Australian Government
Services Australia

medicare

PBS

Ulcerative colitis paediatric change or recommencement authority application

When to use this form

Use this authority application form (this form) to **change or recommence** Pharmaceutical Benefits Scheme (PBS) subsidised biological agents for a paediatric patient aged 6 to 17 years inclusive, with moderate to severe ulcerative colitis.

Important information

Applications to **change or recommence** PBS subsidised treatment must be in writing and must include sufficient supporting information to determine the patient's eligibility according to the PBS criteria.

Applications for balance of supply may 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.

Call charges may apply.

Under no circumstances will phone approvals be granted for **change or recommencement** authority applications to extend the treatment period.

Where the term 'biological agent' 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 before temporarily stopping treatment.

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.

After a written authority application for **initial** treatment has been approved, applications for **continuing** treatment can be made by phone. Call **1800 700 270** Monday to Friday, 8 am to 5 pm, local time.

Call charges may apply.

Continuing treatment with PBS subsidised biosimilar brands of biological agents are Authority Required (Streamlined) and do not require authority approval from Services Australia for the listed quantity and repeats.

Section 100 arrangements for infliximab only

This item is available to a patient who is attending:

- an approved private hospital
- a public participating hospital, **or**
- a public hospital

and is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

This item is not available as a PBS benefit for in-patients of a hospital.

The hospital name and provider number must be included in this form.

Treatment specifics

A patient who has experienced a serious adverse reaction of a severity resulting in the necessity for permanent withdrawal of treatment is not considered to have failed treatment with that PBS subsidised biological agent.

For more information

Go to **servicesaustralia.gov.au/healthprofessionals**

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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 for infliximab only

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
- a consultant physician specialising in gastroenterology (either internal medicine or general medicine)
- a paediatrician
- a paediatric gastroenterologist.

11 Which biological agent is this application for?

- Adalimumab
- Infliximab

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

No

Yes — Give details of prior biological agents including dates and duration of treatment

MCA0PB246 2205

13 The patient is:

☐ **changing** to an alternate PBS subsidised biological agent

▶ *Go to 14*

and/or

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

▶ *Go to 14*

or

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

and

☐ will be submitting a new baseline

and

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

▶ *Go to 17*

14 The patient:

☐ has previously received PBS subsidised treatment with a biological agent 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 agent 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 agent

or

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

Give details of treatment and adverse reaction

or

☐ has demonstrated a response to the previous PBS subsidised biological agent 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

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**).

Score

Date of assessment (DD MM YYYY)

Checklist

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

☐ The completed authority prescription form(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/privacy**

Prescriber's declaration

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 the completed authority prescription form(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.

Prescriber's signature

On completion, print and sign by hand.

Date (DD MM YYYY)

Reset form Print form

Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at **servicesaustralia.gov.au/hpos**

  or

- by post, send this form, the authority prescription form(s) and any relevant attachments to:

  Services Australia
  Complex Drugs Programs
  Reply Paid 9826
  HOBART TAS 7001