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 agents 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.

Call charges may apply.

Under no circumstances will phone approvals be granted for **change** or **recommencement** authority applications.

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 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** 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 i.v. 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 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 agent.

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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Patient's details

1 Medicare card number

Ref no.

or

Department of Veterans' Affairs card number

2 Dr ☐ Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other

Family name

First given name

3 Date of birth (DD MM YYYY)

4 Patient's weight (for infliximab only)

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 i.v. 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 or general medicine).

11 Most recent biological agent

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

12 This application is for:

☐ adalimumab

☐ infliximab i.v. ▶ *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 agent.

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

MCA0PB236 2208

13 The patient is:

☐ **changing** from an alternate PBS-subsidised biological agent, 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 agent 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 agent for this condition in the current treatment cycle

and

☐ has not failed or ceased to respond to PBS-subsidised treatment with the biological agent being applied for this condition more than once in the current treatment cycle

and

☐ has not already failed, or ceased to respond to, PBS-subsidised biological agent 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 agent

or

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

Give details of treatment and adverse reaction

or

☐ has **demonstrated or sustained an adequate response** to the most recent PBS-subsidised biological agent 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.

☐ The completed authority prescription form(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/privacy**

Prescriber's declaration

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 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)

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

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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 Print form