Australian Government
Services Australia

medicare

PBS

Ulcerative colitis adult – initial grandfather authority application

When to use this form

Use this form to apply for **initial grandfather** PBS-subsidised **ozanimod**, **upadacitinib** or **ustekinumab** for patients aged 18 years or older with moderate to severe ulcerative colitis who have received non-PBS-subsidised treatment with ozanimod, upadacitinib or ustekinumab for the same condition prior to **1 May 2023**.

Important information

Initial grandfather applications to start PBS-subsidised treatment must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

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.

Call charges may apply.

Under no circumstances will phone approvals be granted for moderate to severe ulcerative colitis **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.

After a written 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 by phone. Call 1800 700 270 Monday to Friday, 8 am to 5 pm, local time.

Call charges may apply.

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.

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)

Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

7 The patient, at least 18 years old, is being treated by a:

☐ gastroenterologist

☐ consultant physician specialising in gastroenterology (either general medicine or internal medicine)

8 Has the patient received non-PBS-subsidised treatment with this drug for this condition prior to **1 May 2023**?

No ☐

Yes ☐ Date this non-PBS-subsidised treatment was commenced (DD MM YYYY)

9 Is the patient currently receiving treatment with this drug for this condition?

No ☐

Yes ☐

10 Prior to commencing treatment with this drug for this condition, the patient had:

☐ responded inadequately to a 5-aminosalicylate (5-ASA) oral preparation in a standard dose for induction of remission for 3 or more consecutive months

or

☐ experienced a severe intolerance to the above 5-ASA therapy leading to permanent treatment discontinuation.

11 Prior to commencing treatment with this drug for this condition, the patient had responded inadequately to:

☐ azathioprine at a dose of at least 2 mg/kg daily for 3 or more consecutive months

or

☐ 6-mercaptopurine at a dose of at least 1 mg/kg daily for 3 or more consecutive months

or

☐ a tapered course of oral steroids, starting at a dose of at least 40 mg prednisolone (or equivalent) over a 6 week period, **followed by** 3 or more consecutive months of an appropriately dosed thiopurine agent

or

☐ **each of the above 3** therapies due to severe intolerance leading to permanent treatment discontinuation.

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12 Prior to commencing non-PBS-subsidised treatment with this drug for this condition, the patient had:

☐ a baseline Mayo clinic score ≥ 6

Mayo clinic score

Date of assessment (DD MM YYYY)

or

☐ a baseline partial Mayo clinic score ≥ 6, provided the rectal bleeding and stool frequency subscores were both ≥ 2

Partial Mayo clinic score

Rectal bleeding subscore

Stool frequency subscore

Date of assessment (DD MM YYYY)

or

☐ a documented history of moderate to severe refractory ulcerative colitis, where a Mayo clinic or partial Mayo clinic baseline assessment is not available

Provide the reason why this baseline assessment is not available.

13 This application is for:

☐ ozanimod ▶ ***Go to 15***

☐ upadacitinib ▶ ***Go to 15***

☐ ustekinumab

14 Has the patient demonstrated or sustained an adequate response to treatment with this drug for this condition?

No ☐

Yes ☐ ▶ As demonstrated by having a partial Mayo clinic score ≤ 2 with no subscore > 1 while receiving treatment with this drug

Partial Mayo clinic score

Rectal bleeding subscore

Stool frequency subscore

Date of assessment (no more than 4 weeks old) (DD MM YYYY)

Checklist

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

☐ The completed authority prescription form(s).

☐ The completed baseline Mayo clinic or partial Mayo clinic calculation sheet before initiating treatment (if available), including the date of assessment.

Privacy notice

16 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**

17 **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 the completed authority prescription form(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, the authority prescription form(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

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