Australian Government
Services Australia

medicare

PBS

Severe chronic spontaneous urticaria – omalizumab – initial 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** PBS-subsidised omalizumab for patients with severe chronic spontaneous urticaria (CSU).

Important information

Initial 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 CSU **initial** 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** treatment.

After an authority application for **initial** treatment has been approved, applications for **continuing** treatment 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 omalizumab

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

A standard therapy is defined as a combination of therapies that includes H1 antihistamines at maximally tolerated doses in accordance with clinical guidelines, and one of the following:

- a H2 receptor antagonist (150 mg twice per day for ranitidine and nizatidine, and 40 mg per day for famotidine), **or**
- leukotriene receptor antagonist (LTRA) (10 mg per day), **or**
- doxepin (up to 25 mg three times a day).

Patient must not receive more than 12 weeks of treatment under this restriction.

Any patient who ceases therapy and whose CSU relapses will need to re-initiate PBS-subsidised omalizumab as a new patient.

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 is being treated by:

☐ a clinical immunologist

☐ an allergist

☐ a dermatologist

☐ a general physician with expertise in the management of CSU

10 Does the patient have severe CSU based on both physical examination and patient history (to exclude any factors that may be triggering the urticaria)?

Yes ☐

No ☐

11 Has the patient experienced itch and hives that persist on a daily basis for at least 6 weeks despite treatment with H1 antihistamines?

Yes ☐

No ☐

MCA0PB223 2409

12 The patient has:

☐ failed to achieve an adequate response after a minimum of 2 weeks standard therapy ▶ *Go to 13*

or

☐ contraindications to standard therapy according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal

Provide details

▶ *Go to 15*

13 The patient has received a combination of therapies that includes:

☐ H1 antihistamine

Tick one only

☐ bilastine
☐ cetirizine
☐ chlorpheniramine
☐ desloratadine
☐ dexchlorpheniramine
☐ diphenhydramine
☐ fexofenadine
☐ loratadine
☐ promethazine
☐ other

Dose mg/day

and

☐ H2 receptor antagonist

Tick one only

☐ ranitidine
☐ nizatidine
☐ famotidine
☐ other

Dose mg/day

or

☐ LTRA

Tick one only

☐ montelukast
☐ other

Dose mg/day

or

☐ Doxepin

Dose mg/day

14 Provide the patient's current Urticaria Activity Score 7 (UAS7) and itch score as assessed while receiving the above combination of therapies:

UAS7 score (must be at least 28)

Itch score (must be > 8)

15 Will the patient receive more than 12 weeks of treatment under this restriction?

Yes ☐
No ☐

Checklist

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

☐ Details of the proposed prescription(s).

Privacy notice

17 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**

18 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