Australian Government
Services Australia

medicare

PBS

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**

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.

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.

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**

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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 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

MCA0PB246 2504

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 17***

14 The patient:

☐ has previously received PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle (since 1 June 2017)

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 (since 1 June 2017)

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 (since 1 June 2017)

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

or

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

or

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

If the patient is demonstrating a response	▶ ***Go to 16***
If the patient is providing a new baseline	▶ ***Go to 17***
If the patient is not demonstrating a response and is not providing a new baseline	▶ ***Go to 18***

For a patient demonstrating a response

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

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

No ☐

Yes ☐ ▶ Provide details below

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 wakening)	
6	Activity level	
7	**Total PUCAI score** (sum of above items 1-6)	

Date of assessment (DD MM YYYY)

For a patient submitting a new baseline

17 The patient has:

☐ a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of ≥ 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 wakening)	
6	Activity level	
7	**Total PUCAI score** (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 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 wakening)	
6	Activity level	
7	**Total PUCAI score** (sum of above items 1-6)	

Date of assessment (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**

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**

20 **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