Australian Government
Services Australia

medicare

PBS

Severe asthma paediatric – dupilumab – 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 dupilumab for paediatric patients with uncontrolled severe asthma who is/was aged 6 to under 12 years prior to initiating non-PBS-subsidised treatment with dupilumab for the same condition prior to **1 September 2025**.

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 paediatric uncontrolled severe asthma **initial grandfather** authority applications.

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.

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.

Patients may qualify for PBS-subsidised treatment under this restriction once only. For **continuing** PBS-subsidised treatment, a 'grandfathered' patient must qualify under the 'continuing treatment' criteria.

After an authority application for **initial grandfather** treatment has been approved, applications for **continuing** treatment with dupilumab 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 dupilumab

This item is 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.

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 24 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

9 The patient who is/was aged 6 to under 12 years prior to initiating non-PBS-subsidised treatment 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 Has the patient received non-PBS-subsidised treatment with this drug for this condition prior to **1 September 2025**?

- Yes ☐
- No ☐

11 Provide date of commencing non-PBS-subsidised treatment with this drug for this condition (DD MM YYYY)

12 The patient has a diagnosis of asthma, confirmed and documented in the patient's medical records by the above mentioned treating prescriber, defined by at least one of the following standard clinical features:

- ☐ forced expiratory volume (FEV1) reversibility
- ☐ airway hyperresponsiveness
- ☐ peak expiratory flow (PEF) variability

13 Prior to the commencement of non-PBS-subsidised treatment with this drug, did the patient have a duration of asthma of at least 1 year?

- Yes ☐
- No ☐

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14 Prior to 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 6 months

Steroid

Dose

From (DD MM YYYY)

To (DD MM YYYY)

and

☐ adherence to long-acting beta-2 agonist (LABA) therapy for at least 6 months

LABA

Dose

From (DD MM YYYY)

To (DD MM YYYY)

or

☐ if LABA therapy is contraindicated, not tolerated or not effective, montelukast, cromoglycate or nedocromil may be used as an alternative

LABA alternative

Dose

From (DD MM YYYY)

To (DD MM YYYY)

and

☐ treatment with at least 2 courses of oral or IV corticosteroids (daily or alternate day maintenance treatment courses, or 3 to 5 day exacerbation treatment courses) in the previous 12 months.

Steroid course 1

Dose

From (DD MM YYYY)

To (DD MM YYYY)

Steroid course 2

Dose

From (DD MM YYYY)

To (DD MM YYYY)

▶ *Go to 16*

or

☐ contraindications and/or intolerances to prior optimised asthma therapy

▶ *Go to 15*

15 Provide details of contraindications (including those specified in the relevant TGA-approved Product Information) or intolerances of a severity necessitating permanent treatment withdrawal.

Inhaled corticosteroid

Inhaled long-acting beta-2 agonist therapy

Oral or IV corticosteroids

▶ *Go to 17*

16 In the 12 months prior to initiating non-PBS-subsidised treatment with this drug for this condition, the patient failed to achieve adequate control with optimised asthma therapy, despite formal assessment and adherence to correct inhaler technique, which has been documented in the patient's medical records and demonstrated by:

☐ at least 1 admission to hospital for a severe asthma exacerbation while receiving optimised asthma therapy

Date of exacerbation (DD MM YYYY)

or

☐ at least 1 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)

17 Prior to non-PBS-subsidised treatment with this drug for this condition, did the patient have an Asthma Control Questionnaire (ACQ-5 or ACQ-IA) score of at least 2.0?

Yes ☐

No ☐

18 Provide baseline details:

ACQ-5 / ACQ-IA score

Date of assessment (DD MM YYYY)

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

☐ documented 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

☐ blood eosinophil count of at least 150 cells/microlitre

Blood eosinophil count

_____ cells/microlitre

Date (DD MM YYYY)

__ __ __ __ __

or

☐ fractional exhaled nitrous oxide of at least 20 ppb

Fractional exhaled nitrous oxide _____ ppb

Date (DD MM YYYY)

__ __ __ __ __

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

Yes ☐ ***Go to 21***

No ☐ ***Go to 23***

21 Has the assessment of response been conducted immediately (no later than 4 weeks after the last dose of non-PBS-subsidised treatment) prior to this application?

Yes ☐

No ☐

22 The patient has demonstrated or sustained an adequate response to treatment with this drug, 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

From (DD MM YYYY) __ __ __ __ __

To (DD MM YYYY) __ __ __ __ __

and

☐ no deterioration in the ACQ-5 or 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

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.

Reset form

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