

# medicare



# Severe allergic asthma paediatric – omalizumab initial authority application

# **Online PBS Authorities**

You do not need to complete this form if you use the **Online PBS Authorities** system.

For more information and how to access the Online PBS Authorities system, go to servicesaustralia.gov.au/hppbsauthorities

#### When to use this form

Use this form to apply for initial PBS-subsidised omalizumab for paediatric patients 6 to under 12 years, with uncontrolled severe allergic asthma.

## **Important information**

Initial applications to start PBS-subsidised treatment can be made using the Online PBS Authorities system or in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for uncontrolled severe allergic asthma initial authority applications.

Applications for balance of supply can be made in real time using the Online PBS Authorities system or by phone. Call 1800 700 270 Monday to Friday, 8 am and 5 pm, local time.

The information in this form is correct at the time of publishing and may be subject to change.

## **Continuing treatment**

This form is ONLY for initial treatment.

After an authority application for initial treatment has been approved, applications for continuing treatment can be made in real time using the **Online PBS Authorities** system or by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

# **Section 100 arrangements** for omalizumab

This item is available to a patient who is attending:

- an approved private hospital, or
- a public hospital

#### and is a:

- day admitted patient
- non-admitted patient, or
- patient on discharge.

This item is not available as a PBS benefit for in-patients of a public hospital.

The hospital name and provider number must be included in this authority form.

#### **Treatment specifics**

The assessment of the patient's response to the course of treatment must be conducted within the time frame specified in the restriction. Where a demonstration of response is not conducted within the required time frame, the patient will be deemed to have failed treatment with that particular PBS-subsidised biological medicine.

A patient who has experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal is not considered to have failed treatment with that particular PBS-subsidised biological medicine.

The patient must not receive **more than 28 weeks** of treatment under this restriction.

#### For more information

Go to servicesaustralia.gov.au/healthprofessionals

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# Severe allergic asthma paediatric – omalizumab – initial authority application

0	nline PBS Authorities		This hospital is a:
	You do not need to complete this form if you use the		public hospital
	Online PBS Authorities system.		private hospital
	Go to servicesaustralia.gov.au/hppbsauthorities	8	Hospital provider number
Da	tient's details		
_		Col	nditions and criteria
1	Medicare card number		iluluons and criteria
	Ref no.		qualify for PBS authority approval, the
	or	mu	ust be met.
	Department of Veterans' Affairs card number	9	The patient, 6 to under 12 years, is
			practitioner who is:
0	M. D. Miss D. Others		a paediatric respiratory physici
2	Mr Miss Other		a clinical immunologist
	Family name		an allergist
			a paediatrician experienced in with severe asthma, in consulta
	First given name		physician
			a general physician experience
3	Date of birth (DD MM YYYY)		patients with severe asthma, ir
		40	respiratory physician.
		10	Has the patient been under the care least 6 months?
Pr	escriber's details		Yes
4	Prescriber number		No 🗌
7	Tresember number	11	This application is for:
			initial treatment
5	Dr Mr Mrs Miss Ms Other		recommencent after a break of
	Family name		
		12	Has the patient had asthma for at le
	First given name		Yes
			No 🗌
6	Business phone number (including area code)	13	The patient has a diagnosis of seve
U	Dusiness priorie number (including area code)		and documented in the patient's me mentioned treating prescriber, defin
			following standard clinical features:
	Alternative phone number (including area code)		forced expiratory volume (FEV1
			airway hyperresponsiveness
ĮJ.	ponital dataila		peak expiratory flow (PEF) varia
НС	ospital details		
7	Hospital name		

Coı	nditions and criteria
	qualify for PBS authority approval, the following conditions ust be met.
9	The patient, 6 to under 12 years, is being treated by a medical practitioner who is:  a paediatric respiratory physician
	a clinical immunologist an allergist
	a paediatrician experienced in the management of patients with severe asthma, in consultation with a respiratory physician
	a general physician experienced in the management of patients with severe asthma, in consultation with a respiratory physician.
10	Has the patient been under the care of the same physician for at least 6 months?  Yes  No  No
11 This application is for:	
	initial treatment Go to 12
	recommencent after a break of at least 6 months
	▶ Go to 13
12	Has the patient had asthma for at least one year?  Yes  No
13	The patient has a diagnosis of severe allergic asthma, confirmed and documented in the patient's medical records by the above mentioned treating prescriber, defined by at least one of the following standard clinical features:
	forced expiratory volume (FEV1) reversibility
	airway hyperresponsiveness
	peak expiratory flow (PEF) variability.

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e patient nas:  received optimised asthma therapy including:	in the relevant TGA-approved Product Information) and/or
adherence to high dose inhaled corticosteroid (ICS) for	intolerances of a severity necessitating permanent treatment
at least 6 months	withdrawal.
Name of steroid	For details of the toxicity criteria, go to servicesaustralia.gov.au/healthprofessionals
	Inhaled corticosteroid
Davis	
Dose	
From (DD MM YYYY)	
To (DD MM YYYY)	Inheled long action hate 2 against they are
and	Inhaled long-acting beta-2 agonist therapy
adherence to long-acting beta-2 agonist (LABA) therapy for at least 6 months	
Name of LABA	
	Oral or IV corticosteroids
Dose	
From (DD MM YYYY)	
To (DD MM YYYY)	
or	Go to 1
if LABA therapy is contraindicated, not tolerated or	<b>16</b> The patient has failed to achieve adequate control with
not effective, montelukast, cromoglycate or	optimised asthma therapy in the past 12 months, despite forma
nedocromil may be used as an alternative  Name of alternative to LABA	assessment of and adherence to correct inhaler technique,
Name of alternative to LABA	which has been documented in the patient's medical records and demonstrated by:
	at least one admission to hospital for a severe asthma
Dose	exacerbation while receiving optimised asthma therapy
From (DD MM YYYY)	Date of exacerbation (DD MM YYYY)
To (DD MM YYYY)	or
	at least one severe asthma exacerbation, requiring
and	documented use of systemic corticosteroids prescribed or
treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance	supervised by a physician, with either:
treatment courses, or 3 to 5 day exacerbation	OCS initiated or increased for at least 3 days
treatment courses) in the previous 12 months.	Date of exacerbation (DD MM YYYY)
Name of first course steroid	
	or
Dose	parenteral corticosteroids
From (DD MM YYYY)	Date of exacerbation (DD MM YYYY)
To (DD MM YYYY)	17 Does the patient have a baseline Asthma Control Questionnaire
Name of second course steroid	(ACQ-5 or ACQ-IA) score of ≥ 2.0 (no more than one month old)
	Yes
Dose	No L
From (DD MM YYYY)	
To (DD MM YYYY) Go to 16	
, an in 10	
contraindications and/or intolerances to prior optimised	
asthma therapy	
Go to 15	
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40	B			
Ιδ	Provide baseline details:			
	ACQ-5 / ACQ-IA score			
	Date (DD MM YYYY)			
19	The patient has past or current evidence of atopy that is documented by:			
	skin prick testing			
	or			
	an in vitro measure of specific IgE.			
20	·			
20	1			
	$(lgE) \ge 30 lU/mL$ (measured no more than 12 months prior to this application)?			
	No No			
	Yes Provide details			
	res Provide details			
	lgE result IU/mL			
	Date (DD MM YYYY)			
Chí	ecklist			
-				
21	The relevant attachments need to be provided with			
	this form.			
	Details of the proposed prescription(s).			
D				

# **Privacy notice**

Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application.

Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can

be found at servicesaustralia.gov.au/privacypolicy

#### Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at

servicesaustralia.gov.au/hpos

#### 23 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine.
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application.
- I have provided details of the proposed prescription(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction.
- the information I have provided in this form is complete and correct.

#### Lunderstand that

i unuerstanu urat.				
• giving false or misleading information is a serious offence.				
I have read, understood and agree to the above.				
Date (DD MM YYYY) (you <b>must</b> date this declaration)				
Prescriber's signature ( <b>only</b> required if returning by post)				

#### **Returning this form**

Return this form, details of the proposed prescription(s) and any relevant attachments:

 online (no signature required), upload through HPOS at servicesaustralia.gov.au/hpos

or

by post (signature required) to

Services Australia Complex Drugs Programs Reply Paid 9826 HOBART TAS 7001