Australian Government
Services Australia

medicare

PBS

Ulcerative colitis adult – change or recommencement authority application

When to use this form

Use this form to apply for **changing** or **recommencing** PBS-subsidised:

- biological medicines for patients 18 years or over with moderate to severe ulcerative colitis
- etrasimod for patients with moderate to severe ulcerative colitis.

Important information

Authority applications 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.

Under no circumstances will phone approvals be granted for moderate to severe ulcerative colitis **change** or **recommencement** authority applications.

Where the term 'biological medicine' appears, it refers to adalimumab, etrasimod, golimumab, infliximab, ozanimod, tofacitinib, upadacitinib, ustekinumab or vedolizumab.

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 **changing** or **recommencing** treatment.

After a written authority application for **changing** or **recommencing** 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.

Subsequent continuing treatments with PBS-subsidised biosimilar brands of biological medicines are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

Section 100 arrangements for infliximab i.v., ustekinumab i.v. and vedolizumab i.v.

These items are 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.

These items are 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.

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)

4 Patient's weight kg

Prescriber's details

5 Prescriber number

6 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

7 Business phone number (including area code)

Alternative phone number (including area code)

Hospital details

8 Hospital name

This hospital is a:

☐ public hospital

☐ private hospital

9 Hospital provider number

Conditions and criteria

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

10 The patient is being treated by a:

☐ gastroenterologist

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

11 Most recent biological medicine

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

12 This application is for:

☐ adalimumab

☐ golimumab

☐ infliximab i.v.

☐ ozanimod

☐ tofacitinib

☐ upadacitinib

☐ ustekinumab

☐ vedolizumab i.v.

☐ vedolizumab s.c. with i.v. loading
(and an authority prescription for at least 2 i.v. doses at weeks 0 and 2 is attached)

▶ *Go to 14*

or

☐ etrasimod ▶ *Go to 15*

or

☐ infliximab s.c. with i.v. loading ▶ *Go to 13*

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13 The patient is:

☐ **changing** from an alternate PBS-subsidised biological medicine and an authority prescription for at least 2 i.v. doses of infliximab at weeks 0 and 2 is attached

or

☐ **recommencing** PBS-subsidised infliximab after a treatment break, and an authority prescription for 1 i.v. dose of infliximab at week 0 is attached.

14 Is the patient 18 years or over?

No ☐

Yes ☐

15 The patient:

☐ is **recommencing** or **changing** PBS-subsidised biological medicine treatment for this condition after a break **< 5 years** (including **no break** for the change)

▶ ***Go to 16***

or

☐ is **recommencing** PBS-subsidised biological medicine treatment for this condition after a break **> 5 years**

and

☐ has previously received PBS-subsidised treatment with a biological medicine for this condition

and

☐ has had a break in treatment of 5 years or more from the most recently approved PBS-subsidised biological medicine for this condition

and

☐ will be submitting a new baseline.

▶ ***Go to 19***

16 The patient:

☐ has received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle (since 1 July 2021)

and

☐ has not failed or ceased to respond to PBS-subsidised treatment with this drug (the biological medicine this application is for) for this condition during the current treatment cycle (since 1 July 2021)

and

☐ the patient's total number of biological medicine **failures** for this condition in the current treatment cycle **since 1 July 2021** is:

17 The patient:

☐ has **failed** to demonstrate or sustain a response to the most recent PBS-subsidised biological medicine

or

☐ has experienced a **serious adverse reaction** of a severity necessitating permanent withdrawal of the most recent PBS-subsidised biological medicine.

Provide details of treatment and adverse reaction

or

☐ has **demonstrated or sustained an adequate response** to the most recent PBS-subsidised biological medicine.

If the patient is demonstrating a response	▶ ***Go to 18***
If the patient is providing a new baseline	▶ ***Go to 19***
If the patient is not demonstrating a response and is not providing a new baseline	▶ ***Go to 20***

For a patient demonstrating a response (to current or previous biological medicine)

The response assessment should be conducted while still on treatment, but **no later than 4 weeks** following cessation of treatment.

18 The patient has demonstrated an adequate response to treatment evidenced by having a partial Mayo clinic score ≤ 2 with no subscore > 1.

Partial Mayo clinic score

Rectal bleeding subscore

Stool frequency subscore

Date of assessment (DD MM YYYY)

▶ ***Go to 20***

For a patient submitting a new baseline

19 The patient has:

☐ a Mayo clinic score ≥ 6

Mayo clinic score

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

or

☐ a partial Mayo clinic score ≥ 6, provided the rectal bleeding and stool frequency subscores are both ≥ 2 (endoscopy subscore is not required for a partial Mayo clinic score)

Partial Mayo clinic score

Rectal bleeding subscore

Stool frequency subscore

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

or

☐ has received induction therapy with **infliximab i.v.** for an **acute** severe episode of ulcerative colitis in the last **4 months**, and has demonstrated an adequate response to it by achieving and maintaining a partial Mayo clinic score ≤ 2 with no subscore > 1 (only applies to **infliximab applications**)

Partial Mayo clinic score

Rectal bleeding subscore

Stool frequency subscore

Date of assessment (DD MM YYYY)

Checklist

20

The relevant attachments need to be provided with this form.

☐ Details of the proposed prescription(s).

☐ The completed Mayo clinic or partial Mayo clinic calculation sheet including the date of assessment of the patient's condition.

Privacy notice

21 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**

22 **I declare that**:

- I am aware 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 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