

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 with the originator brand of 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.

Continuing treatments with PBS-subsidised biosimilar brand of omalizumab are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

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 (150mg twice per day for ranitidine and nizatidine), **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

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

- | | |
|---|--|
| <input type="checkbox"/> bilastine | <input type="checkbox"/> dexchlorpheniramine |
| <input type="checkbox"/> cetirizine | <input type="checkbox"/> diphenhydramine |
| <input type="checkbox"/> chlorpheniramine | <input type="checkbox"/> fexofenadine |
| <input type="checkbox"/> desloratadine | <input type="checkbox"/> loratadine |
| <input type="checkbox"/> other | <input type="checkbox"/> promethazine |

Dose of H1 antihistamine mg/day

and

- H2 receptor antagonist

Tick one only

- ranitidine
 nizatidine
 other

Dose of H2 receptor antagonist mg/day

or

- LTRA

Tick one only

- montelukast
 other

Dose of LTRA 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)

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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