Australian Government
Services Australia

medicare

PBS

# Severe asthma paediatric – dupilumab or omalizumab – initial or recommencement 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** or **recommencing** PBS-subsidised biological medicines for paediatric patients 6 to under 12 years, with uncontrolled severe asthma or uncontrolled severe allergic asthma.

## Important information

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 asthma or severe allergic asthma **initial** or **recommencement** authority applications.

Where the term 'biological medicine' appears, it refers to dupilumab and omalizumab.

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** or **recommencement** of treatment.

After an authority application for **initial** treatment has been approved, applications for **continuing** treatment with the originator brand of omalizumab 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. **Continuing** treatment with PBS-subsidised biosimilar brand of omalizumab are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

Applications for **continuing** treatment with **dupilumab** 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.

## Section 100 arrangements for dupilumab and omalizumab

These items are 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.

These items are 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 should receive **no more than 32 weeks** of treatment with dupilumab and **no more than 28 weeks** of treatment with omalizumab under this restriction.

## For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

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## Online PBS Authorities

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## Patient's details

**1** Medicare card number

Ref no.

**or**

Department of Veterans' Affairs card number

**2** Family name

First given name

**3** Date of birth (DD MM YYYY)

## Prescriber's details

**4** Prescriber number

**5** 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 is 6 to under 12 years and 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

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**11** The patient has:

☐ not received PBS-subsidised treatment with a biological medicine for severe asthma or severe allergic asthma

**or**

☐ had at least a 12-month break in treatment from the most recently approved PBS-subsidised biological medicine for severe asthma or severe allergic asthma.

**12** Will this treatment be used in combination with and **within 4 weeks** of another PBS-subsidised biological medicine prescribed for nasal polyps, uncontrolled severe allergic asthma, uncontrolled severe asthma, or uncontrolled chronic obstructive pulmonary disease?

Yes ☐
No ☐

**13** Has the patient had asthma for at least one year?

Yes ☐
No ☐

**14** The patient has a diagnosis of 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.

**15** The patient has:

☐ received optimised asthma therapy including:

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

Name of steroid

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 of LABA

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 of alternative to LABA

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 of first course steroid

Dose

From (DD MM YYYY)

To (DD MM YYYY)

Name of second course steroid

Dose

From (DD MM YYYY)

To (DD MM YYYY)

***Go to 17***

**or**

☐ contraindications and/or intolerances to prior optimised asthma therapy

***Go to 16***

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

**Inhaled corticosteroid**

**Inhaled long-acting beta-2 agonist therapy**

**Oral or IV corticosteroids**

▶ *Go to 18*

**17** 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)

**18** 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 ☐

**19** Provide baseline details:

ACQ-5 / ACQ-IA score

Date (DD MM YYYY)

**20** This application is for:

☐ dupilumab ▶ *Go to 21*

☐ omalizumab ▶ *Go to 22*

**21** In the last 12 months, the patient has had a:

☐ total serum human immunoglobulin E (IgE) of at least 30 IU/mL with past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE

IgE result IU/mL

Date (DD MM YYYY)

**or**

☐ blood eosinophil count of at least 150 cells/microlitre

Blood eosinophil count cells/microlitre

Date (DD MM YYYY)

**or**

☐ fractional exhaled nitrous oxide of at least 20 ppb

Fractional exhaled nitrous oxide ppb

Date (DD MM YYYY)

▶ *Go to 24*

**22** The patient has past or current evidence of atopy that is documented by:

☐ skin prick testing

**or**

☐ an in vitro measure of specific IgE.

**23** Does the patient have a total serum human immunoglobulin E (IgE) of at least 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

**24** The relevant attachments need to be provided with this form.

☐ Details of the proposed prescription(s).

## Privacy notice

**25** 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**

**26** **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**
- by post (signature required) to

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001

Reset form