



Crohn disease

Initial PBS authority application

Supporting information

Important information

The attached supporting information form is to 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 (TNF) alfa antagonist for Crohn disease.

Where the term TNF alfa antagonist appears it refers to adalimumab and infliximab only. Patients are eligible for PBS subsidised treatment with only one TNF alfa 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.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than one month after stopping the most recent prior treatment.

Where applicable, any one of the baseline criteria supplied with the initial application may be used to determine response to a course of treatment and eligibility for continued therapy, according to the criteria for the continuing treatment restriction.

Patients who are approved for PBS subsidised treatment based on a Crohn Disease Activity Index (CDAI) score must demonstrate a response to treatment with a CDAI score of 150, or less, within one month of stopping treatment.

The lodgement of this application must be made within one month of the date of all assessments, pathology tests and diagnostic imaging studies.

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 either

- 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 is not 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 of six 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 form 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 supporting information 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) for 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 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 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.medicareaustralia.gov.au > For health professionals > PBS > Specialised drugs (PBS) A-I > Crohn disease**

Lodgement

Send the completed authority application form, a completed authority prescription form and all relevant attachments to:

Medicare Australia

Prior written approval of specialised drugs

GPO Box 9826

Hobart TAS 7001

(no stamp required if posted in Australia)

Print in **BLOCK LETTERS**

Tick where applicable



Crohn disease Initial PBS authority application

Patient's details

1 Medicare/DVA 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 TNF alfa antagonists for Crohn disease will stop if:

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

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

Patient's signature

Date
 / /

Prescriber's details

Important: prescriber must be 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).

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 TNF alfa antagonists for 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
 / /

TNF alfa antagonist details

10 Which TNF alfa antagonist is this application for?

adalimumab
 infliximab

Patient and hospital details

11 Patient's weight
 kg

Patient's height
 cm

For infliximab only:

Hospital name

Hospital provider number

Conditions and prior treatment

12 To qualify for PBS authority approval, under this criterion, the following conditions must be met.

The patient has:

- confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist

and

- signed the patient's acknowledgement

and

- failed to achieve an adequate response to prior systemic therapy including:

- a tapered course of steroids starting at a dose of at least 40 mg prednisolone (or equivalent) over a six week period

Drug

Starting dose mg

from /

to /

and either

- azathioprine at a dose of at least 2 mg per kg per day for three or more months

Dose mg

from /

to /

or

- 6-mercaptopurine at a dose of at least 1 mg per kg per day for three or more months

Dose mg

from /

to /

or

- methotrexate at a dose of at least 15 mg weekly for three or more months.

Dose mg

from /

to /

Provide details of contraindications or intolerance including the degree of toxicity.

Details of the toxicity criteria are available at www.medicareaustralia.gov.au Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Contraindication or toxicity and grade

Prednisolone

Azathioprine
6-Mercaptopurine
Methotrexate

Criteria

13 The following initiation criteria indicate failure to achieve an adequate response to prior treatment. All assessments, pathology tests and diagnostic imaging studies must be made preferably whilst still on treatment, but no longer than one month after stopping the most recent prior treatment.

Choose one of the following criteria.

This patient has:

either

- a Crohn Disease Activity Index (CDAI) assessment which is 300 or more

Go to Attachments

or

- extensive small intestine disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine

Go to 14 and/or 15

or

- diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy and has evidence of intestinal inflammation.

Go to 15

The patient has:

- 14** a CDAI assessment which is 220 or more

and/or

- 15** a) evidence of active intestinal inflammation including:

i) *Blood*

- higher than normal platelet count

and/or

- an elevated Erythrocyte Sedimentation Rate (ESR) greater than 25 mm per hour

and/or

- a C-Reactive Protein (CRP) greater than 15 mg per L

and/or

ii) *Faeces*

- a higher than normal lactoferrin level

and/or

- a higher than normal calprotectin level

and/or

iii) *Diagnostic imaging*

- demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery

and/or

- b) been assessed clinically as being in a high faecal output state

Date of assessment

and/or

- c) been assessed clinically as requiring surgery or Total Parenteral Nutrition (TPN) as the next therapeutic option, in the absence of TNF alfa antagonist treatment.

Date of assessment

Attachments



Attach all relevant CDAI, pathology and diagnostic imaging reports and a completed authority prescription form(s).

Prescriber's declaration

16 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 Health and Ageing, Department of Veterans' Affairs or as authorised or required by law.



Adult Crohn Disease Activity Index

1 Week ending

Patient's full name

Sex Male Female

Each parameter in this table must be assigned a value.

			Factor	Subtotal
Liquid stools (cumulative total over the last seven days)	Number of liquid or soft stools over the last seven days	sum =	x 2	
	<input type="text"/>			
Abdominal pain † (cumulative total over the last seven days)	Daily assessment †	sum =	x 5	
	<input type="text"/>			
General well being ‡ (cumulative total over the last seven days)	Daily assessment †	sum =	x 7	
	<input type="text"/>			
Extra-intestinal				
Arthritis/arthralgia	None = 0	score =	x 20	
	Yes = 1			
Iritis/uveitis	None = 0	score =	x 20	
	Yes = 1			
Skin/mouth lesions	None = 0	score =	x 20	
	Yes = 1			
Peri-anal disease	None = 0	score =	x 20	
	Yes = 1			
Other fistula	None = 0	score =	x 20	
	Yes = 1			
Fever > 37.8°C	None = 0	score =	x 20	
	Yes = 1			
Anti-diarrhoeals	None = 0	score =	x 30	
	Yes = 1			
Abdominal mass	None = 0	score =	x 10	
	Questionable = 2			
	Definite = 5			
Haematocrit (Hct)	Males (47 – Hct)	score =	x 6	
	Females (42 – Hct)	score =	x 6	
Weight (Maximum deduction of -10 for overweight patients)	Standard kg	kg	$100 \times \left(1 - \frac{\text{current}}{\text{standard}}\right)$	
	Current kg	kg		
TOTAL CDAI SCORE				<input type="text"/>

† Abdominal pain	None = 0
	Intermediate = 1 or 2
	Severe = 3
‡ General well being	Well = 0
	Intermediate = 1, 2 or 3
	Terrible = 4

Prescriber's declaration

2 I declare that:

- the information provided on this form is correct.

Name of prescriber

Print full name in BLOCK LETTERS

Signature of prescriber

Date