



Crohn disease

Continuing PBS authority application

Supporting information

Important information

All patients

You must lodge this form for a patient who is either:

- continuing PBS subsidised treatment (all patients) or
- changing to an alternate PBS subsidised treatment for which the adult patient is eligible or
- demonstrating a response to the current PBS subsidised treatment for all patients not continuing treatment at this time.

Where the term Tumour Necrosis Factor (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.

Paediatric patients

The attached supporting information form is to be completed by a gastroenterologist (code 87) or a paediatrician (code 11) or a consultant physician in consultation with a gastroenterologist. Paediatric patients are not eligible for treatment with adalimumab.

Adult patients

The attached supporting information form is to be completed by the relevant specialist.

- *For continuing treatment or for demonstrating a response to treatment immediately before a break in treatment* the form must be completed by a gastroenterologist (code 87), a consultant physician in internal medicine specialising in gastroenterology (code 81), a consultant physician in general medicine specialising in gastroenterology (code 82) or other consultant physician in consultation with a gastroenterologist.
- *For changing treatment* the 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) only.

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

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.

Adult 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.

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

A demonstration of response before stopping treatment temporarily may be submitted using this form and faxed to **1300 154 019**.

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.

Authority prescription form

Continuing treatment for all patients

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 adult patients

For change to 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 doses 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 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 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 response to be demonstrated.

Assessment following a continuous treatment course should be made after 20 weeks of treatment. Patients may qualify to receive up to 24 weeks of continuing treatment with that TNF alfa antagonist provided they have demonstrated an adequate response 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(s) and all relevant attachments to:

Medicare Australia
Prior written approval of specialised drugs
GPO Box 9826
Hobart TAS 7001

Print in **BLOCK LETTERS**

Tick where applicable



Crohn disease Continuing 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
 / /

Prescriber's details

4 Prescriber number

5 Family name

 First given name

6 Work phone number
 ()
 Alternative phone number

 Fax number
 ()

TNF alfa antagonist details

7 This application is for:
 continuing treatment with the current PBS subsidised TNF alfa antagonist
 changing treatment to an alternate PBS subsidised TNF alfa antagonist for which the adult patient is eligible
 demonstrating a response to the current PBS subsidised TNF alfa antagonist before temporarily stopping treatment.

8 Which TNF alfa antagonist is this application for?
 adalimumab (For adults only)
 infliximab

Patient and hospital details

9 Patient's weight
 kg
 Patient's height
 cm

For infliximab:
 Hospital name

 Hospital provider number

Current assessment of patient

10 The patient has:
 demonstrated a response to current treatment
Go to 11
or
 failed to demonstrate a response to current treatment
and
 I wish to use a previous baseline set
Go to 15
or
 this assessment is to be considered as the new baseline.
Go to 12

11 The patient has demonstrated a response to treatment by one of the following options (which must have been provided at baseline):
either
 a current CDAI score which is 150 or less
Go to Attachments
or
 a current Paediatric Crohn Disease Activity Index (PCDAI) score reduced by at least 15 points as compared to baseline and is 30 or less
Go to Attachments
or
 a) the patient has improvement of intestinal inflammation as documented by:
i) Blood
 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

ii) *Faeces*

a normalisation of lactoferrin level

and/or

a normalisation of calprotectin level

and/or

iii) *Diagnostic imaging*

evidence of mucosal healing as demonstrated by diagnostic imaging findings

and/or

b) reversal of high faecal output state

Date of assessment

/ /

and/or

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

Date of assessment

/ /

Go to Attachments

12 The patient has failed to respond to treatment and the following assessment is to be considered the new baseline.

The patient has:

a CDAI assessment which is 300 or more

Go to Attachments

or

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

Go to 13 and/or 14

or

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

Go to 14

13 The patient has:

a CDAI assessment which is 220 or more

and/or

14 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*

(i) a higher than normal lactoferrin level

and/or

(ii) 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, PCDAI, pathology and diagnostic imaging reports and a completed authority prescription form(s).

Prescriber's declaration

15 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.



Paediatric Crohn Disease Activity Index

1 Week ending / / for (patient's full name)

Age years Sex Male Female

Each parameter in this table must be assigned a value.

		Score	Subtotal
Abdominal pain	No abdominal pain	0	
	Mild; no interference with Activities of Daily Living (ADL)	5	
	Moderate/severe; daily, nocturnal, interferes with ADL	10	
Stools/day	0-1 liquid, no blood	0	
	≤ 2 semi-formed + small blood or 2-5 liquid	5	
	≥ 6 liquid stools, gross blood, or nocturnal diarrhoea	10	
General function	Well, no limitations of activities	0	
	Below par, occasional difficulty with activities	5	
	Very poor, frequent limitation of activities	10	
Examination			
Weight	Weight gain (or voluntarily stable/reduction)	0	
	Weight loss < 10% (or involuntarily stable)	5	
	Weight loss ≥ 10%	10	
Height† (at diagnosis)	< 1 channel decrease from previous percentile	0	
	1 to < 2 channel decrease from previous percentile	5	
	≥ 2 channel decrease from previous percentile	10	
or			
Height velocity††	≤ -1 standard deviation from normal	0	
	-1 to < -2 standard deviation from normal	5	
	≥ -2 standard deviation from normal	10	
Abdomen	No tenderness or mass	0	
	Tenderness, or mass without tenderness	5	
	Tenderness, involuntary guarding, definite mass	10	
Peri-rectal disease	None, asymptomatic tags	0	
	1-2 indolent fistula, scant drainage, non-tender	5	
	Active fistula, drainage, tenderness, or abscess	10	
Extra-intestinal†††	None	0	
	1 manifestation	5	
	≥ 2 manifestations	10	
Laboratory			
Haematocrit (%) M = Male F = Female	M/F 6-10 years: ≥ 33	0	
	M 11-14 years: ≥ 35		
	F 11-19 years: ≥ 34		
	M 15-19 years: ≥ 37		
	M/F 6-10 years: 28-32	2.5	
	M 11-14 years: 30-34		
	F 11-19 years: 29-33		
	M 15-19 years: 32-36	5	
	M/F 6-10 years: < 28		
	M 11-14 years: < 30		
	F 11-19 years: < 29		
	M 15-19 years: < 32		
ESR (mm / hr)	< 20	0	
	20-50	2.5	
	> 50	5	
Albumin (g / L)	≥ 35	0	
	31-34	5	
	≤ 30	10	

† Height-channel represents lines on the standard percentile chart eg 10 - > 25 - > 50 percentile is two channels difference

†† Height velocity is calculated from measurements over last 6-12 months in cm / year compared to standard deviation below (minus to) normal

††† Extra-intestinal implies fever of > 38.5°C over three days over last week, arthritis, uveitis, Erythema nodosum or Pyoderma gangrenosum

TOTAL PCDAI SCORE

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



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"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
Abdominal pain † (cumulative total over the last seven days)	Daily assessment †	sum =	x 5
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>		
General well being ‡ (cumulative total over the last seven days)	Daily assessment †	sum =	x 7
	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <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