Australian Government
Services Australia

medicare

PBS

Severe asthma – adolescent and adult – initial or recommencement after 12 months break authority application

When to use this form

Use this form to apply for **initial** or **recommencing** PBS-subsidised biological medicines for patients 12 years or over with uncontrolled severe asthma.

Important information

Initial or **recommencement** applications to start PBS-subsidised treatment must be 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 and 5 pm, local time.

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

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 **initial** or **recommencement** of treatment.

Following the completion of an **initial** 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 must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Applications for **continuing** treatment with 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.

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.

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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Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ 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, 12 years or over, 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 The patient has:

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

or

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

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

No ☐

Yes ☐

13 Has the patient had asthma for at least 1 year?

No ☐

Yes ☐

MCA0PB075 2410

14 The patient has a diagnosis of asthma, confirmed and documented in the patient's medical records by either:

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

▶ *Go to 15*

or

- ☐ at least 2 physicians experienced in the management of patients with severe asthma.

▶ *Go to 16*

15 The patient's diagnosis was defined at the time by at least one of the following standard clinical features:

- ☐ forced expiratory volume (FEV1) reversibility ≥ 12% and ≥ 200 mL at baseline within 30 minutes after administration of salbutamol (200 to 400 mcg)
- ☐ airway hyperresponsiveness with FEV1 decline > 20% during a direct bronchial provocation test
- ☐ airway hyperresponsiveness with FEV1 decline > 15% during an indirect bronchial provocation test
- ☐ peak expiratory flow (PEF) variability > 15% between the 2 highest and 2 lowest PEF rates during 14 days.

16 The patient has received optimised asthma therapy including:

- ☐ adherence to high dose inhaled corticosteroid (ICS) for at least 12 months

From (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

To (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

and

- ☐ adherence to long acting beta-2 agonist (LABA) therapy for at least 12 months

From (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

To (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

and

for dupilumab 300 mg applications only:

- ☐ regular maintenance oral corticosteroids (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

17 If applicable, provide details of contraindications and/or intolerances of a severity necessitating permanent treatment withdrawal to standard therapy according to the relevant TGA-approved Product Information.

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

Inhaled corticosteroid

Inhaled long acting beta-2 agonist therapy

Oral corticosteroids

18 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) ☐☐ ☐☐ ☐☐☐☐

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

No ☐

Yes ☐ ▶ Provide details

ACQ-5 Score

Date (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

20 This application is for:

- ☐ Benralizumab ▶ ***Go to 22***
- ☐ Dupilumab ▶ ***Go to 21***
- ☐ Mepolizumab ▶ ***Go to 22***
- ☐ Omalizumab ▶ ***Go to 23***

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

- ☐ Blood eosinophil count ▶ ***Go to 22***
- ☐ IgE level ▶ ***Go to 23***

22 In the last 12 months, the patient has 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 25***

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 25***

23 In the last 12 months, the patient has 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

24 Provide the patient's total serum human IgE (no more than 12 months old)

IgE result _____ IU/mL

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

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

26 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**

27 **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