Australian Government
Services Australia

medicare

PBS

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

When to use this form

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

- **initiating** PBS-subsidised treatment
- **initiating** PBS-subsidised treatment for patient's who have received non-PBS-subsidised ustekinumab for the same condition prior to **1 January 2024**.
- **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.

Call charges may apply.

Under no circumstances will phone approvals be granted for complex refractory fistulising Crohn's disease **initial**, **grandfather** 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, **grandfather** 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. only

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**

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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 i.v. and ustekinumab i.v. 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. and ustekinumab 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

☐ 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

☐ ustekinumab s.c (grandfather only) ▶ *Go to 14*

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

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.

▶ *Go to 16*

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Grandfather treatment

14 Prior to commencing non-PBS-subsidised treatment, the patient:

☐ had 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

☐ had an externally draining enterocutaneous or rectovaginal fistula

and

☐ had previously received non-PBS-subsidised treatment with ustekinumab for this condition prior to **1 January 2024**

and

☐ has demonstrated an adequate response to treatment with ustekinumab for this condition if the patient had received at least 12 weeks of initial non-PBS-subsidised therapy

Go to 15

or

☐ not applicable as the patient has not had 12 weeks of non-PBS-subsidised therapy.

Go to 16

15 The patient has demonstrated an adequate response to treatment with ustekinumab defined as:

☐ a decrease from baseline in the number of open draining fistulae of greater than or equal to 50%

and/or

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

Checklist

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

☐ The completed authority prescription form(s).

and

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

or (grandfather applications only)

☐ The completed baseline **Fistula assessment form** on page 4 of this form prior to initiating non-PBS-subsidised treatment.

and, if applicable

☐ The completed current **Fistula assessment form** on page 5 of this form no more than 1 month old at the time of application for patients who have received at least 12 weeks of non-PBS-subsidised treatment to demonstrate an adequate response to treatment.

Privacy notice

17 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**

18 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.

☐ 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, the authority prescription form(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

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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	

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Fistula assessment form

PRINT IN BLOCK LETTERS

Patient's full name

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