

Ulcerative colitis adult – change or recommencement 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 **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 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.

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 an 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

Ulcerative colitis adult – change or recommencement authority application

Online PBS Authorities



You do not need to complete this form if you use the **Online PBS Authorities** system.

Go to servicesaustralia.gov.au/hppbsauthorities

Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight

 kg

Prescriber's details

5 Prescriber number

6 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. (at a dose of 5 mg/kg)
 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



MCA0PB245 2605

13 Does the patient have a concurrent PBS authority application for the IV form of infliximab that is approved or to be approved?

Yes

No

14 Is the patient at least 18 years of age?

Yes

No

15 The patient:

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

▶ **Go to 16**

or

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

▶ **Go to 16**

or

is **recommencing** PBS-subsidised treatment after a break **> 5 years** from the most recently approved PBS-subsidised biological medicine for this condition

and

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

and

will be submitting a new baseline.

▶ **Go to 22**

16 The patient:

has received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle

and

has not already 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

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:

demonstrated an adequate response to the most recent course of PBS-subsidised biological medicine treatment

▶ **Go to 19**

or

failed to demonstrate an adequate response to the most recent course of PBS-subsidised biological medicine treatment

▶ **Go to 18**

or

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

▶ **Go to 18**

18 Is the patient submitting a new baseline?

Yes ▶ **Go to 22**

No ▶ **Go to 23**

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

19 Has the assessment of response been conducted within the time frame specified in the PBS restriction?

Yes

No

20 Has the patient demonstrated an adequate response to the most recent course of treatment evidenced by having a partial Mayo clinic score of 2 or less, with no subscore > 1?

Yes

No

21 Provide partial Mayo scoring details

Number	Item	Score
1	Stool frequency	
2	Rectal bleeding	
3	Physician's global assessment	
Partial Mayo clinic score (sum of above items 1-3)		

Date of assessment (DD MM YYYY)

Response assessment must be conducted following a **minimum of**, or **up to 12 weeks** of treatment, or **between 8 and 16 weeks** of therapy depending on the biological medicine requested. This assessment must be submitted **no later than 4 weeks** from the cessation of treatment.

▶ **Go to 23**

For a patient submitting a new baseline

22 The patient has:

- a Mayo clinic score ≥ 6 :

Number	Item	Score
1	Stool frequency	
2	Rectal bleeding	
3	Physician's global assessment	
4	Endoscopic findings	
Total Mayo clinic score (sum of above items 1-4)		

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):

Number	Item	Score
1	Stool frequency	
2	Rectal bleeding	
3	Physician's global assessment	
Partial Mayo clinic score (sum of above items 1-3)		

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

--	--	--

or (for **infliximab** applications only)

- previously 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

Number	Item	Score
1	Stool frequency	
2	Rectal bleeding	
3	Physician's global assessment	
Partial Mayo clinic score (sum of above items 1-3)		

Date of assessment (DD MM YYYY)

--	--	--

Checklist

- 23  The relevant attachments need to be provided with this form.

- Details of the proposed prescription(s).

Privacy notice

24 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 servicessaustralia.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 servicessaustralia.gov.au/hpos

25 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)



Returning this form

Return this form, details of the proposed prescription(s) and any relevant attachments:

- online** (no signature required), upload through HPOS at servicessaustralia.gov.au/hpos
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001