Australian Government
Services Australia

medicare

PBS

Ulcerative colitis paediatric – initial authority application

When to use this form

Use this form to apply for **initial** PBS-subsidised biological medicines for paediatric patients 6 to 17 years inclusive, with moderate to severe ulcerative colitis.

Important information

Initial applications to start PBS-subsidised treatment must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

Under no circumstances will phone approvals be granted for paediatric moderate to severe ulcerative colitis **initial** authority applications.

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.

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 **initial** treatment.

After a written 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. only

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 Mr ☐ Miss ☐ 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, 6 to 17 years inclusive, is being treated by a:

☐ gastroenterologist

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

☐ paediatrician

☐ paediatric gastroenterologist.

11 This application is for:

☐ adalimumab ▶ ***Go to 13***

☐ infliximab ▶ ***Go to 12***

12 For **infliximab i.v. applications** only

Has the patient demonstrated an adequate response to **induction therapy** with PBS-subsidised treatment with infliximab i.v. for an **acute severe** episode of ulcerative colitis in the **last 4 months**, by achieving and maintaining a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of < 10?

No ☐ ***Go to 13***

Yes ☐ Provide details below

PUCAI score

Date of assessment (DD MM YYYY)

▶ ***Go to 16***

MCA0PB215 2406

13 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

Dose ____ mg

From (DD MM YYYY) __ __ / __ __ / ____

To (DD MM YYYY) __ __ / __ __ / ____

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) __ __ / __ __ / ____

To (DD MM YYYY) __ __ / __ __ / ____

or

☐ a tapered course of oral steroids, 1 to 2 mg/kg up to 40 mg of 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

Starting dose ____ mg

From (DD MM YYYY) __ __ / __ __ / ____

To (DD MM YYYY) __ __ / __ __ / ____

Name of thiopurine agent

Starting dose ____ mg

From (DD MM YYYY) __ __ / __ __ / ____

To (DD MM YYYY) __ __ / __ __ / ____

14 If applicable, provide details of contraindications or intolerances necessitating permanent treatment withdrawal

Provide details below where either:

- treatment with any of the drugs is contraindicated according to the relevant Product Information, approved by the Therapeutic Goods Administration.
- intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal.

Include the degree of toxicity. For details of the accepted toxicities, including severity, go to **servicesaustralia.gov.au/healthprofessionals**

Provide details of contraindication or intolerance (including the degree of toxicity) to any of the following:

	Grade
5-ASA oral preparation	
Azathioprine	
6-Mercaptopurine	
Oral steroid	
Thiopurine agent	

15 The patient has:

☐ a PUCAI score ≥ 30:

PUCAI score

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

Checklist

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

☐ Details of the proposed prescription(s).

☐ The completed Paediatric Ulcerative Colitis Activity Index (PUCAI) calculation sheet.

Privacy notice

17 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**

18 **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)

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