

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

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

Form with three horizontal dotted lines for text entry.

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 $\geq 50\%$

Date of assessment (DD MM YYYY)

Form with three boxes for date entry: 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)

Form with three boxes for date entry: 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)

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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

PRINT IN BLOCK LETTERS

Patient's full name

Date of assessment (DD MM YYYY)

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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			