Australian Government
Department of Human Services

medicare

PBS

Severe chronic spontaneous urticaria – omalizumab Initial PBS authority application

Supporting information

Purpose of this form

You must lodge this authority application form for a patient starting **initial** Pharmaceutical Benefits Scheme (PBS) subsidised treatment with omalizumab for severe chronic spontaneous urticaria (CSU).

Important information

Initial authority applications must be 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 **initial** authority applications.

The patient must be treated by a clinical immunologist, allergist, dermatologist, or general physician with expertise in the management of CSU.

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), **or**
- a leukotriene receptor antagonist (LTRA) (10 mg per day), **or**
- doxepin (up to 25mg three times a day).

The patient's acknowledgement and the prescriber's declaration must be completed and signed before this authority application form is submitted.

The information in this authority application form is correct at the time of publishing and is subject to change.

Authority prescription form

A completed authority prescription form **must** be attached to this authority application form.

Section 100 arrangements

This item is available to a patient 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.

This item is not available as a PBS benefit for in-patients of a hospital. The hospital name and provider number must be included in this authority application form.

Continuing treatment

After a written authority application for initial treatment has been approved, application for **continuing** treatment can be made by phone. Call **1800 700 270** Monday to Friday, between 8.00 am and 5.00 pm, Australian Eastern Standard Time.

Note: Call charges may apply.

Filling in this form

- **Please use black or blue pen**
- Print in BLOCK LETTERS
- Mark boxes like this ☐ with a ✓ or ✗
- Where you see a box like this ☐ ***Go to 5*** skip to the question number shown. You do not need to answer the questions in between.

Returning your form

Check that all required questions are answered and that this authority application form is signed and dated.

Upload this authority application form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **humanservices.gov.au/hpos**

or

Send this authority application form, the authority prescription form(s) and any relevant attachments to:

Department of Human Services
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

For more information

Go to **humanservices.gov.au/healthprofessionals** or call **1800 700 270** Monday to Friday, between 8.00 am and 5.00 pm, Australian Eastern Standard Time.

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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

[ ] / [ ] / [ ]

Patient's acknowledgement

4 I acknowledge that the prescriber has explained:

- the circumstances governing PBS subsidised treatment with omalizumab for severe CSU.
- that cessation of therapy should be considered after I have demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy.
- that if CSU relapses after cessation of therapy, I will need to re-initiate PBS subsidised omalizumab as a new patient.

Patient's signature

[ ]

Date

[ ] / [ ] / [ ]

For patients under 18 years of age

Family name of parent or authorised guardian

[ ]

First given name of parent or authorised guardian

[ ]

Signature of parent or authorised guardian

[ ]

Date

[ ] / [ ] / [ ]

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

[ ]

9 Hospital provider number

[ ][ ][ ][ ][ ][ ][ ][ ]

Conditions and criteria

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

No ☐
Yes ☐

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

No ☐
Yes ☐

12 Has the patient failed to achieve an adequate response after a minimum of 2 weeks standard therapy?

No ☐ ***Go to 14***
Yes ☐ Provide details

H1 antihistamine name and dose

H2 receptor antagonist name and dose

LTRA name and dose

Doxepin dose

13 What are the patient's current Urticaria Activity Score 7 (UAS7) and itch scores as assessed while receiving the above combination of therapies?

UAS7 score

Itch score

14 Does the patient have contraindications to standard therapy according to the relevant TGA-approved Product Information and/or intolerances of a severity necessitating permanent treatment withdrawal?

No ☐
Yes ☐ Provide details of contraindication and/or intolerance

Attachments

15 Attach the completed authority prescription form.

Privacy notice

16 Your personal information is protected by law (including the *Privacy Act 1988*) and is collected by the Australian Government Department of Human Services for the assessment and administration of payments and services. This information is required to process your application or claim.

Your information may be used by the department, or given to other parties where you have agreed to that, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

You can get more information about the way in which the department will manage your personal information, including our privacy policy, at **humanservices.gov.au/privacy**

Prescriber's declaration

17 **I have explained to the patient or the parent/authorised guardian** (if patient is under 18 years of age):

- the circumstances governing Pharmaceutical Benefits Scheme subsidised treatment with omalizumab for severe chronic spontaneous urticaria.
- the nature of ongoing monitoring and testing required to demonstrate eligibility for continued Pharmaceutical Benefits Scheme subsidised treatment with omalizumab for this condition.
- that cessation of therapy should be considered after the patient has demonstrated clinical benefit with omalizumab to re-evaluate the need for continued therapy.
- that if the severe chronic spontaneous urticaria relapses after the cessation of therapy, the patient will need to re-initiate Pharmaceutical Benefits Scheme subsidised omalizumab as a new patient.

I believe these to be understood and accepted by the patient or the parent/authorised guardian.

I declare that:

- the patient specified in this application is eligible for Pharmaceutical Benefits Scheme subsidised treatment with omalizumab for severe chronic spontaneous urticaria.
- I have attached the completed authority prescription form and any relevant attachments.
- 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

/ /

Reset form Print form