



Crohn disease PBS authority application

For **initial** Pharmaceutical Benefits Scheme (PBS) subsidised treatment for **continuing** treatment of patients who were receiving treatment for Crohn disease with adalimumab before 9 November 2007 or infliximab before 7 March 2007.

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) or other consultant physician in consultation with a gastroenterologist..

You must lodge this form for a patient starting initial PBS subsidised treatment, for continuing 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. 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 the patient is still on treatment, but no longer than one month after stopping the most recent prior treatment and must be made within one month of the date of application.

Patients who were started on TNF alfa antagonist 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 information on this form is correct at the time of publishing and is subject to change.

Assistance

If you need assistance in completing this form call Medicare Australia on **1800 700 270*** and select option 4 (8 am to 5 pm EST Monday to Friday), or visit **www.medicareaustralia.gov.au**

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

Reply Paid 9826

GPO Box 9826

Hobart TAS 7001

(no stamp required if posted in Australia)

Section 100 arrangements—only 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.

Authority prescription form

A completed authority prescription form must be attached to this form.

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 authority applications, or for treatment that would otherwise extend the treatment period.

Applications for continuing treatment

Applications for continuing treatment should be made before the completion of the previous course to ensure continuity of treatment for those patients who meet continuation criteria.

This assessment 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.

*** Call charges apply from mobile and pay phones only**



Crohn disease PBS authority application Supporting information form

For **initial** PBS subsidised treatment for **continuing** treatment of patients who were receiving treatment for Crohn disease with adalimumab prior to 9 November 2007 or infliximab prior to 7 March 2007.

Complete all relevant parts of this application

Print in **BLOCK LETTERS**

Tick where applicable

Patient's details

1 Medicare/DVA number

2 Family name

First given name

3 Date of birth

Acknowledgements

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

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

Signature of patient

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) or other consultant physician in consultation with a gastroenterologist.

5 Prescriber number

6 Family name

First given name

Phone

Fax

Prescriber's acknowledgement

7 **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.

Signature of prescriber

Date

Witness's details

8 Family name

First given name

I have witnessed the signature of **BOTH** the patient and the prescriber.

Signature of witness (over 18 years of age)

Date

TNF alfa antagonist details

9 Which TNF alfa antagonist is this application for?

adalimumab

infliximab

Patient details, prior treatment and hospital details

10 Patient's weight

kg

11 Patient's height

cm

12 Prior treatment details

First injection/infusion date

/ /

Last injection/infusion date

/ /

Only for infliximab:

Hospital name

Hospital provider number

Conditions and criteria

13 To qualify for PBS authority approval, under this criterion, the patient must have demonstrated an appropriate response to prior TNF alfa antagonist treatment *within one month of the treatment stopping*.

The patient has:

either

a documented history of severe refractory Crohn disease, who before starting treatment with either adalimumab or infliximab, had a baseline Crohn Disease Activity Index (CDAI) assessment which is 300 or more, and this assessment is attached

Go to 14

or

a documented history of 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 with a documented history of intestinal inflammation.

Go to 15

14 The patient can demonstrate a response to prior TNF alfa treatment by a CDAI assessment which is 150 or less, within one month of stopping prior TNF alfa treatment.

Go to attachments

15 The patient has:

improvement of intestinal inflammation as documented by:

Blood

a normalisation of platelet count

and/or

an Erythrocyte Sedimentation Rate (ESR) no greater than 25 mm per hour

and/or

a C-Reactive Protein (CRP) no greater than 15 mg per L

and/or

Faeces

a normalisation of lactoferrin level

and/or

a normalisation of calprotectin level

and/or

Diagnostic imaging

evidence of mucosal healing as demonstrated by diagnostic imaging findings

and/or

reversal of high faecal output state

Date of assessment

/ /

and/or

has been assessed clinically as no longer requiring surgery or Total Parenteral Nutrition (TPN).

Date of assessment

/ /

Attachments



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

Prescriber's declaration

16 I declare that the information provided on this form is correct.

Signature of prescriber

Date

/ /

Privacy note

The information provided on this form will be used to assess applications and eligibility for the nominated patient under the restrictions for PBS subsidised treatment for Crohn disease. The collection of this information is authorised by the *National Health Act 1953* and may be disclosed to the Department of Health and Ageing, 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/arthritis	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

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