



# Crohn disease

## Initial paediatric PBS authority application

### Supporting information

#### Important information

To be completed by a gastroenterologist or paediatrician.

You must lodge this form for a patient aged six to 17 years starting **initial** PBS subsidised treatment with infliximab for Crohn's disease.

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

The Paediatric Crohn's Disease Assessment Index (PCDAI) assessment should be performed preferably whilst the patient is still on treatment, but no longer than one month after stopping the most recent prior treatment.

This application must be lodged within one month of the date of the PCDAI assessment.

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

#### Section 100 arrangements

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

#### Acknowledgements

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

#### 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 telephone 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 an initial course of treatment must be made up to 12 weeks after the first dose (six weeks following the third dose) so that 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 with infliximab.

#### 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](http://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 current PCDAI to:

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

Print in **BLOCK LETTERS**

Tick where applicable



## 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

a parent or authorised guardian has signed the patient acknowledgement

and

had failed to achieve an adequate response to two of the following three conventional prior therapies including:

a tapered course of steroids starting at a dose of at least 1 mg per kg or 40 mg (whichever is the lesser) of prednisolone (or equivalent) over a six week period

Drug

Starting dose

 mg

from

 / /

to

 / /

and/or

an eight week course of enteral nutrition

from

 / /

to

 / /

and/or

immunosuppressive therapy

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 10 mg per m<sup>2</sup> weekly for three or more months

Dose

 mg

from

 / /

to

 / /

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

Details of the toxicity criteria are available at [www.medicareaustralia.gov.au](http://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.

This patient has:

a Paediatric Crohn Disease Activity Index (PCDAI) score  $\geq$  30.

### Attachments



Attach a PCDAI assessment and a completed authority prescription 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 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	
<b>Examination</b>			
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	
<b>Laboratory</b>			
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	2.5	
	M/F 6-10 years: 28-32		
	M 11-14 years: 30-34		
	F 11-19 years: 29-33	5	
	M 15-19 years: 32-36		
	M/F 6-10 years: < 28		
	M 11-14 years: < 30	5	
	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 2 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 3 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