Australian Government
Services Australia

medicare

PBS

Fistulising Crohn's disease – change, recommencement (treatment break less than 5 years) or demonstration of response authority application

When to use this form

Use this form to apply for **changing** or **recommencing** PBS-subsidised biological medicines for patients with complex refractory fistulising Crohn's disease **after a treatment break less than 5 years**.

This form can also be used for **demonstrating a response** to the current PBS-subsidised treatment before temporarily stopping treatment.

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 complex refractory fistulising Crohn's disease **change** or **recommencement** authority applications.

Where the term 'biological medicine' appears, it refers to adalimumab, infliximab or ustekinumab.

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** treatment or **recommencing** treatment after a treatment break less than 5 years or **demonstrating a response** to treatment before temporarily stopping treatment.

After a written authority application for the **first continuing** treatment has been approved, **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. and ustekinumab i.v.

These items are 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.

These items are 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 PBS-subsidised biological medicine.

For more information

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

Australian Government
Services Australia

medicare

PBS

Fistulising Crohn's disease – change, recommencement (treatment break less than 5 years) or demonstration of response authority application

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 or general medicine).

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 i.v.
- ☐ ustekinumab s.c. with i.v. loading ▶ *Go to 14*

or

- ☐ infliximab s.c. with i.v. loading ▶ *Go to 13*

or

- ☐ **demonstrating a response** to the current PBS-subsidised treatment before temporarily stopping treatment with this biological medicine.

Demonstration of response can be submitted when recommencing treatment. ▶ *Go to 16*

MCA0PB236 2506

13 The patient is:

☐ **changing** from an alternate PBS-subsidised biological medicine, and an authority prescription for at least 2 i.v. doses of infliximab at weeks 0 and 2 is attached

or

☐ **recommencing** PBS-subsidised infliximab after a treatment break, and an authority prescription for 1 i.v. dose of infliximab at weeks 0 is attached

14 The patient:

☐ is **changing** PBS-subsidised biological treatment for this condition after a break **< 5 years**

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

or

☐ is **recommencing** PBS-subsidised biological medicine treatment for this condition after a break **< 5 years**

and

☐ the demonstration of response from the time of cessation is provided with this application

or

☐ the demonstration of response was submitted to Services Australia at the time of treatment cessation

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

15 The patient:

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

and

☐ has not failed or ceased to respond to PBS-subsidised treatment with this drug (the biological medicine this application is for) for this condition more than once in the current treatment cycle

and

☐ has not already failed, or ceased to respond to, PBS-subsidised biological medicine treatment for this condition 3 times in the current treatment cycle

16 The patient:

☐ has **failed** to demonstrate or sustain a response to the most recent PBS-subsidised biological medicine

or

☐ has experienced a **serious adverse reaction** of a severity necessitating permanent withdrawal of the most recent PBS-subsidised biological medicine.

Give details of treatment and adverse reaction

or

☐ has **demonstrated or sustained an adequate response** to the most recent PBS-subsidised biological medicine by having:

☐ a decrease from baseline in the number of open draining fistulae of ≥ 50%

Date of assessment (DD MM YYYY)

and/or

☐ a marked reduction in drainage of all fistula(e) from baseline, together with less pain and induration as reported by the patient.

Date of assessment (DD MM YYYY)

Checklist

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

☐ Details of the proposed prescription(s).

☐ The completed **Fistula assessment form** on page 5 of this form.

Privacy notice

18 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**

19 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

Australian Government
Services Australia

medicare

PBS

Fistula assessment form

PRINT IN BLOCK LETTERS

Patient's full name

Date of assessment (DD MM YYYY)

Number of externally draining complex fistulae

Fistulae symptom grading table

Note: Each parameter in this table must be assigned a value

Symptom	Descriptions	Score	Subtotal
Discharge	no discharge	0	
	minimal mucous discharge	1	
	moderate mucous or purulent discharge	2	
	substantial discharge	3	
	gross faecal soiling	4	
Pain	no pain	0	
	mild discomfort	1	
	moderate discomfort	2	
	marked discomfort	3	
	severe pain	4	
Degree of induration	no induration	0	
	minimal induration	1	
	moderate induration	2	
	substantial induration	3	
	gross fluctuance/abscess	4	
		Fistulae symptom grading total score	

Reset form