

Asthma – adolescent and adult initial PBS authority application

When to use this form

Use this authority application form (this form) to apply for **initial** Pharmaceutical Benefits Scheme (PBS) subsidised biological agents for adolescent and adult uncontrolled severe allergic asthma or uncontrolled severe eosinophilic asthma for a patient aged 12 years or older.

Important information

Initial applications must be in writing and must include sufficient supporting information to determine the patient's eligibility according to the PBS criteria.

Applications for balance of supply may be made by contacting Services Australia on **1800 700 270** Monday to Friday, 8 am to 5 pm, Australian Eastern Standard Time.

Note: Call charges may apply.

Under no circumstances will phone approvals be granted for **initial** authority applications for treatment that would extend the relevant treatment period.

Where the term 'biological agent' appears, it refers to benralizumab, 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** treatment.

The first assessment should, where possible, be completed by the same physician who initiated treatment with the biological agent.

The assessment of the patient's response to an initial course of treatment must be made at the time specified in the restriction and should be completed, where possible, by the same physician who initiated treatment with the biological agent.

Section 100 arrangements

These items are available to a patient who is attending:

- an approved private hospital
- a public participating hospital, **or**
- a public hospital

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

These items are not available as a PBS benefit for in-patients of the hospital. The hospital name and provider number must be included in this form.

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
 / /
- 4** Patient's current weight
 kg

Prescriber's details

- 5** Prescriber number
- 6** Dr Mr Mrs Miss Ms Other
Family name

First given name
- 7** Business phone number
 ()
Alternative phone number

Fax number
 ()

Hospital details

- 8** Hospital name
- This hospital is a:
 public hospital
 private hospital
- 9** Hospital provider number

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

- 10** Is the patient being treated by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma?
No
Yes
- 11** The patient:
 is under the care of the same physician for at least 6 months
or
 has been diagnosed by a multidisciplinary severe asthma clinic team.
- 12** The patient:
 has not received PBS subsidised treatment with a biological medicine for severe asthma
or
 has failed treatment with omalizumab where it's the only appropriate biological agent for severe asthma
and
 has had at least 6 months break in therapy
or
 has failed treatment with 2 (for patients eligible for mepolizumab and benralizumab only) or 3 biological agents for severe asthma
and
 has had at least 12 months break in therapy.
- 13** Has the patient had asthma for at least 1 year?
No
Yes

- 14** The patient has a diagnosis of asthma:
- confirmed and documented by a respiratory physician, clinical immunologist, allergist or general physician experienced in the management of patients with severe asthma, defined by standard clinical features
- ▶ **Go to 15**

or

- from at least 2 physicians experienced in the management of patients with severe asthma.
- ▶ **Go to 16**

- 15** The patient:
- has a diagnosis of asthma defined by standard clinical features, including:
 - FEV1 reversibility $\geq 12\%$ and $\geq 200\text{mL}$ at baseline within 30 minutes after administration of salbutamol (200 to 400 μg)
 - or
 - airway hyperresponsiveness $> 20\%$ decline in FEV1 during a direct bronchial provocation test or $> 15\%$ decline during an indirect bronchial provocation test
 - or
 - peak expiratory flow (PEF) variability $> 15\%$ between the 2 highest and 2 lowest peak expiratory flow 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 to

and

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

and treatment with oral corticosteroid, either as:

- a daily oral corticosteroids for ≥ 6 weeks
- Name of steroid

Dose mg/day

From to

or

- a cumulative dose of oral corticosteroids of $\geq 500\text{mg}$ prednisolone equivalent in the previous 12 months.
- Name of steroid

Dose mg

From to

Name of steroid

Dose mg

From to

- 17** Provide details of contraindications or intolerances to any of the prior therapies including the degree of toxicity.
- For details of the toxicity criteria, go to **servicesaustralia.gov.au/healthprofessionals**
- Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Inhaled corticosteroid

Inhaled long acting beta-2 agonist therapy

Oral corticosteroids

- 18** The patient:
- has failed to achieve adequate control with optimised asthma therapy despite formal assessment of and adherence to correct inhaler technique as indicated by:
 - an Asthma Control Questionnaire (ACQ-5) score, assessed in the previous month:
- ACQ-5 score:

and while receiving optimised asthma therapy in the previous 12 months, has experienced:

- at least 1 admission to hospital for a severe asthma exacerbation

Date of exacerbation

or

- at least 1 severe asthma exacerbation requiring documented use of systemic corticosteroids prescribed or supervised by a physician

either:

- oral corticosteroids initiated or increased for at least 3 days

or

- parenteral corticosteroids.

Date of exacerbation

- 19** Will the patient receive treatment in combination with or within 4 weeks of another PBS subsidised biological agent treatment for severe asthma?

No

Yes

- 20** The patient has:

- Severe allergic asthma

- Severe eosinophilic asthma

▶ **Go to 21**

▶ **Go to 23**

21 Does the patient have past or current evidence of atopy, documented by skin prick testing or an in vitro measure of specific IgE, that's no more than 1 year old?

No

Yes

Date

22 What is the patient's total serum human immunoglobulin E?

Date

► **Go to 24**

23 The patient has blood eosinophil count greater than or equal to:

300 cells per microlitre in the last 12 months

Provide the blood eosinophil count:

Date


or

150 cells per microlitre while receiving treatment with oral corticosteroids in the last 12 months.

Provide the blood eosinophil count:

Date

Checklist

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

The completed authority prescription form(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 servicessaustralia.gov.au/privacy

Prescriber's declaration

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 the completed authority prescription form(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.

Prescriber's signature

Date

Returning your form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at servicessaustralia.gov.au/hpos
- **by post**, send this form, the authority prescription form(s) and any relevant attachments to:

**Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001**