Australian Government
Services Australia

medicare

PBS

# Severe asthma – adolescent and adult – change 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 biological medicines for patients 12 years or over with uncontrolled severe 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 benralizumab, dupilumab, mepolizumab and 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** 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 providing they have demonstrated an adequate response to treatment.

Applications for **continuing** treatment with benralizumab, dupilumab or mepolizumab 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 **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** treatments 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.

## Section 100 arrangements for benralizumab, dupilumab, mepolizumab 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.

Swapping between **dupilumab 200 mg** and **300 mg** strengths is **not permitted** as the respective strengths are PBS approved for different patient cohorts. The patient must not receive **more than 32 weeks** of treatment 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 being treated by a medical practitioner who is:

- ☐ a respiratory physician
- ☐ a clinical immunologist
- ☐ an allergist
- ☐ a general physician experienced in the management of patients with severe asthma.

**10** The patient has been:

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

**or**

- ☐ diagnosed by a multidisciplinary severe asthma clinic team.

**11** Has the patient received prior PBS-subsidised treatment with a biological medicine for severe asthma in this treatment cycle?

- ☐ No
- ☐ Yes ▶ Provide details

Prior biological medicine

From (DD MM YYYY)

To (DD MM YYYY)

**12** Has the patient failed, or ceased to respond to, PBS-subsidised treatment with this drug (the biological medicine this application is for) for severe asthma during the current treatment cycle?

- ☐ Yes
- ☐ No

MCA0PB285 2512

**13** Will this treatment be used in combination with and **within 4 weeks** of another PBS-subsidised biological medicine for severe asthma?

Yes ☐
No ☐

**14** The patient is switching biological medicine treatment due to:

☐ failure to demonstrate or sustain response to prior biological medicine treatment for severe asthma

***Go to 15***

**or**

☐ partial response to prior biological medicine treatment for severe asthma

***Go to 16***

**or**

☐ experiencing an adverse event due to prior biological medicine treatment for severe asthma

***Go to 15***

**or**

☐ other reason

***Go to 15***

**15** The patient:

☐ is submitting a new baseline Asthma Control Questionnaire (ACQ-5) 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 after the first dose of this treatment

**or**

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

**and**

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

***Go to 17***

**16** The patient has demonstrated a response to the most recent PBS-subsidised biological medicine treatment for severe asthma, assessed **no more than 4 weeks** after the last dose of biological medicine and evidenced by:

☐ a reduction in the ACQ-5 score of at least 0.5 from baseline

Current ACQ-5 Score

Date of current score (DD MM YYYY)

**or**

☐ a reduction in the 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 score from baseline

Current ACQ-5 Score

Date of current score (DD MM YYYY)

**or**

☐ an increase of up to 0.5 in the ACQ-5 score from baseline

Current ACQ-5 Score

Date of current score (DD MM YYYY)

**17** This application is for:

☐ benralizumab ***Go to 20***
☐ dupilumab 200 mg ***Go to 19***
☐ dupilumab 300 mg ***Go to 18***
☐ mepolizumab ***Go to 20***
☐ omalizumab ***Go to 21***

Swapping between **dupilumab 200 mg** and **300 mg** strengths is **not permitted** as the respective strengths are PBS approved for different patient cohorts.

**18** The patient has:

☐ been receiving regular maintenance OCS in the last 6 months with a stable daily OCS dose of 5 to 35 mg/day of prednisolone or equivalent over the 4 weeks prior to treatment initiation

**or**

☐ contraindication and/or intolerance of a severity necessitating permanent treatment withdrawal to the regular maintenance OCS therapy according to the relevant TGA-approved Product Information

Provide details

**19** Which qualifying blood test results will be provided with this authority application?

☐ Blood eosinophil count ▶ *Go to 20*

☐ IgE level ▶ *Go to 21*

**20** In the 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, the patient had:

☐ a baseline blood eosinophil count ≥ 150 cells/microlitre while receiving treatment with OCS

Blood eosinophil count ____ cells per microlitre

Date (DD MM YYYY) __ __ / __ __ / __ __ __ __

▶ *Go to 23*

**or (not applicable to dupilumab 300 mg applications)**

☐ a baseline blood eosinophil count ≥ 300 cells/microlitre

Blood eosinophil count ____ cells per microlitre

Date (DD MM YYYY) __ __ / __ __ / __ __ __ __

▶ *Go to 23*

**21** In the 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma, the patient had:

☐ total serum human immunoglobulin E (IgE) ≥ 30 IU/mL with past or current evidence of atopy, documented by skin prick testing

**or**

☐ total serum human IgE ≥ 30 IU/mL with past or current evidence of atopy, documented by an in vitro measure of specific IgE

**22** Provide the patient's total serum human IgE (no older than 12 months immediately prior to commencing PBS-subsidised biological medicine treatment for severe asthma)

IgE result ____ IU/mL

Date (DD MM YYYY) __ __ / __ __ / __ __ __ __

## Checklist

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

☐ Details of the proposed prescription(s).

## Privacy notice

**24** 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**

**25** **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