

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

## When to use this form

Use this form to apply for **changing** or **recommencing** PBS-subsidised biological medicines for paediatric patients 6 to 17 years inclusive, 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 paediatric moderate to severe ulcerative colitis **change** or **recommencement** authority applications.

Where the term 'biological medicine' appears, it refers to adalimumab or infliximab.

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.

Applications for **subsequent continuing** treatment with PBS-subsidised **adalimumab** are **Authority Required (STREAMLINED)** and do not require authority approval from Services Australia for the listed quantity and repeats.

Applications for **continuing** treatment with PBS-subsidised biosimilar brands of **infliximab** 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.

This item is 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.

This item is 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**



# Ulcerative colitis paediatric – 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](http://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  
internal medicine or general medicine)

paediatrician

specialist paediatric gastroenterologist.

**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

infliximab i.v. (at a dose of 5 mg/kg)



MCA0PB246 2605

13 The patient:

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

▶ **Go to 14**

or

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

▶ **Go to 14**

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 20**

14 The patient:

has previously received 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 **more than once** with this drug (the biological medicine this application is for) for this condition during the current treatment cycle

and

has **not** failed to respond to PBS-subsidised biological medicine treatment **3 times** (twice with one agent) for this condition within this treatment cycle

and

the patient's total number of biological medicine **failures** for this condition in the current treatment cycle **since 1 June 2017** is:

15 The patient has:

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

▶ **Go to 17**

or

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

▶ **Go to 16**

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 16**

16 Is the patient submitting a new baseline?

Yes  ▶ **Go to 20**

No  ▶ **Go to 21**

### For a patient demonstrating a response

17 Has the assessment of response been conducted following a **minimum of 12 weeks** of treatment (for **adalimumab**) or **up to 12 weeks** of treatment (for **infliximab**) and **no later than 4 weeks** from the cessation of the most recent course of treatment?

Yes

No

18 Has the patient demonstrated an adequate response to the most recent course of treatment evidenced by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of **< 10**?

Yes

No

19 Provide PUCAI scoring details

Number	Item	Score
1	Abdominal pain	
2	Rectal bleeding	
3	Stool consistency of most stools	
4	Score for the number of stools per 24 hours	
5	Nocturnal stools (any episode causing waking)	
6	Activity level	
<b>Total PUCAI score</b> (sum of above items 1-6)		

Date of assessment (DD MM YYYY)

▶ **Go to 21**

## For a patient submitting a new baseline

20 The patient has:

- a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of  $\geq 30$

Number	Item	Score
1	Abdominal pain	
2	Rectal bleeding	
3	Stool consistency of most stools	
4	Score for the number of stools per 24 hours	
5	Nocturnal stools (any episode causing waking)	
6	Activity level	
<b>Total PUCAI score</b> (sum of above items 1-6)		

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 PUCAI score  $< 10$

Number	Item	Score
1	Abdominal pain	
2	Rectal bleeding	
3	Stool consistency of most stools	
4	Score for the number of stools per 24 hours	
5	Nocturnal stools (any episode causing waking)	
6	Activity level	
<b>Total PUCAI score</b> (sum of above items 1-6)		

Date of assessment (DD MM YYYY)

--	--	--

## Checklist

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

- Details of the proposed prescription(s).

## Privacy notice

22 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)

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