Australian Government
Medicare Australia

PBS

Fistulising Crohn Disease
Initial 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 starting **initial** PBS subsidised treatment with a Tumour Necrosis Factor alfa antagonist (TNFα) for complex refractory fistulising Crohn disease.

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.

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 most recent 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.

Acknowledgements

The patient's and the prescriber's acknowledgements must be signed in front of a witness (over 18 years of age).

Authority prescription form

Adalimumab: Two completed prescriptions must be attached to this form. One prescription must be written for the induction pack, quantity 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.

Infliximab: A completed authority 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 an initial course of treatment must be made following a minimum of 12 weeks of therapy for adalimumab and up to 12 weeks after the first dose (six weeks following the third dose) of infliximab so there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must following a minimum of 12 weeks of therapy for adalimumab and be submitted to Medicare Australia no later than one month from the date of completion of this initial course of 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 ☑

4237.22.03.11

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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

[/ /]

Patient's acknowledgement

4 I acknowledge that PBS subsidised treatment with TNFα antagonists for complex refractory fistulising Crohn disease will stop if:

- subsequent testing demonstrates that I have failed to demonstrate or sustain a response to treatment as detailed in the criteria
- I have failed three TNFα antagonist treatment courses for which I was eligible.

My prescriber has explained the nature of the ongoing monitoring and testing required to demonstrate an adequate response to therapy.

Patient's signature

[✍]

Date

[/ /]

Prescriber's details

5 Prescriber number

[ ][ ][ ][ ][ ][ ][ ]

6 Family name

[ ]

First given name

[ ]

7 Work phone number

[( )]

Alternative phone number

[ ]

Fax number

[( )]

Prescriber's acknowledgement

8 **I have explained:**

- The circumstances governing PBS subsidised treatment with a TNFα antagonists for complex refractory fistulising Crohn disease
- The nature of the ongoing monitoring and testing required to demonstrate an adequate and sustained response to therapy.

I believe these to be understood and accepted by the patient.

Prescriber's signature

[✍]

Date

[/ /]

Witness's acknowledgement

9 I have witnessed the signatures of **BOTH** the patient and the prescriber.

Witness's full name (over 18 years of age)

[ ]

Witness's signature

[✍]

Date

[/ /]

TNFα antagonist details

10 Which TNFα antagonist is this application for?

☐ adalimumab

☐ infliximab

Patient and hospital details

11 Patient's weight

[kg]

12 **For infliximab only:**

Hospital name

[ ]

Hospital provider number

[ ][ ][ ][ ][ ][ ][ ]

Conditions and criteria

To qualify for PBS authority approval the following conditions must be met.

13 The patient:

☐ has confirmed complex refractory fistulising Crohn 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 (codes 87, 81 or 82 only)

and

☐ has an externally draining enterocutaneous or rectovaginal fistula

Attachments

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

Prescriber's declaration

14 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 / /