

Severe asthma adolescent and adult – tezepelumab – initial grandfather 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 grandfather** PBS-subsidised treatment with tezepelumab for patients 12 years or older with uncontrolled severe asthma who have received non-PBS-subsidised treatment with tezepelumab for the same condition prior to **1 July 2026**.

Important information

Initial grandfather 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 severe asthma **initial grandfather** authority applications.

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 grandfather** treatment.

A patient may qualify for PBS-subsidised treatment under this restriction once only.

After an authority application for **initial grandfather** treatment has been approved, applications for **continuing** treatment can be made in real time 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 tezepelumab

This item is available to a patient who is attending:

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

and is:

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

This item is 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 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 12 years or older and 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 Has the patient received non-PBS-subsidised treatment with this drug for this condition prior to **1 July 2026**?

Yes ☐

No ☐

11 Prior to initiating non-PBS-subsidised treatment with this drug for this condition, did the patient have asthma for at least one year?

Yes ☐

No ☐

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 ☐



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- 13** The patient has a diagnosis of asthma, confirmed and documented in the patient's medical records by:
- ☐ a respiratory physician
 - ☐ a clinical immunologist
 - ☐ an allergist
 - ☐ a general physician experienced in the management of patients with severe asthma

► **Go to 14**

or

- ☐ at least 2 physicians experienced in the management of patients with severe asthma, prior to initiation of non-PBS-subsidised treatment with this drug for this condition

► **Go to 15**

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

- ☐ forced expiratory volume (FEV1) reversibility $\geq 12\%$ 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

- 15** Prior to initiating non-PBS-subsidised treatment with this drug for this condition, the patient had:

- ☐ received optimised asthma therapy including:
 - ☐ adherence to high dose inhaled corticosteroid (ICS) for at least 12 months

From (DD MM YYYY)

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To (DD MM YYYY)

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and

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

From (DD MM YYYY)

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To (DD MM YYYY)

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► **Go to 17**

or

- ☐ contraindications and/or intolerances to prior optimised asthma therapy

► **Go to 16**

- 16** 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.

Inhaled corticosteroid

Inhaled long acting beta-2 agonist therapy

► **Go to 18**

- 17** In the 12 months prior to initiating non-PBS-subsidised treatment with this drug for this condition, the patient had documented a failure to achieve adequate control with optimised asthma therapy, despite formal assessment and adherence to correct inhaler technique, demonstrated by:

- ☐ at least one admission to hospital for a severe asthma exacerbation while receiving optimised asthma therapy

Date of exacerbation (DD MM YYYY)

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or

- ☐ at least one severe asthma exacerbation requiring documented use of systemic corticosteroids prescribed or supervised by a physician, with either:

- ☐ oral corticosteroid (OCS) initiated or increased for at least 3 days

Date of exacerbation (DD MM YYYY)

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or

- ☐ parenteral corticosteroids

Date of exacerbation (DD MM YYYY)

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- 18** Prior to initiating non-PBS-subsidised treatment with this drug for this condition, did the patient have a baseline Asthma Control Questionnaire (ACQ-5) score of at least 2.0?

Yes ☐

No ☐

- 19** Baseline ACQ-5 score

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Date (DD MM YYYY)

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20 In the 12 months prior to initiation of non-PBS-subsidised treatment with this drug for this condition, the patient had a:

- ☐ total serum human immunoglobulin E (IgE) $\geq$ 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)

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or

- ☐ blood eosinophil count $\geq$ 150 cells/microlitre while receiving treatment with OCS

Blood eosinophil count cells per microlitre

Date (DD MM YYYY)

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or

- ☐ blood eosinophil count $\geq$ 300 cells/microlitre

Blood eosinophil count cells per microlitre

Date (DD MM YYYY)

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21 Has the patient received at least 28 weeks of non-PBS-subsidised treatment with this drug for this condition?

Yes ☐ **Go to 22**

No ☐ **Go to 23**

22 Has the patient demonstrated or sustained an adequate response to treatment with this drug?

Yes ☐

No ☐

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)

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Prescriber's signature (**only** required if returning by post)



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