Australian Government
Medicare Australia

PBS

Fistulising Crohn Disease
Continuing PBS authority application
Supporting information

Important information

This form must be completed by a gastroenterologist (code 87), a consultant physician in internal medicine specialising in gastroenterology (code 81) or a consultant physician in general medicine specialising in gastroenterology (code 82).

You must lodge this form for a patient who is:

- continuing PBS subsidised treatment
- changing to the alternate PBS subsidised treatment for which the patient is eligible
- demonstrating a response to current PBS subsidised treatment

Where the term TNFα antagonist appears, it refers to adalimumab and infliximab only. Patients are only eligible for PBS subsidised treatment with only one TNFα antagonist at any time.

Applications for patients who wish to change to the alternate TNFα antagonist should be accompanied by the previously approved authority prescription or the remaining repeats for the TNFα antagonist the patient is stopping.

All applications must be in writing and must include sufficient information to determine the patient's eligibility according to the PBS criteria.

The lodgement of this application must be made within one month of the date of the fistula assessment.

The information on this form is correct at the time of publishing and is subject to change.

Section 100 arrangements—for infliximab

This item is only available to a patient who is attending:

- an approved private hospital
- a public participating hospital

or

- a public hospital

and is either:

- 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 the hospital. The hospital provider number must be included on the application form.

Authority prescription form

Continuing treatment

For all continuing applications a completed prescription form must be attached to this form.

Adalimumab: The prescription must be written for a quantity of two and five repeats. The form of adalimumab required must be stipulated as either pre filled syringe or pre filled pen.

Infliximab: The prescription must be written for a quantity of vials sufficient to dose the patient at 5 mg/kg and two repeats.

Change treatment

For change to **adalimumab**: two completed prescriptions must be attached to this form. One prescription must be written for the induction pack quantity of one and no repeats. The second prescription must be written for a quantity of two and two repeats. The form of adalimumab required must be stipulated as either pre filled syringe or pre filled pen.

For change to **infliximab**: one completed prescription must be attached to this form and must be written for a quantity of vials sufficient to dose the patient at 5 mg/kg and two repeats.

The medical indication section of the authority prescription form does not need to be completed when submitted with this form.

Phone approvals

Under no circumstance will phone approvals be granted for complete initial authority applications, or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment

The assessment of the patient's response to a change course of treatment must be made after a minimum of 12 weeks of initial treatment with adalimumab and up to 12 weeks after the first dose (six weeks following the third dose) for infliximab so there is adequate time for a responsse to be demonstrated. Assessments before 12 weeks of treatment with adalimumab have been completed will not be considered.

Assessment following a continuous treatment course should be made after 20 weeks of treatment. The patient may qualify to receive up to 24 weeks of continuing treatment with that TNFα antagonist provided they have demonstrated an adequate response to treatment.

Where a response assessment is not undertaken and submitted to Medicare Australia within these time frames, the patient will be deemed to have failed to respond to treatment.

Assistance

If you need assistance in completing this form or need more information call **1800 700 270** (call charges may apply) and select option 4, between 8.00 am and 5.00 pm EST, Monday to Friday or go to **www.medicareasutralia.gov.au > For health professionals > PBS > Specialised drugs (PBS) A-I > Fistulising Crohn disease**

Lodgement

Send the completed authority application form, completed authority prescription form(s) and all relevant attachments to:

Medicare Australia
Prior written approval of specialised drugs
Reply Paid 9826
Hobart TAS 7001

Print in **BLOCK LETTERS**

Tick where applicable ☑

4238.22.03.11

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Fistulising Crohn Disease
Continuing PBS authority application

Patient's details

1 Medicare/DVA card number

[ ][ ][ ][ ] – [ ][ ][ ][ ][ ] – [ ] Ref no. [ ]

2 Mr ☐ Mrs ☐ Miss ☐ Ms ☐ Other ☐

Family name

First given name

3 Date of birth

/ /

Prescriber's details

4 Prescriber number

5 Family name

First given name

6 Work phone number

( )

Alternative phone number

Fax number

( )

TNFα antagonist details

7 This application is for:

☐ **continuing** treatment with the current PBS subsidised TNFα antagonist

☐ **changing** treatment to the alternate PBS subsidised TNFα antagonist for which the patient is eligible

☐ **demonstrating** a response to the current PBS subsidised TNFα antagonist before temporarily stopping treatment

8 Which TNFα antagonist is this application for?

☐ adalimumab

☐ infliximab

Patient and hospital details

9 Patient's weight

kg

10 **For infliximab only:**

Hospital name

Hospital provider number

Current assessment of patient

11 The patient has:

☐ demonstrated a response to current treatment

Go to Attachments

or

☐ failed to demonstrate a response to current treatment

and

☐ I wish to use a previous baseline set

Go to Attachments

or

☐ this assessment is to be considered as the new baseline

Go to Attachments

Attachments

Attach a completed authority prescription form(s) and completed Fistula assessment form

Prescriber's declaration

12 **I declare that:**

- the information on this form is correct

Prescriber's signature

Date

/ /

Privacy note

The information provided on this form will be used to assess eligibility of a nominated person to receive PBS subsidised treatment. The collection of this information is authorised by the *National Health Act 1953*. This information may be disclosed to the Department of Heath and Ageing, Department of Veterans' Affairs or as authorised or required by law.

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Fistula Assessment Form

PRINT IN BLOCK LETTERS

1 Patient's full name

Sex Male ☐ Female ☐

Date of assessment / /

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	

Prescriber's declaration

2 **I declare that**:

- the information provided on this form is correct.

Name of prescriber

Signature of prescriber ✍

Date / /