for its relevant indications.

Economic analysis

5.8 The submission used a cost-minimisation approach to compare the currently listed strengths and PFS form of omalizumab with the proposed new strength and new PFS and PFP forms at a 1:1 milligram ratio. Table 4 provides the proposed approved ex-manufacturer price (AEMP) for each strength, which are consistent across all currently listed indications.

Table 4: Proposed AEMPs in the submission

Strength/Forms	AEMP
75 mg/0.5 ml PFS and PFP	\$107.60
150 mg/ml PFS and PFP	\$215.19
300 mg/2 ml PFS and PFP	\$430.38

Source: Table 1.5, 1.6, 1.7, 3.1 of the submission

Abbreviations: PFS = pre-filled syringe, PFP = pre-filled pen, AEMP = approved ex-manufacturer price

5.9 A Category 3 submission to list a biosimilar brand of omalizumab (Omyclo®) in 75 mg/0.5 mL and 150 mg/1 mL PFS forms under the same circumstances as the currently PBS-listed reference biologic, Xolair®, was recommended at the March 2025 PBAC meeting.

5.10 The current price of omalizumab reflects a weighted price between the severe asthma and CSU indications.

Estimated PBS usage and financial implications

- 5.11 The submission adopted a market share approach to estimate the utilisation and financial impact of listing the new forms and strength of omalizumab. The requested price was based on the AEMPs of 75 mg/0.5 ml PFS and 150 mg/ml PFS of omalizumab as of September 2024.
- 5.12 Table 5 presents the estimated extent of use, cost to the PBS/RPBS and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.
- 5.13 The submission indicated that, while the estimated net financial impact to the PBS/RPBS was \$0 to < \$10 million over six years (Year 1 \$0 to < \$10 million to Year 6 \$0 to < \$10 million) in the model, nil net financial implications are expected from the requested listing of the new forms. The evaluation estimated that the requested listings of the new 300 mg/2 mL strength and the new PFS and PFP forms would have no financial impact to the PBS/RPBS, as no change in market uptake was anticipated.

Table 5: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed for USA (continuing)	1	1	1	1	1	1
Number of scripts dispensed for USA (initial)	2	2	2	2	2	2
Number of scripts dispensed for CSU	3	3	4	5	6	7
Estimated financial implications of the existing strengths and form of omalizumab						
Cost to PBS/RPBS less co-payment for USA (continuing)	8	8	8	8	8	8
Cost to PBS/RPBS less co-payment for USA (initial)	8	8	8	8	8	8
Cost to PBS/RPBS less co-payment for CSU	12	9	9	9	9	10
Estimated financial implications of the new strength and forms of omalizumab						
Cost to PBS/RPBS less co-payment for USA (continuing)	11	11	11	11	11	11
Cost to PBS/RPBS less co-payment for USA (initial)	11	11	11	11	11	11
Cost to PBS/RPBS less co-payment for CSU	11	11	11	11	11	11
Net financial implications						
Net cost to PBS/RPBS	8	8	8	8	8	8

Source: Utilisation and cost-model workbooks

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; USA = Uncontrolled severe asthma; CSU = chronic spontaneous urticaria

Note: the submission assumed:

- a 5% decrease in USA patients and a 14% increase in CSU patients over the next 6 years, based on historical trends and available data in the market;
- a 60% uptake rate for the use of the pen device; and
- there would be no financial impact from the requested listings for USAA, as the new PFP and 300 mg strength are not requested for this indication.

The redacted values correspond to the following ranges:

- 1 10,000 to < 20,000
- 2 500 to < 5,000
- 3 40,000 to < 50,000
- 4 50,000 to < 60,000
- 5 60,000 to < 70,000
- 6 70,000 to < 80,000
- 7 80,000 to < 90,000
- 8 \$0 to < \$10 million
- 9 \$20 million to < \$30 million
- 10 \$30 million to < \$40 million
- 11 net cost saving
- 12 \$10 million to < \$20 million

5.14 As a Category 4 submission, the financial estimates have not been independently evaluated.

Quality use of medicines

- 5.15 The submission claimed that the new 300 mg strength will improve patient convenience and adherence by reducing multiple injections for high-dose patients, while the new PFP and PFS forms offer easier administration and enhanced safety.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of a new 300 mg/2 mL strength and a new pre-filled pen (PFP) form of omalizumab (Xolair®) under the same conditions as the current PBS listings of the pre-filled syringe (PFS) form for the treatment of uncontrolled severe asthma (USA) and severe chronic spontaneous urticaria (CSU) as Section 100 (Highly Specialised Drugs Program) Authority Required. The PBAC considered it appropriate for the new pre-filled syringe (PFS) form with a new safety device in 75 mg/0.5 mL and 150 mg/mL strengths to be listed under the same PBS item codes as the existing PFS form for the treatment of USA, CSU, and uncontrolled severe allergic asthma (USAA).
- 6.2 The PBAC considered the currently PBS-listed omalizumab 150 mg/mL PFS to be an appropriate comparator and acknowledged that the new forms would substitute for the existing PFS forms for all PBS-listed indications. However, the PBAC noted other relevant comparators for the treatment of USA and CSU based on previous recommendations. Mepolizumab was recommended on a cost-minimisation basis with omalizumab, and benralizumab on a cost-minimisation basis with mepolizumab for USA at the July 2016 and March 2018 PBAC meetings, respectively. Omalizumab was recommended on a cost-minimisation basis with ciclosporin for CSU at the November 2015 PBAC meeting. Therefore, the PBAC considered mepolizumab and benralizumab for USA, and ciclosporin for CSU as appropriate alternative comparators. The PBAC advised that the new forms of omalizumab should be cost-minimised to the lowest cost PBS-listed alternative comparator for the respective indications.
- 6.3 The PBAC considered that the clinical evidence provided in the submission supported the bioequivalence of the PFS and PFP forms. The PBAC advised, under Section 101 (4AACD) of the *National Health Act 1953*, that the PFS and PFP forms of omalizumab should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule) for the treatment of USA and CSU.
- 6.4 The PBAC noted that the submission did not request the 300 mg/2 mL PFS and all strengths of PFP be listed for USAA, as these forms are not intended for use in patients under 12 years of age. The PBAC advised that a caution stating "the 300 mg/2 mL pre-filled syringe and all dose strengths of the pen device are not intended for use in children under 12 years of age" should be included in the restriction for USAA.
- 6.5 The PBAC noted that the consumer comments highlighted the benefits of having multiple strengths and forms of omalizumab available on the PBS. These benefits include mitigating the risk of supply issues, providing dosing flexibility, and reducing

the number of injections with the 300 mg strength, which may improve safety and treatment adherence.

- 6.6 The PBAC considered that listing the new forms of omalizumab is expected to be cost-neutral to the Government, given that the new forms will likely substitute for the currently PBS-listed form of omalizumab and therefore will not increase overall market utilisation. As a result, there will be no net financial implications to the PBS/RPBS.
- 6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because the new forms of omalizumab are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over the currently listed PFS form, 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 noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

Add new item:

Uncontrolled severe asthma - Initial 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	10110D/ Public	1	1	7	*Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	10118M/ Private	1	1	7	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW/ Public	1	1	7	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW/ Private	1	1	7	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)				
Presc ribing	Administrative Advice: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA				

	<p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.</p> <p>A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.</p> <p>A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.</p> <p>Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.</p> <p>A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.</p> <p>Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.</p> <p>Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.</p> <p>Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.</p> <p>(1) Initial treatment:</p> <p>Applications for initial treatment should be made where:</p> <ul style="list-style-type: none"> (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below]. <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment:</p> <p>Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response:</p> <p>Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.</p> <p>For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.</p>
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	<p>However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.</p> <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com</p>
	<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
	<p>Administrative Advice: Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringes and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen devices are equivalent for the purposes of substitution.</p>
<p>Restriction Summary 15845/ Treatment of Concept: 15846: Authority Required</p>	
	<p>Indication: Uncontrolled severe asthma</p>
	<p>Treatment Phase: Initial treatment - Initial 1 (New patients; or Re commencement of treatment in a new treatment cycle following a break in PBS subsidised biological medicine therapy)</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma</p>
	<p>Clinical criteria:</p>
	<p>Patient must be under the care of the same physician for at least 6 months; or</p>

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	Patient must have been diagnosed by a multidisciplinary severe asthma clinic team
	AND
	Clinical criteria:
	Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; or
	Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma
	AND
	Clinical criteria:
	Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; or
	Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records
	AND
	Clinical criteria:
	Patient must have a duration of asthma of at least 1 year
	AND
	Clinical criteria:
	Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE
	AND
	Clinical criteria:
	Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application
	AND
	Clinical criteria:
	Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records
	AND
	Clinical criteria:
	Patient must not receive more than 32 weeks of treatment under this restriction
	AND
	Clinical criteria:
	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma
	Population criteria:
	Patient must be aged 12 years or older

	<p>Prescribing Instructions: Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p>
	<p>Prescribing Instructions: The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 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 and for the application for the first continuing therapy to be processed. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator.</p>
<p>FULL</p>	<p>Prescribing Instructions: The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>

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	<p>Prescribing Instructions: The following must be provided at the time of application and documented in the patient's medical records: (a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (d) the IgE result and date; and (e) Asthma Control Questionnaire (ACQ-5) score.</p>
	<p>Administrative Advice: The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.</p>
	<p>Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).</p>
Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required	
	Indication: Uncontrolled severe asthma
	Treatment Phase: Initial treatment - Initial 2 (Change of treatment)
	Treatment criteria:
	Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma
	Clinical criteria:
	Patient must be under the care of the same physician for at least 6 months; or
	Patient must have been diagnosed by a multidisciplinary severe asthma clinic team
	AND
	Clinical criteria:
	Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle
	AND
	Clinical criteria:
	Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle
	AND
	Clinical criteria:
	Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma
	AND
	Clinical criteria:
	Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma
	AND
	Clinical criteria:

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	Patient must not receive more than 32 weeks of treatment under this restriction
	AND
	Clinical criteria:
	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma
	Population criteria:
	Patient must be aged 12 years or older
	<p>Prescribing Instructions: An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <p>(i) A respiratory physician; and</p> <p>(ii) A pharmacist, nurse or asthma educator.</p>
	<p>Prescribing Instructions: The authority application must be made in writing and must include:</p> <p>(1) details of the proposed prescription; and</p> <p>(2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>
	<p>Prescribing Instructions: The following must be provided at the time of application and documented in the patient's medical records:</p> <p>(a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and</p> <p>(b) details (date and duration of treatment) of prior biological medicine treatment; and</p> <p>(c) the IgE results and date; and</p> <p>(d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and</p> <p>(e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).</p>

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	10109C/ Public	1	1	7	*Xolair
omalizumab 150 mg/mL injection, 1 mL syringe	10122R/ Private	1	1	7	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Public	1	1	7	

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omalizumab 150 mg/mL injection, 1 mL pen device		NEW/ Private	1	1	7	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)					
Prescribing rule level	<p>Administrative Advice: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA</p> <p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.</p> <p>A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.</p> <p>A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.</p> <p>Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.</p> <p>A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.</p> <p>Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.</p> <p>Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.</p> <p>Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.</p> <p>(1) Initial treatment:</p> <p>Applications for initial treatment should be made where:</p> <p>(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or</p> <p>(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or</p> <p>(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].</p> <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment:</p> <p>Following the completion of an initial treatment course with a specific biological medicine, a patient may</p>					

	<p>qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response: Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.</p> <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com</p>
	<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
	<p>Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.</p>

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Restriction Summary 15845/ Treatment of Concept: 15846: Authority Required	
	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)
	Treatment criteria:
	Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma
	Clinical criteria:
	Patient must be under the care of the same physician for at least 6 months; or
	Patient must have been diagnosed by a multidisciplinary severe asthma clinic team
	AND
	Clinical criteria:
	Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; or
	Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma
	AND
	Clinical criteria:
	Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; or
	Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records
	AND
	Clinical criteria:
	Patient must have a duration of asthma of at least 1 year
	AND
	Clinical criteria:
	Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE
	AND
	Clinical criteria:
	Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application
	AND
	Clinical criteria:
	Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records
	AND
	Clinical criteria:
	Patient must not receive more than 32 weeks of treatment under this restriction
	AND

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	Clinical criteria:
	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma
	Population criteria:
	Patient must be aged 12 years or older
	<p>Prescribing Instructions: Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p>
	<p>Prescribing Instructions: The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 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 and for the application for the first continuing therapy to be processed. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator.</p>
	<p>Prescribing Instructions: The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>
	<p>Prescribing Instructions: The following must be provided at the time of application and documented in the patient's medical records: (a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and</p>

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	(b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (d) the IgE result and date; and (e) Asthma Control Questionnaire (ACQ-5) score.
	Administrative Advice: The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.
	Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required	
	Indication: Uncontrolled severe asthma
	Treatment Phase: Initial treatment - Initial 2 (Change of treatment)
	Treatment criteria:
	Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma
	Clinical criteria:
	Patient must be under the care of the same physician for at least 6 months; or
	Patient must have been diagnosed by a multidisciplinary severe asthma clinic team
	AND
	Clinical criteria:
	Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle
	AND
	Clinical criteria:
	Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle
	AND
	Clinical criteria:
	Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma
	AND
	Clinical criteria:
	Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma
	AND
	Clinical criteria:
	Patient must not receive more than 32 weeks of treatment under this restriction
	AND
	Clinical criteria:

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	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma
	Population criteria:
	Patient must be aged 12 years or older
	<p>Prescribing Instructions:</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator.
	<p>Prescribing Instructions:</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
	<p>Prescribing Instructions:</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (date and duration of treatment) of prior biological medicine treatment; and (c) the IgE results and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

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MEDICINAL PRODUCT medicinal product pack		PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
OMALIZUMAB						
omalizumab 300 mg/2 mL injection, 2 mL syringe		NEW/ Public	1	1	7	ªXolair
omalizumab 300 mg/2 mL injection, 2 mL syringe		NEW/ Private	1	1	7	
omalizumab 300 mg/2 mL injection, 2 mL pen device		NEW/ Public	1	1	7	
omalizumab 300 mg/2 mL injection, 2 mL pen device		NEW/ Private	1	1	7	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)					
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)					
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)					
Prescribing rule level	<p>Administrative Advice: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'. A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time. A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle. Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy. A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below]. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma. (1) Initial treatment: Applications for initial treatment should be made where: (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or</p>					

	<p>(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or</p> <p>(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].</p> <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment: Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response: Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:</p> <p>(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or</p> <p>(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and</p> <p>(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.</p> <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com</p>
	<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au</p>

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	<p>Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
	<p>Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.</p>
<p>Restriction Summary 15845/ Treatment of Concept: 15846: Authority Required</p>	
	<p>Indication: Uncontrolled severe asthma</p>
	<p>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)</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma</p>
	<p>Clinical criteria:</p>
	<p>Patient must be under the care of the same physician for at least 6 months; or</p>
	<p>Patient must have been diagnosed by a multidisciplinary severe asthma clinic team</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must not have received PBS-subsidised treatment with a biological medicine for severe asthma; or</p>
	<p>Patient must have had a break in treatment of at least 12 months from the most recently approved PBS-subsidised biological medicine for severe asthma</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility greater than or equal to 12% and greater than or equal to 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 micrograms), (b) airway hyperresponsiveness defined as a greater than 20% decline in FEV1 during a direct bronchial provocation test or greater than 15% decline during an indirect bronchial provocation test, (c) peak expiratory flow (PEF) variability of greater than 15% between the two highest and two lowest peak expiratory flow rates during 14 days; or</p>
	<p>Patient must have a diagnosis of asthma from at least two physicians experienced in the management of patients with severe asthma with the details documented in the patient's medical records</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must have a duration of asthma of at least 1 year</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must have past or current evidence of atopy that is no more than 1 year old at the time of application that is documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application</p>

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	AND
	Clinical criteria:
	Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records
	AND
	Clinical criteria:
	Patient must not receive more than 32 weeks of treatment under this restriction
	AND
	Clinical criteria:
	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma
	Population criteria:
	Patient must be aged 12 years or older
	Prescribing Instructions: Optimised asthma therapy includes adherence to maximal inhaled therapy, including high dose inhaled corticosteroid (ICS) plus long-acting beta-2 agonist (LABA) therapy for at least 12 months, unless contraindicated or not tolerated. If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.
	Prescribing Instructions: The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) an Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month, AND (b) while receiving optimised asthma therapy in the past 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) assessment of the patient's response to this initial course of treatment, and the assessment of oral corticosteroid dose, should be made at around 28 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 and for the application for the first continuing therapy to be processed. This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this drug. If a patient fails to demonstrate a response to treatment with this drug they will not be eligible to receive further PBS-subsidised treatment with this drug for severe asthma within the same treatment cycle. A treatment break in PBS-subsidised biological medicine therapy of at least 12 months must be observed in a patient who has either failed to achieve or sustain a response to treatment with 4 biological medicines for severe asthma within the same treatment cycle. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine was administered until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks. A multidisciplinary severe asthma clinic team comprises of: (i) A respiratory physician; and

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	(ii) A pharmacist, nurse or asthma educator.
	Prescribing Instructions: The authority application must be made in writing and must include: (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
	Prescribing Instructions: The following must be provided at the time of application and documented in the patient's medical records: (a) details of prior optimised asthma drug therapy (dosage, date of commencement, duration of therapy); and (b) If applicable, details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information; and (c) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (d) the IgE result and date; and (e) Asthma Control Questionnaire (ACQ-5) score.
	Administrative Advice: The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.
	Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).
Restriction Summary 15883 / Treatment of Concept: 15870: Authority Required	
	Indication: Uncontrolled severe asthma
	Treatment Phase: Initial treatment - Initial 2 (Change of treatment)
	Treatment criteria:
	Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma
	Clinical criteria:
	Patient must be under the care of the same physician for at least 6 months; or
	Patient must have been diagnosed by a multidisciplinary severe asthma clinic team
	AND
	Clinical criteria:
	Patient must have received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle
	AND
	Clinical criteria:
	Patient must not have failed, or ceased to respond to, PBS-subsidised treatment with this drug for severe asthma during the current treatment cycle
	AND
	Clinical criteria:
	Patient must have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE in the past 12 months or in the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma

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	AND
	Clinical criteria:
	Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to initiating PBS-subsidised treatment with a biological medicine for severe asthma
	AND
	Clinical criteria:
	Patient must not receive more than 32 weeks of treatment under this restriction
	AND
	Clinical criteria:
	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma
	Population criteria:
	Patient must be aged 12 years or older
	<p>Prescribing Instructions:</p> <p>An application for a patient who has received PBS-subsidised biological medicine treatment for this condition who wishes to change therapy to this biological medicine, must be accompanied by the results of an ACQ-5 assessment of the patient's most recent course of PBS-subsidised biological medicine treatment. The assessment must have been made not more than 4 weeks after the last dose of biological medicine. Where a response assessment was not undertaken, the patient will be deemed to have failed to respond to treatment with that previous biological medicine.</p> <p>An ACQ-5 assessment of the patient may be made at the time of application for treatment (to establish a new baseline score), but should be made again around 28 weeks after the first PBS-subsidised dose of this biological medicine under this restriction so that there is adequate time for a response to be demonstrated and for the application for the first continuing therapy to be processed.</p> <p>This assessment, which will be used to determine eligibility for the first continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with this biological medicine.</p> <p>At the time of the authority application, medical practitioners should request an appropriate maximum quantity based on IgE level and body weight (refer to the TGA-approved Product Information) to be administered every 2 to 4 weeks and up to 7 repeats to provide for an initial course sufficient for up to 32 weeks of therapy.</p> <p>A multidisciplinary severe asthma clinic team comprises of:</p> <ul style="list-style-type: none"> (i) A respiratory physician; and (ii) A pharmacist, nurse or asthma educator.
	<p>Prescribing Instructions:</p> <p>The authority application must be made in writing and must include:</p> <ul style="list-style-type: none"> (1) details of the proposed prescription; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).
	<p>Prescribing Instructions:</p> <p>The following must be provided at the time of application and documented in the patient's medical records:</p> <ul style="list-style-type: none"> (a) Asthma Control Questionnaire (ACQ-5 item version) score (where a new baseline is being submitted or where the patient has responded to prior treatment); and (b) details (date and duration of treatment) of prior biological medicine treatment; and (c) the IgE results and date; and (d) if applicable, the dose of the maintenance oral corticosteroid (where the response criteria or baseline is based on corticosteroid dose); and (e) the reason for switching therapy (e.g. failure of prior therapy, partial response to prior therapy, adverse event to prior therapy).

Uncontrolled severe asthma - 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	11835X/ Public	1	1	5	aXolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11840E/ Private	1	1	5	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW/ Public	1	1	5	
omalizumab 75 mg/0.5 mL injection, 0.5 mL pen device	NEW/ Private	1	1	5	

Restriction Summary 15379/ Treatment of Concept: 15347

Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)

Prescribing rule level	<p>Administrative Advice: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA</p> <p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.</p> <p>A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.</p> <p>A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.</p> <p>Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.</p> <p>A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.</p> <p>Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.</p> <p>Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.</p> <p>Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.</p> <p>(1) Initial treatment: Applications for initial treatment should be made where:</p>
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	<p>(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or</p> <p>(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or</p> <p>(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].</p> <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment: Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response: Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:</p> <p>(i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or</p> <p>(ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and</p> <p>(iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.</p> <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com</p>

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	<p>Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).</p>
	<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) 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>Administrative Advice: Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringes and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen devices are equivalent for the purposes of substitution.</p>
<p>Restriction Summary 15379 / Treatment of Concept: 15347: Authority Required</p>	
	<p>Indication: Uncontrolled severe asthma</p>
	<p>Treatment Phase: Continuing treatment</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma</p>
	<p>Clinical criteria:</p>
	<p>Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must not receive more than 24 weeks of treatment under this restriction</p>
	<p>Population criteria:</p>
	<p>Patient must be aged 12 years or older</p>
	<p>Prescribing Instructions: An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).</p>

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	<p>Prescribing Instructions: All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. 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. Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment. A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.</p>
	<p>Prescribing Instructions: The following information must be provided at the time of application 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>

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	11824H/ Public	1	1	5	*Xolair
omalizumab 150 mg/mL injection, 1 mL syringe	11864K/ 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	

Restriction Summary 15379/ Treatment of Concept: 15347

Presc ribing	Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
		Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
		Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
		Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)
		Administrative Advice: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA

	<p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.</p> <p>A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.</p> <p>A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.</p> <p>Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.</p> <p>A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.</p> <p>Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.</p> <p>Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.</p> <p>Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.</p> <p>(1) Initial treatment:</p> <p>Applications for initial treatment should be made where:</p> <ul style="list-style-type: none"> (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below]. <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment:</p> <p>Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response:</p> <p>Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.</p> <p>For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response.</p>
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	<p>However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:</p> <ul style="list-style-type: none"> (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle. <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com</p>
	<p>Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).</p>
	<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) 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>Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.</p>
<p>Restriction Summary 15379 / Treatment of Concept: 15347: Authority Required</p>	
	<p>Indication: Uncontrolled severe asthma</p>
	<p>Treatment Phase: Continuing treatment</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma</p>
	<p>Clinical criteria:</p>
	<p>Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle</p>
	<p>AND</p>
	<p>Clinical criteria:</p>

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	Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma
	AND
	Clinical criteria:
	Patient must not receive more than 24 weeks of treatment under this restriction
	Population criteria:
	Patient must be aged 12 years or older
	Prescribing Instructions: An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).
	Prescribing Instructions: All applications for second and subsequent continuing treatments with this drug must include a measurement of response to the prior course of therapy. 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. Where treatment was ceased for clinical reasons despite the patient experiencing improvement, an assessment of the patient's response to treatment made at the time of treatment cessation or retrospectively will be considered to determine whether the patient demonstrated or sustained an adequate response to treatment. A patient who fails to respond to treatment with this biological medicine for uncontrolled severe asthma will not be eligible to receive further PBS-subsidised treatment with this biological medicine for severe asthma within the current treatment cycle. At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of this biological medicine consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for up to 24 weeks of therapy.
	Prescribing Instructions: The following information must be provided at the time of application 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.

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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 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	5	*Xolair
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	5	
Restriction Summary 15379/ Treatment of Concept: 15347					
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)				
Prescribing rule level	<p>Administrative Advice: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'. A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time. A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle. Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy. A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment. Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once. Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment. Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below]. The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle. There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma. (1) Initial treatment: Applications for initial treatment should be made where: (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or</p>				

	<p>(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or</p> <p>(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below].</p> <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment: Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response: Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.</p> <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: For copies of the ACQ and the calculation sheets please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com</p>
	<p>Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).</p>

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	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.
Restriction Summary 15379 / Treatment of Concept: 15347: Authority Required	
	Indication: Uncontrolled severe asthma
	Treatment Phase: Continuing treatment
	Treatment criteria:
	Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma
	Clinical criteria:
	Patient must have received this drug as their most recent course of PBS-subsidised biological agent treatment for this condition in this treatment cycle
	AND
	Clinical criteria:
	Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	The treatment must not be used in combination with and within 4 weeks of another PBS-subsidised biological medicine prescribed for severe asthma
	AND
	Clinical criteria:
	Patient must not receive more than 24 weeks of treatment under this restriction
	Population criteria:
	Patient must be aged 12 years or older
	Prescribing Instructions: An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 score from baseline or an increase in ACQ-5 score from baseline less than or equal to 0.5, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline (this criterion is only applicable for patients transitioned from the paediatric to the adolescent/adult restriction).

	<p>TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA</p> <p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.</p> <p>A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.</p> <p>A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.</p> <p>Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.</p> <p>A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.</p> <p>Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.</p> <p>Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.</p> <p>Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.</p> <p>(1) Initial treatment:</p> <p>Applications for initial treatment should be made where:</p> <ul style="list-style-type: none">(i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or(ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or(iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below]. <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment:</p> <p>Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response:</p> <p>Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.</p>
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	<p>For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.</p> <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) 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>Administrative Advice: Pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL syringes and pharmaceutical benefits that have the form omalizumab 75 mg/0.5 mL pen devices are equivalent for the purposes of substitution.</p>
<p>Restriction Summary 15349/ Treatment of Concept: 15376: Authority Required</p>	
	<p>Indication: Uncontrolled severe asthma</p>
	<p>Treatment Phase: Balance of supply</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma</p>
	<p>Clinical criteria:</p>
	<p>Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; or</p>
	<p>Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; or</p>
	<p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment</p>
	<p>AND</p>

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	Clinical criteria:
	The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; or
	The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Availab le brands
OMALIZUMAB					
omalizumab 150 mg/mL injection, 1 mL syringe	11828M/ Public	1	1	0	aXolair
omalizumab 150 mg/mL injection, 1 mL syringe	11825J/ Private	1	1	0	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Public	1	1	0	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Private	1	1	0	

Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)

Prescribing rule level	<p>Administrative Advice: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA</p> <p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.</p> <p>A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.</p> <p>A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.</p> <p>Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.</p> <p>A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.</p> <p>Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.</p> <p>Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.</p> <p>Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p>
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	<p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime. How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.</p> <p>(1) Initial treatment: Applications for initial treatment should be made where:</p> <ul style="list-style-type: none"> (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below]. <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment: Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response: Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained. For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing:</p> <ul style="list-style-type: none"> (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle. <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
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	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.
Restriction Summary 15349/ Treatment of Concept: 15376: Authority Required	
	Indication: Uncontrolled severe asthma
	Treatment Phase: Balance of supply
	Treatment criteria:
	Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma
	Clinical criteria:
	Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; or
	Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; or
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment
	AND
	Clinical criteria:
	The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; or
	The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Availab le brands
OMALIZUMAB					
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	0	aXolair
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	0	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	0	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	0	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)				

<p>Prescribing rule level</p>	<p>Administrative Advice: TREATMENT OF ADULT AND ADOLESCENT PATIENTS WITH UNCONTROLLED SEVERE ASTHMA</p> <p>The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of the biological medicines for uncontrolled severe asthma. Where the term biological medicine appears in the following notes and restrictions it refers to all PBS benefits with the specific PBS indication of 'uncontrolled severe asthma'.</p> <p>A patient is eligible for PBS-subsidised treatment with only 1 biological medicine for uncontrolled severe asthma at any one time.</p> <p>A patient receiving PBS-subsidised treatment for uncontrolled severe asthma is able to commence a treatment cycle where they may trial a biological medicine without having to experience a disease flare when swapping to an alternate biological medicine within the same treatment cycle.</p> <p>Under these arrangements, within a treatment cycle, a patient may receive long-term treatment with a biological medicine as long as they sustain a response to therapy.</p> <p>A patient currently receiving PBS-subsidised treatment as of 1 April 2021 is considered to have started a cycle of treatment.</p> <p>Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised biological medicine more than once.</p> <p>Therefore, once a patient fails to meet the response criteria for a PBS-subsidised biological medicine, they must change to an alternate biological medicine if they wish to continue PBS-subsidised biological treatment.</p> <p>Once a patient has either failed to achieve or sustain a response to treatment 4 times, they are deemed to have completed a single treatment cycle. They must have at least a 12-month break in PBS-subsidised biological medicine therapy before they are eligible to recommence another new treatment cycle [further details are under 'Recommencement of treatment after a treatment break in PBS-subsidised therapy' below].</p> <p>The length of the break in therapy is measured from the date the most recent treatment with a PBS-subsidised biological medicine is ceased until the date of the first application for recommencement of treatment with a biological medicine under the new treatment cycle.</p> <p>There is no limit to the number of treatment cycles that a patient may undertake in their lifetime.</p> <p>How to prescribe PBS-subsidised biological medicine treatment for uncontrolled severe asthma.</p> <p>(1) Initial treatment: Applications for initial treatment should be made where:</p> <ul style="list-style-type: none"> (i) a patient has not received prior PBS-subsidised biological medicine treatment and wishes to commence such therapy (Initial 1 restriction); or (ii) a patient has received prior PBS-subsidised treatment with a biological medicine and wishes to recommence a new treatment cycle with this biological medicine following a treatment break in PBS-subsidised therapy (Initial 1 restriction); or (iii) a patient has received prior PBS-subsidised biological medicine therapy and wishes to trial an alternate biological medicine within the same treatment cycle (Initial 2 restriction) - [further details are under 'Swapping therapy' below]. <p>All applications for initial treatment will be limited to provide for a maximum of up to 32 weeks of therapy of a biological medicine. It is recommended that a patient be reviewed in the month prior to completing their course of initial treatment to ensure uninterrupted biological medicine supply.</p> <p>(2) Continuing treatment: Following the completion of an initial treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of continuing treatment with that biological medicine providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing biological medicine treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response. It is recommended that a patient be reviewed the month prior to completing their current course of treatment to ensure uninterrupted biological medicine supply.</p> <p>(3) Baseline measurements to determine response: Baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or oral corticosteroid dose submitted with the Initial authority application for a biological medicine must be used to determine whether an adequate response to treatment has been achieved or sustained.</p>
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	<p>For patients transitioned from the paediatric to the adolescent/adult restriction, the exacerbation history may also be used to determine response. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and these new baseline measurements may be used to assess response.</p> <p>(4) Swapping therapy within the same treatment cycle. Once initial treatment with the first PBS-subsidised biological medicine is approved, a patient may swap to an alternate biological medicine at any time by qualifying under an Initial 2 restriction. However, they cannot swap to a particular biological medicine if they have failed to respond to prior treatment with that drug within the same treatment cycle. Within the same treatment cycle a patient may alternate between therapy with any biological medicine of their choice (1 at a time) providing: (i) they have not received PBS-subsidised treatment with that particular biological medicine previously; or (ii) they have demonstrated an adequate response to that particular biological medicine if they have previously trialled it on the PBS; and (iii) they have not previously failed to respond to treatment with all 4 biological medicines in this treatment cycle.</p> <p>(5) Re-commencement of a new treatment cycle after a treatment break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent new treatment cycle, following a break in PBS-subsidised therapy of at least 12 months (in patients who have failed to achieve or ceased to sustain a response to treatment 4 times within a treatment cycle), must re-qualify through an Initial 1 restriction.</p> <p>(6) Monitoring of patients: Omalizumab only: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) 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>Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.</p>
<p>Restriction Summary 15349/ Treatment of Concept: 15376: Authority Required</p>	
	<p>Indication: Uncontrolled severe asthma</p>
	<p>Treatment Phase: Balance of supply</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a medical practitioner who is either a: (i) respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) general physician experienced in the management of patients with severe asthma</p>
	<p>Clinical criteria:</p>
	<p>Patient must have received insufficient therapy with this drug under the Initial 1 (new patients or recommencement of treatment in a new treatment cycle) restriction to complete 32 weeks treatment; or</p>
	<p>Patient must have received insufficient therapy with this drug under the Initial 2 (change of treatment) restriction to complete 32 weeks treatment; or</p>
	<p>Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment</p>
	<p>AND</p>

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	Clinical criteria:
	The treatment must not provide more than the balance of up to 32 weeks of treatment if the most recent authority approval was made under an Initial treatment restriction; or
	The treatment must not provide more than the balance of up to 24 weeks of treatment if the most recent authority approval was made under the Continuing treatment restriction

Uncontrolled severe allergic asthma - Initial 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	10967F/ Public	1	1	6	Xolair
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	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)				
Prescribing rule level	<p>Administrative Advice: TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction. Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised omalizumab therapy. (a) Initial treatment: Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy. All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab. (b) Continuing treatment: Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. (2) Baseline measurements to determine response:</p>				

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	<p>Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements.</p> <p>(3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.</p> <p>(4) Monitoring of patients: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: The Services Australia website (www.servicesaustralia.gov.au) has details of the accepted toxicities, including severity, which will be accepted for the purposes of exempting a patient from the requirement of treatment with optimised asthma therapy.</p>
	<p>Administrative Advice: For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com</p>
	<p>Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).</p>
	<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au. Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos. Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
	<p>Administrative Advice: No increase in the maximum number of repeats may be authorised.</p>
<p>Restriction Summary 15351/ Treatment of Concept: 15350 : Authority Required</p>	
	<p>Indication: Uncontrolled severe allergic asthma</p>
	<p>Treatment Phase: Initial treatment</p>
	<p>Clinical criteria:</p>
	<p>Patient must have a diagnosis of asthma confirmed and documented in the patient's medical records by either: a (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma in consultation with a respiratory physician, defined by at least one of the following standard clinical features: (a) forced expiratory volume (FEV1) reversibility, (b) airway hyperresponsiveness, (c) peak expiratory flow (PEF) variability</p>
	<p>AND</p>
	<p>Clinical criteria:</p>

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	Patient must have a duration of asthma of at least 1 year
	AND
	Clinical criteria:
	Patient must have past or current evidence of atopy, documented by either: (i) skin prick testing, (ii) an in vitro measure of specific IgE
	AND
	Clinical criteria:
	Patient must have total serum human immunoglobulin E of at least 30 IU/mL, measured no more than 12 months prior to the time of application
	AND
	Clinical criteria:
	Patient must have failed to achieve adequate control with optimised asthma therapy, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records
	AND
	Clinical criteria:
	Patient must not receive more than 28 weeks of treatment under this restriction
	Population criteria:
	Patient must be aged 6 to less than 12 years
	Treatment criteria:
	Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician
	Clinical criteria:
	Patient must be under the care of the same physician for at least 6 months
	<p>Prescribing Instructions:</p> <p>Optimised asthma therapy includes:</p> <p>(i) Adherence to optimal inhaled therapy, including high dose inhaled corticosteroid (ICS) and long-acting beta-2 agonist (LABA) therapy for at least six months. If LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative;</p> <p>AND</p> <p>(ii) treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3-5 day exacerbation treatment courses), in the previous 12 months, unless contraindicated or not tolerated.</p> <p>If the requirement for treatment with optimised asthma therapy cannot be met because of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the Authority application.</p>

	<p>Prescribing Instructions: The following initiation criteria indicate failure to achieve adequate control and must be demonstrated in all patients at the time of the application: (a) An Asthma Control Questionnaire (ACQ-5) score of at least 2.0, as assessed in the previous month (for children aged 6 to 10 years it is recommended that the Interviewer Administered version - the ACQ-IA be used), AND (b) while receiving optimised asthma therapy in the previous 12 months, experienced at least 1 admission to hospital for a severe asthma exacerbation, OR 1 severe asthma exacerbation, requiring documented use of systemic corticosteroids (oral corticosteroids initiated or increased for at least 3 days, or parenteral corticosteroids) prescribed/supervised by a physician. The Asthma Control Questionnaire (5 item version) or ACQ-IA assessment of the patient's response to this initial course of treatment, the assessment of oral corticosteroid dose, and the assessment of exacerbation rate should be made at around 24 weeks after the first dose so that there is adequate time for a response to be demonstrated and for the application for continuing therapy to be processed. This assessment, which will be used to determine eligibility for continuing treatment, should be conducted within 4 weeks of the last dose of biological medicine. Where a response assessment is not undertaken and provided, the patient will be deemed to have failed to respond to treatment with omalizumab. A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased. At the time of the authority application, medical practitioners should request the appropriate maximum quantity and number of repeats to provide for an initial course of omalizumab of up to 28 weeks, consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information) to be administered every 2 or 4 weeks.</p>
	<p>Prescribing Instructions: The authority application must be made in writing and must include: (1) a completed authority prescription form; and (2) a completed authority application form relevant to the indication and treatment phase (the latest version is located on the website specified in the Administrative Advice).</p>
	<p>Prescribing Instructions: The following must be provided at the time of application and documented in the patient's medical records: (a) details of prior optimised asthma drug therapy (dosage, date of commencement and duration of therapy); and (b) details of severe exacerbation/s experienced in the past 12 months while receiving optimised asthma therapy (date and treatment); and (c) the IgE result and date; and (d) Asthma Control Questionnaire (ACQ-5) score; or (e) Asthma Control Questionnaire interviewer administered version (ACQ-IA) score.</p>
<p>Caution¹[New]</p>	<p>The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.</p>
<p>Caution²[New]</p>	<p>The 300mg/2mL omalizumab syringe device is not intended for use in children under 12 years of age for this indication.</p>

Uncontrolled severe allergic asthma - 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	11946R/ Public	1	1	5	Xolair
omalizumab 75 mg/0.5 mL injection, 0.5 mL syringe	11952C/ Private	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	11945Q/ Public	1	1	5	
omalizumab 150 mg/mL injection, 1 mL syringe	11953D/ Private	1	1	5	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)				
Prescribing rule level	<p>Administrative Advice: TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction. Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised omalizumab therapy. (a) Initial treatment: Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy. All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab. (b) Continuing treatment: Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. (2) Baseline measurements to determine response: Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements. (3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy:</p>				

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	<p>A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed.</p> <p>(4) Monitoring of patients: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: For copies of the ACQ please contact Novartis Medical Information on 1800 671 203 or medinfo.phauno@novartis.com</p>
	<p>Administrative Advice: Formal assessment and correction of inhaler technique should be performed in accordance with the National Asthma Council (NAC) Information Paper for Health Professionals on Inhaler Technique (available at www.nationalasthma.org.au); the assessment and adherence to correct technique should be documented in the patient's medical records. Patients can obtain support with inhaler technique through their local Asthma Foundation (1800 645 130).</p>
	<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) 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>Administrative Advice: No increase in the maximum number of repeats may be authorised.</p>
<p>Restriction Summary 15382/ Treatment of Concept: 15352 : Authority Required</p>	
	<p>Indication: Uncontrolled severe allergic asthma</p>
	<p>Treatment Phase: Continuing treatment</p>
	<p>Clinical criteria:</p>
	<p>Patient must have a documented history of severe allergic asthma</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must have demonstrated or sustained an adequate response to PBS-subsidised treatment with this drug for this condition</p>
	<p>AND</p>
	<p>Clinical criteria:</p>
	<p>Patient must not receive more than 24 weeks of treatment under this restriction</p>
	<p>Treatment criteria:</p>
	<p>Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician</p>
	<p>Prescribing Instructions: An adequate response to omalizumab treatment is defined as: (a) a reduction in the Asthma Control Questionnaire (ACQ-5) or ACQ-IA score of at least 0.5 from baseline, OR (b) maintenance oral corticosteroid dose reduced by at least 25% from baseline, and no deterioration in ACQ-5 or ACQ-IA score from baseline, OR (c) a reduction in the time-adjusted exacerbation rates compared to the 12 months prior to baseline.</p>

	<p>Prescribing Instructions:</p> <p>A measurement of response to the prior course of therapy must be provided at the time of application and should be used to determine eligibility for continuing treatment. The Asthma Control Questionnaire (5 item version) or Asthma Control Questionnaire interviewer administered version (ACQ-IA) assessment of the patient's response to the prior course of treatment, the assessment of systemic corticosteroid dose, and the assessment of time-adjusted exacerbation rate should be made from 20 weeks after the first dose of PBS-subsidised omalizumab so that there is adequate time for a response to be demonstrated. The first assessment should, where possible, be completed by the same physician who initiated treatment with omalizumab.</p> <p>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 omalizumab.</p> <p>A patient who fails to respond to a course of PBS-subsidised omalizumab for the treatment of uncontrolled severe allergic asthma will not be eligible to receive further PBS-subsidised treatment with omalizumab for this condition within 6 months of the date on which treatment was ceased.</p> <p>At the time of the authority application, medical practitioners should request the appropriate quantity and number of repeats to provide for a continuing course of omalizumab consisting of the recommended number of doses for the baseline IgE level and body weight of the patient (refer to the TGA-approved Product Information), sufficient for 24 weeks of therapy.</p>
	<p>Prescribing Instructions:</p> <p>The following information must be provided at the time of application and must be documented in the patient's medical records:</p> <p>(a) If applicable, the baseline and maintenance oral corticosteroid dose; and</p> <p>(b) baseline and current Asthma Control Questionnaire (ACQ-5) date and score; or</p> <p>(c) baseline and current Asthma Control Questionnaire interviewer administered version (ACQ-IA) date and score; and</p> <p>(d) if applicable, confirmation that the time-adjusted exacerbation rate has reduced.</p> <p>The most recent Asthma Control Questionnaire (ACQ-5) score or Asthma Control Questionnaire interviewer administered version (ACQ-IA) score must be no more than 4 weeks old at the time of application.</p>
Caution ¹ [New]	The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.
Caution ² [New]	The 300mg/2mL omalizumab syringe device is not intended for use in children under 12 years of age for this indication.

Uncontrolled severe allergic asthma - Balance of supply in a patient aged 6 to 12 years

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	Xolair
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	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				

	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)
Prescribing rule level	<p>Administrative Advice: TREATMENT OF PAEDIATRIC PATIENTS WITH UNCONTROLLED SEVERE ALLERGIC ASTHMA Patients are eligible to commence an 'omalizumab treatment cycle' (initial treatment course with or without continuing treatment course/s) if they satisfy the eligibility criteria as detailed under the initial treatment restriction. Once a patient has either failed to achieve or maintain a response to omalizumab, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 6 month break in PBS-subsidised omalizumab therapy before they are eligible to commence the next cycle. The length of a treatment break is measured from the date the most recent treatment with PBS-subsidised omalizumab treatment is stopped to the date of the first application for initial treatment with omalizumab under the new treatment cycle. There is no limit to the number of treatment cycles a patient may undertake in their lifetime. (1) How to prescribe PBS-subsidised omalizumab therapy. (a) Initial treatment: Applications for initial treatment should be made where a patient has received no prior PBS-subsidised omalizumab treatment in this treatment cycle and wishes to commence such therapy. All applications for initial treatment will be limited to provide for a maximum of 28 weeks of therapy for omalizumab. (b) Continuing treatment: Following the completion of the initial treatment course with omalizumab, a patient may qualify to receive up to a further 24 weeks of continuing treatment with omalizumab providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing omalizumab treatment in courses of up to 24 weeks providing they continue to sustain the response. (2) Baseline measurements to determine response: Services Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the Asthma Control Questionnaire (ACQ; 5 item version) or ACQ-IA, systemic corticosteroid dose and time-adjusted exacerbation rate, submitted with the Initial authority application for omalizumab. However, prescribers may provide new baseline measurements when a new Initial treatment authority application is submitted and Services Australia will assess response according to these revised baseline measurements. (3) Re-commencement of treatment after a 6 month break in PBS-subsidised therapy: A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised omalizumab therapy of at least 6 months, must re-qualify for initial treatment with respect to the indices of disease severity (systemic corticosteroid dose, Asthma Control Questionnaire (ACQ-5) score or ACQ-IA, and relevant exacerbation history). Patients must have received optimised standard therapy, at adequate doses and for the minimum period specified, immediately prior to the time the new baseline assessments are performed. (4) Monitoring of patients: Anaphylaxis and anaphylactoid reactions have been reported following first or subsequent administration of omalizumab (see Product Information). Patients should be monitored post-injection, and medications for the treatment of anaphylactic reactions should be available for immediate use following administration of omalizumab. Patients should be informed that such reactions are possible and prompt medical attention should be sought if allergic reactions occur.</p>
	<p>Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) 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>
Restriction Summary 15381/ Treatment of Concept: 15403: Authority Required	
	Indication: Uncontrolled severe allergic asthma
	Treatment Phase: Balance of supply in a patient aged 6 to 12 years
	Treatment criteria:

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	Must be treated by a medical practitioner who is either a: (i) paediatric respiratory physician, (ii) clinical immunologist, (iii) allergist, (iv) paediatrician or general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician
	Clinical criteria:
	Patient must have received insufficient therapy with this drug under the Initial treatment restriction to complete 28 weeks treatment; or
	Patient must have received insufficient therapy with this drug under the Continuing treatment restriction to complete 24 weeks treatment
	AND
	Clinical criteria:
	The treatment must provide no more than the balance of up to 28 weeks treatment available under the Initial restriction or up to 24 weeks treatment available under the Continuing restriction
	The omalizumab pen device is not intended for use in children below 12 years of age. For children below 12 years of age with uncontrolled severe allergic asthma, the omalizumab syringe is the appropriate form for this population.
	The 300mg/2mL omalizumab syringe device is not intended for use in children under 12 years of age for this indication.

Severe chronic spontaneous urticaria - 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	11176F/ Public	2	2	2	*Xolair
omalizumab 150 mg/mL injection, 1 mL syringe	11175E/ Private	2	2	2	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Public	2	2	2	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW/ Private	2	2	2	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)				
Restriction Summary 7055/ Treatment of Concept:7055: Authority Required					
	Indication: Severe chronic spontaneous urticaria				
	Treatment Phase: Initial treatment				
	Treatment criteria:				
	Must be treated by a clinical immunologist; or				
	Must be treated by an allergist; or				
	Must be treated by a dermatologist; or				
	Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU)				
	Clinical criteria:				
	The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria)				
	AND				
	Clinical criteria:				

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	Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines
	AND
	Clinical criteria:
	Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy
	AND
	Clinical criteria:
	Patient must not receive more than 12 weeks of treatment under this restriction
	Prescribing Instructions: A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following: 1) a H2 receptor antagonist (150 mg twice per day); or 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or 3) doxepin (up to 25 mg three times a day)
	Prescribing Instructions: If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.
	Prescribing Instructions: A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.
	Prescribing Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include: (i) demonstration of failure to achieve an adequate response to standard therapy; and (ii) drug names and doses of standard therapies that the patient has failed; and (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.
	Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001
	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.

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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 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	2	aXolair
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	2	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	2	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	2	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (in writing only via post/HPOS upload)				
Restriction Summary 7055/ Treatment of Concept:7055 : Authority Required					
	Indication: Severe chronic spontaneous urticaria				
	Treatment Phase: Initial treatment				
	Treatment criteria:				
	Must be treated by a clinical immunologist; or				
	Must be treated by an allergist; or				
	Must be treated by a dermatologist; or				
	Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU)				
	Clinical criteria:				
	The condition must be based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria)				
	AND				
	Clinical criteria:				
	Patient must have experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines				
	AND				
	Clinical criteria:				
	Patient must have failed to achieve an adequate response after a minimum of 2 weeks treatment with a standard therapy				
	AND				
	Clinical criteria:				
	Patient must not receive more than 12 weeks of treatment under this restriction				
	Prescribing Instructions: A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following: 1) a H2 receptor antagonist (150 mg twice per day); or 2) a leukotriene receptor antagonist (LTRA) (10 mg per day); or 3) doxepin (up to 25 mg three times a day)				
	Prescribing Instructions: If the requirement for treatment with H1 antihistamines and a H2 receptor antagonist, or a leukotriene receptor antagonist or doxepin cannot be met because of contraindications according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal, details of the contraindication and/or intolerance must be provided in the authority application.				

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	<p>Prescribing Instructions: A failure to achieve an adequate response to standard therapy is defined as a current Urticaria Activity Score 7 (UAS7) score of equal to or greater than 28 with an itch score of greater than 8, as assessed while still on standard therapy.</p>
	<p>Prescribing Instructions: The authority application must be made in writing and must include: (a) a completed authority prescription form; and (b) a completed Chronic Spontaneous Urticaria Omalizumab Initial PBS Authority Application - Supporting Information Form which must include: (i) demonstration of failure to achieve an adequate response to standard therapy; and (ii) drug names and doses of standard therapies that the patient has failed; and (iii) a signed patient acknowledgment that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.</p>
	<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to the Department of Human Services on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Department of Human Services website at www.humanservices.gov.au Applications for authority to prescribe should be forwarded to: Department of Human Services Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
	<p>Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.</p>

Severe chronic spontaneous urticaria - Continuing 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	11168T/ Public	2	2	5	aXolair
omalizumab 150 mg/mL injection, 1 mL syringe	11163M/ Private	2	2	5	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW	2	2	5	
omalizumab 150 mg/mL injection, 1 mL pen device	NEW	2	2	5	
Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)				
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)				
Prescribing rule level	Administrative Advice: A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.				
	Administrative Advice: Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.				

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	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) 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).
	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 150 mg/mL syringes and pharmaceutical benefits that have the form omalizumab 150 mg/mL pen devices are equivalent for the purposes of substitution.

Restriction Summary 10734/ Treatment of Concept:7046: Authority Required

Indication: Severe chronic spontaneous urticaria
Treatment Phase: Continuing treatment
Treatment criteria:
Must be treated by a clinical immunologist; or
Must be treated by an allergist; or
Must be treated by a dermatologist; or
Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU)
Clinical criteria:
Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition
AND
Clinical criteria:
Patient must not receive more than 24 weeks per authorised course of treatment under this restriction

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
OMALIZUMAB					
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Public	1	1	5	*Xolair
omalizumab 300 mg/2 mL injection, 2 mL syringe	NEW/ Private	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Public	1	1	5	
omalizumab 300 mg/2 mL injection, 2 mL pen device	NEW/ Private	1	1	5	

Concept ID (for internal Dept. use)	Category / Program: Section 100 – Highly Specialised Drugs Program – Public (Code HB) / Private (Code HS)
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners
	Restriction type: <input checked="" type="checkbox"/> Authority Required (telephone/online PBS Authorities system)
	Authority type: <input checked="" type="checkbox"/> Complex Authority Required (CAR)

Prescribing rule level	Administrative Advice: A proportion of patients respond to 150 mg 4-weekly so where a substantial improvement has been obtained with a 300 mg dose it is reasonable to back-titrate dose after initial treatment.
	Administrative Advice: Cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy. Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.
	Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) 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).

	Administrative Advice: Pharmaceutical benefits that have the form omalizumab 300 mg/2 mL syringes and pharmaceutical benefits that have the form omalizumab 300 mg/2 mL pen devices are equivalent for the purposes of substitution.
Restriction Summary 10734/ Treatment of Concept:7046: Authority Required	
	Indication: Severe chronic spontaneous urticaria
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	Treatment criteria:
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	Must be treated by an allergist; or
	Must be treated by a dermatologist; or
	Must be treated by a general physician with expertise in the management of chronic spontaneous urticaria (CSU)
	Clinical criteria:
	Patient must have demonstrated a response to the most recent PBS-subsidised treatment with this drug for this condition
	AND
	Clinical criteria:
	Patient must not receive more than 24 weeks per authorised course of treatment under this restriction

These restrictions 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.