Australian Government
Services Australia

medicare

PBS

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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Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Mr ☐ Miss ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

Prescriber's details

4 Prescriber number

5 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

6 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

7 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

8 Hospital provider number

Conditions and criteria

To qualify for PBS authority approval, the following conditions must 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 ☐

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.

MCA0PB188 2502

14 The patient has received optimised asthma therapy including:

☐ adherence to high dose inhaled corticosteroid (ICS) for at least 6 months

Name

Dose

From (DD MM YYYY)

To (DD MM YYYY)

and

☐ adherence to long-acting beta-2 agonist (LABA) therapy for at least 6 months

Name

Dose

From (DD MM YYYY)

To (DD MM YYYY)

or

☐ if LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

Name

Dose

From (DD MM YYYY)

To (DD MM YYYY)

and

☐ treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3 to 5 day exacerbation treatment courses) in the previous 12 months.

Name

Dose

From (DD MM YYYY)

To (DD MM YYYY)

Name

Dose

From (DD MM YYYY)

To (DD MM YYYY)

Go to 16

or

☐ contraindications and/or intolerances to prior optimised asthma therapy

Go to 15

15 Provide details of contraindications (including those specified in the relevant TGA-approved Product Information) and/or intolerances of a severity necessitating permanent treatment withdrawal.

For details of the toxicity criteria, go to **servicesaustralia.gov.au/healthprofessionals**

Inhaled corticosteroid

Inhaled long-acting beta-2 agonist therapy

Oral or IV corticosteroids

Go to 16

16 The patient has failed to achieve adequate control with optimised asthma therapy in the past 12 months, despite formal assessment of and adherence to correct inhaler technique, which has been documented in the patient's medical records and demonstrated by:

☐ at least one admission to hospital for a severe asthma exacerbation while receiving optimised asthma therapy

Date of exacerbation (DD MM YYYY)

or

☐ at least one severe asthma exacerbation, requiring documented use of systemic corticosteroids prescribed or supervised by a physician, with either:

☐ OCS initiated or increased for at least 3 days

Date of exacerbation (DD MM YYYY)

or

☐ parenteral corticosteroids

Date of exacerbation (DD MM YYYY)

17 Does the patient have a baseline Asthma Control Questionnaire (ACQ-5 or ACQ-IA) score of ≥ 2.0 (no more than one month old)?

Yes ☐

No ☐

18 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 Does the patient have a total serum human immunoglobulin E (IgE) ≥ 30 IU/mL (measured no more than 12 months prior to this application)?

No ☐

Yes ☐ Provide details

IgE result IU/mL

Date (DD MM YYYY)

Checklist

21 The relevant attachments need to be provided with this form.

☐ Details of the proposed prescription(s).

Privacy notice

22 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.

I understand that:

- giving false or misleading information is a serious offence.

☐ I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

Prescriber's signature (**only** required if returning by post)

If returning by post, print and sign by hand.

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

Reset form