



## Supporting information for Crohn's disease PBS authority application

For **initial** PBS subsidised treatment for **continuing** treatment of **patients aged 6 to 17 years** inclusive who were receiving treatment with infliximab for Crohn's disease before 4 July 2007.

### Important information

To be completed by a gastroenterologist **or** paediatrician **or** consultant physician in consultation with a gastroenterologist.

You must lodge this form for a patient aged 6 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.

This application must be lodged within one month of the date of the Paediatric Crohn's Disease Activity Index (PCDAI) assessment.

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, or more information, 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](http://www.medicareaustralia.gov.au)**

### Lodgement

Send the completed authority application form, a completed authority prescription form and current PCDAI to:

**Medicare Australia**  
**Prior written approval of specialised drugs**  
**Reply Paid 9826**  
**GPO Box 9826**  
**Hobart Tasmania 7001**  
(no stamp required if posted in Australia)

### 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 this form.

### Patient's acknowledgement

To be signed by the parent or authorised guardian and the prescriber in the presence 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

Applications for continuing treatment should be made prior to 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 a 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.

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



# Crohn's disease PBS authority application Supporting information form

For **initial** PBS subsidised treatment for **continuing** treatment of **patients aged 6 to 17 years** inclusive who were receiving treatment with infliximab for Crohn's disease before 4 July 2007.

Complete all parts of this application  
**Print neatly in BLOCK LETTERS.**  
Tick where applicable

### Patient's details

1 Medicare number

2 Family name

First given name

Date of birth

### Patient's acknowledgement

This acknowledgement must be signed by the parent or authorised guardian and the prescriber in the presence of a witness (over 18 years of age).

3 I acknowledge that:

- Pharmaceutical Benefits Scheme (PBS) subsidised treatment with infliximab for Crohn's disease will stop if subsequent testing demonstrates that the patient named above has failed to achieve or sustain a response to treatment as detailed in the criteria.

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

Family name (of parent or authorised guardian)

First given name (of parent or authorised guardian)

**Signature of parent or authorised guardian**

Date

### Prescriber's details

**Note:** Prescriber must be a gastroenterologist or paediatrician or consultant physician in consultation with a gastroenterologist.

4 Prescriber number

5 Family name

First given name

Phone number

Fax number

### Prescriber's acknowledgement

6 I have explained:

- the circumstances governing PBS subsidised treatment with infliximab for Crohn's 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 parent or authorised guardian.

**Signature of prescriber**

Date

### Witness's details

7 Family name

First given name

I have witnessed the signature of **BOTH** the parent or authorised guardian and the prescriber.

**Signature of witness** (over 18 years of age)

Date

# Crohn's disease PBS authority application Supporting information form

## Hospital, patient details and prior treatment

8 Hospital name

9 Hospital provider number

10 Patient's weight

 kg

11 Patient's height

 cm

12 First infusion date

 / /

13 Last infusion date

 / /

## Conditions and criteria

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

The patient has:

a documented history of moderate to severe refractory Crohn's disease

**and**

a baseline Paediatric Crohn's Disease Activity Index (PCDAI) score more than 30 before starting infliximab

**and**

demonstrated a response to treatment by a current PCDAI score which is reduced by at least 15 points as compared to baseline and is 30 or less.

## Attachments



Attach baseline and current PCDAI assessments and a completed authority prescription form.

## Prescriber's declaration

15 I declare that:

- the information provided in this form is correct.

**Signature of prescriber**

Date

 / /

## Privacy note

This information provided on this form will be used to assess applications and eligibility for the nominated patient under the PBS subsidised treatment for Crohn's 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.



# Paediatric Crohn's 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
<b>Abdominal pain</b>	No abdominal pain	0	
	Mild; no interference with Activities of Daily Living (ADL)	5	
	Moderate/severe; daily, nocturnal, interferes with ADL	10	
<b>Stools/day</b>	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	
<b>General function</b>	Well, no limitations of activities	0	
	Below par, occasional difficulty with activities	5	
	Very poor, frequent limitation of activities	10	
<b>Examination</b>			
<b>Weight</b>	Weight gain (or voluntarily stable/reduction)	0	
	Weight loss < 10% (or involuntarily stable)	5	
	Weight loss ≥ 10%	10	
<b>Height† (at diagnosis)</b>	< 1 channel decrease from previous percentile	0	
	1 to < 2 channel decrease from previous percentile	5	
	≥ 2 channel decrease from previous percentile	10	
<b>or</b>			
<b>Height velocity††</b>	≤ -1 standard deviation from normal	0	
	-1 to < -2 standard deviation from normal	5	
	≥ -2 standard deviation from normal	10	
<b>Abdomen</b>	No tenderness or mass	0	
	Tenderness, or mass without tenderness	5	
	Tenderness, involuntary guarding, definite mass	10	
<b>Peri-rectal disease</b>	None, asymptomatic tags	0	
	1-2 indolent fistula, scant drainage, non-tender	5	
	Active fistula, drainage, tenderness, or abscess	10	
<b>Extra-intestinal†††</b>	None	0	
	1 manifestation	5	
	≥ 2 manifestations	10	
<b>Laboratory</b>			
<b>Haematocrit (%)</b> 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		
<b>ESR (mm / hr)</b>	< 20	0	
	20-50	2.5	
	> 50	5	
<b>Albumin (g / L)</b>	≥ 35	0	
	31-34	5	
	≤ 30	10	

**TOTAL PCDAI SCORE**

† 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

## 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

/
/