

# Fistulising Crohn's disease – initial or recommencement (treatment break greater than 5 years) authority application

## When to use this form

Use this form to apply for **initial** or **recommencing** PBS-subsidised biological medicines for patients with complex refractory fistulising Crohn's disease who are either:

- **initiating** PBS-subsidised treatment
- **recommencing** PBS-subsidised treatment **after a treatment break greater than 5 years**.

## Important information

Authority applications to start or recommence PBS-subsidised treatment 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 **initial** 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 **initial** treatment or **recommencing** treatment after a treatment break greater than 5 years.

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](https://servicesaustralia.gov.au/healthprofessionals)

**medicare**



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## 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 This application is for:

☐ adalimumab

☐ infliximab i.v.

☐ ustekinumab s.c with i.v. loading

► Go to 13

or

☐ infliximab s.c. with i.v. loading

► Go to 12

12 The patient:

☐ has not received any prior PBS-subsidised biological medicine treatment for this condition, and an authority prescription for at least 2 i.v. doses of infliximab at weeks 0 and 2 is attached

or

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



MCA0PB092 2506

**13** The patient:

- ☐ has confirmed complex refractory fistulising Crohn's disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician specialising in gastroenterology

and

- ☐ has an externally draining enterocutaneous or rectovaginal fistula.

**Checklist**

- 14**  The relevant attachments need to be provided with this form.

- ☐ Details of the proposed prescription(s).

and

- ☐ The completed **Fistula assessment form** on page 4 of this form.

**Privacy notice**

- 15** 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](https://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](https://servicesaustralia.gov.au/hpos)

**16 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](https://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)




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			