Australian Government
Services Australia

medicare

PBS

Severe asthma paediatric – change or continuing 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 **changing** PBS-subsidised dupilumab or omalizumab or **continuing** PBS-subsidised dupilumab for paediatric patients aged 6 to under 12 years with uncontrolled severe asthma or uncontrolled severe allergic asthma.

Important information

Authority applications 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.

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 to 5 pm, local time.

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

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 **changing** or **continuing** treatment.

Following the completion of a **change** of treatment course with a specific biological medicine, a patient may qualify to receive up to 24 weeks of **continuing** treatment with that biological medicine, provided they have demonstrated an adequate response to treatment.

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 biosimilar brand of **omalizumab** are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

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.

Under the **change** of treatment restriction, the patient must receive **no more than 32 weeks** of treatment with **dupilumab** and **no more than 28 weeks** of treatment with **omalizumab**.

For **continuing** treatment, the patient must **not** receive **more than 24 weeks** of treatment.

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 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

9 The patient 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 This application is for the:

- ☐ **continuing** treatment with **dupilumab** ▶ ***Go to 11***

or

- ☐ **change** of treatment to:
  - ☐ dupilumab ▶ ***Go to 12***
  - ☐ omalizumab ▶ ***Go to 12***

11 Does the patient have a documented history of either severe asthma or severe allergic asthma?

- Yes ☐ ▶ ***Go to 18***
- No ☐

12 The patient has:

- ☐ been under the care of the same physician for at least 6 months

and

- ☐ received prior PBS-subsidised treatment with a biological medicine in this treatment cycle for either severe asthma or severe allergic asthma

  Most recent biological medicine

  From (DD MM YYYY)

  To (DD MM YYYY)

and

- ☐ **not** failed, or ceased to respond to, PBS-subsidised treatment with this drug (the biological medicine this application is for) for this condition during the current treatment cycle

and

- ☐ **not** failed, or ceased to respond to, PBS-subsidised treatment with **2** biological medicines for this condition within this treatment cycle.

MCA0PB385 2609

13 Will the 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 ☐

14 In the 12 months prior to initiating PBS-subsidised treatment with a biological medicine for either severe asthma or severe allergic asthma, the patient 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 (applies to **dupilumab** only)

☐ blood eosinophil count of at least 150 cells per microlitre

Blood eosinophil count [cells/microlitre]

Date (DD MM YYYY)

[ ] [ ] [ ]

or (applies to **dupilumab** only)

☐ fractional exhaled nitrous oxide of at least 20 ppb

Fractional exhaled nitrous oxide [ppb]

Date (DD MM YYYY)

[ ] [ ] [ ]

15 The patient is switching PBS-subsidised biological medicine treatment for this condition due to:

☐ failure of prior therapy

or

☐ partial response to prior therapy

or

☐ adverse event to prior therapy

or

☐ other reason

[ ]

16 The patient:

☐ is submitting a new baseline Asthma Control Questionnaire (ACQ-5 or ACQ-IA) score of:

[ ]

and

☐ if applicable, is receiving maintenance oral corticosteroids (OCS) dose of:

[mg/day]

and

☐ an assessment of response will be conducted around 28 weeks (for dupilumab) or 24 weeks (for omalizumab) after the first dose of this treatment

▶ ***Go to 19***

or

☐ is using the previously submitted baseline ACQ-5 or ACQ-IA score of:

[ ]

and

☐ future demonstrations of response will be assessed against the previously recorded baseline

▶ ***Go to 19***

or

☐ is providing assessment result(s) as a demonstration of response

▶ ***Go to 17***

17 Has the assessment been made no more than 4 weeks after the last dose of biological medicine for this condition?

Yes ☐
No ☐

18 The patient has demonstrated or sustained an adequate response to the most recent PBS-subsidised biological medicine treatment for this condition, as evidenced by a reduction in the:

☐ ACQ-5 or ACQ-IA score of at least 0.5 from baseline

Current ACQ-5 / ACQ-IA score

Date of response assessment (DD MM YYYY)

or

☐ maintenance dose of oral corticosteroid (OCS) by at least 25% from baseline

Name of steroid

Current dose mg/day

and

☐ no deterioration in the ACQ-5 / ACQ-IA score from baseline

Current ACQ-5 / ACQ-IA score

Date of response assessment (DD MM YYYY)

or

☐ time-adjusted exacerbation rates compared to the 12 months prior to baseline

Date of response assessment (DD MM YYYY)

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

20 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**

21 **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