Australian Government
Services Australia

medicare

PBS

Ulcerative colitis paediatric – change or recommencement authority application

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 must be 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 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 made following a **minimum of 12 weeks** of treatment for adalimumab and **up to 12 weeks** after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

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

☐ infliximab

12 Has the patient received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle **since 1 June 2017**?

No ☐

Yes ☐ Provide details below:

Most recent biological medicine

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

MCA0PB246 2406

13 The patient is:

☐ **changing** to an alternate PBS-subsidised biological medicine

▶ ***Go to 14***

and/or

☐ **recommencing** PBS-subsidised biological medicine treatment after a break **< 5 years** from the most recent PBS-subsidised biological medicine for this condition

▶ ***Go to 14***

or

☐ **recommencing** PBS-subsidised biological medicine treatment after a break **> 5 years** from the most recent PBS-subsidised biological medicine for this condition

and

☐ will be submitting a new baseline

and

☐ has previously received PBS-subsidised biological medicine treatment for this condition.

▶ ***Go to 17***

14 The patient:

☐ has previously received PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle

and

☐ has not failed, or ceased to respond to, PBS-subsidised 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 **failed** to demonstrate or sustain a response with the previous biological medicine

or

☐ has experienced a **serious adverse reaction** of a severity resulting in the necessity for permanent withdrawal of the previous PBS-subsidised biological medicine

Provide details of treatment and adverse reaction

or

☐ has demonstrated a response to the previous PBS-subsidised biological medicine treatment.

If the patient is demonstrating a response ▶ ***Go to 16***

16 The patient:

☐ demonstrated or sustained an adequate response to the most recent PBS-subsidised biologic treatment by having a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of < 10.

PUCAI score

Date of assessment (DD MM YYYY)

▶ ***Go to 18***

17 The patient's new baseline:

☐ has a Paediatric Ulcerative Colitis Activity Index (PUCAI) score of ≥ 30

PUCAI score

Date of assessment (DD MM YYYY)

or

☐ has trialled the above mentioned treatments for the minimum required timeframes prior to receiving induction therapy with **infliximab** for an acute severe episode of ulcerative colitis in the **last 4 months**, and demonstrated an adequate response to induction therapy by achieving and maintaining a PUCAI score < 10 (only applies to **infliximab applications**).

PUCAI score

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