

Ulcerative colitis paediatric – 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

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 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.

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 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.

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

☐ gastroenterologist

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

☐ paediatrician

☐ specialist paediatric gastroenterologist.

11 This application is for:

☐ adalimumab ► **Go to 13**

☐ infliximab ► **Go to 12**



MCA0PB215 2504

12 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 Paediatric Ulcerative Colitis Activity Index (PUCAI) score of < 10?

No ☐ **Go to 13**

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)

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Go to 16

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

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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)

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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

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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 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

5-ASA oral preparation

Azathioprine

6-mercaptopurine

Oral steroid

Thiopurine agent

- 15** Does the patient have a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of at least 30?

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 waking)	
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)

Checklist

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

☐ Details of the proposed prescription(s).

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)

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