

# Ulcerative colitis adult – 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](https://servicesaustralia.gov.au/hppbsauthorities)

## When to use this form

Use this form to apply for **initial** 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

**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.

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 **initial** 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 **initial** treatment.

After an authority application for **initial** 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](https://servicesaustralia.gov.au/healthprofessionals)

**medicare**



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## 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 This application is for:

☐ adalimumab

☐ tofacitinib

☐ golimumab

☐ upadacitinib

☐ ozanimod

☐ ustekinumab

☐ vedolizumab i.v.

► **Go to 14**

or

☐ vedolizumab s.c.

► **Go to 12**

or

☐ etrasimod

► **Go to 15**

or

☐ infliximab i.v.

☐ infliximab 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 13**



MCA0PB127 2504

**12** The patient has:

- ☐ received at least 2 of the 3 initial i.v. infusions with vedolizumab for this condition at weeks 0, 2 and 6

► **Go to 18**

or

- ☐ a concurrent authority application for at least 2 of the 3 initial i.v. infusions with vedolizumab for this condition at weeks 0, 2 and 6.

► **Go to 14**

**13** Has the patient previously received **induction therapy** with PBS-subsidised treatment with infliximab i.v. for an **acute severe** episode of ulcerative colitis in the **last 4 months**, and demonstrated an adequate response to it by achieving and maintaining a partial Mayo clinic score  $\leq 2$ , with no subscore  $> 1$ ?

No ☐ ► **Go to 14**

Yes ☐ ► Provide details below

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

Date of assessment (DD MM YYYY)

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► **Go to 18**

**14** Is the patient 18 years or over?

Yes ☐

No ☐

**15** The patient has failed to achieve an adequate response to:

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

Name of drug

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Dose  mg

From (DD MM YYYY)

--	--	--	--	--	--

To (DD MM YYYY)

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and

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

Dose  mg

From (DD MM YYYY)

--	--	--	--	--	--

To (DD MM YYYY)

--	--	--	--	--	--

or

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

Dose  mg

From (DD MM YYYY)

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To (DD MM YYYY)

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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.

Name of oral steroid

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Starting dose  mg

From (DD MM YYYY)

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To (DD MM YYYY)

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Name of thiopurine agent

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Starting dose  mg

From (DD MM YYYY)

--	--	--	--	--	--

To (DD MM YYYY)

--	--	--	--	--	--

- 16** If applicable, provide details of contraindications according to the Therapeutic Goods Administration (TGA) approved Product Information and/or intolerances of severity necessitating permanent treatment withdrawal to any of the following prior therapies.

For details of the accepted toxicities, including severity, go to [servicesaustralia.gov.au/healthprofessionals](https://servicesaustralia.gov.au/healthprofessionals)

5-ASA oral preparation

Azathioprine

6-mercaptopurine

Oral steroid

Thiopurine agent

- 17** The patient has a:

☐ Mayo clinic score  $\geq 6$ :

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

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

or

☐ partial Mayo clinic score  $\geq 6$ , provided the rectal bleeding and stool frequency subscores are both  $\geq 2$  (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	
4	<b>Partial Mayo clinic score</b> (sum of above items 1-3)	

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

## Checklist

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

☐ Details of the proposed prescription(s).

## Privacy notice

- 19** 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](https://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](https://servicesaustralia.gov.au/hpos)

### 20 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)

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](https://servicesaustralia.gov.au/hpos)
- or
- by post (signature required) to  
Services Australia  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001