

# Crohn's disease paediatric continuing authority application

## When to use this form

Use this authority application form (this form) to apply for **continuing** Pharmaceutical Benefits Scheme (PBS) subsidised biological agents for a paediatric patient aged 6 to 17 years inclusive, with Crohn's disease.

This form can also be used for demonstrating a patient's response to a PBS subsidised biological agent before temporarily stopping treatment.

## Important information

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

Applications for balance of supply may be made in real time using the Online PBS Authorities System or by phone. Call **1800 700 270** Monday to Friday, 8 am to 5 pm, local time.

Call charges may apply.

Under no circumstances will phone approvals be granted for the **first continuing** authority applications to extend the treatment period.

The patient must be treated by a gastroenterologist (code 87), a consultant physician (internal medicine specialising in gastroenterology) (code 81), a consultant physician (general medicine specialising in gastroenterology) (code 82), a paediatrician or a specialist paediatric gastroenterologist.

Where the term 'biological agent' appears, it refers to adalimumab or infliximab.

A copy of the Paediatric Crohn's Disease Activity Index is provided for your convenience, but is not required to be submitted with this application.

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

## Continuing treatment

This form is **ONLY** for **continuing** treatment.

The patient remains eligible to receive continuing treatment providing they continue to sustain a response to treatment.

After a written authority application for the **first continuing** treatment has been approved, **subsequent continuing** treatment with PBS subsidised biosimilar brands of biological agents are Authority Required (Streamlined) and do not require authority approval from Services Australia for the listed quantity and repeats.

## Section 100 arrangements for infliximab only

This item is available to a patient who is attending:

- an approved private hospital
- a public participating hospital, **or**
- a public hospital

**and** is:

- a day admitted patient
- a non-admitted patient, **or**
- a patient on discharge.

This item is not available as a PBS benefit for in-patients of a hospital.

The hospital name and provider number must be included in this form.

## Treatment specifics

Continuing treatment authorisations will be limited to provide a **maximum of 24 weeks** of therapy for adalimumab and infliximab.

## For more information

Go to [servicesaustralia.gov.au/healthprofessionals](https://servicesaustralia.gov.au/healthprofessionals)

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## Patient's details

- 1 Medicare card number  
-- Ref no.
- or  
Department of Veterans' Affairs card number
- 2 Mr  Miss  Other   
Family name
- First given name
- 3 Date of birth  /  /
- 4 Patient's weight  kg
- 5 Patient's height  cm

## Prescriber's details

- 6 Prescriber number
- 7 Dr  Mr  Mrs  Miss  Ms  Other   
Family name
- First given name
- 8 Business phone number  
 ( )
- Alternative phone number
- Fax number  
 ( )

## Hospital details for infliximab only

- 9 Hospital name
- This hospital is a:  
 public hospital  
 private hospital
- 10 Hospital provider number

## Conditions and criteria

To qualify for PBS authority approval, the following conditions must be met.

- 11 For this application the patient is:  
 **demonstrating** a response to the current PBS subsidised biological agent before temporarily stopping treatment. **Go to 14**
- or  
 **continuing** treatment with the current PBS subsidised biological antagonist
- 12 Which biological agent is this application for?  
 Adalimumab  
 Infliximab
- 13 Has the patient received previous PBS subsidised treatment with this drug for this condition?  
No   
Yes
- 14 The patient has demonstrated an adequate response to treatment with this drug by:  
 a reduction in Paediatric Crohn's Disease Activity Index (PCDAI) score by at least 15 points from baseline  
**and**  
 a PCDAI score  $\leq 30$  for moderate to severe disease (infliximab only)
- or  
 a PCDAI score  $\leq 40$  for severe disease (adalimumab only).
- PCDAI score
- Date of assessment  /  /

## Checklist

- 15  The relevant attachments need to be provided with this form.

The completed authority prescription form(s).

## Privacy notice

- 16 Personal information is protected by law (including the *Privacy Act 1988*) and is collected by Services Australia for the purposes of assessing and processing this authority application. Personal information may be used by Services Australia, or given to other parties where the individual has agreed to this, or where it is required or authorised by law (including for the purpose of research or conducting investigations).

More information about the way in which Services Australia manages personal information, including our privacy policy, can be found at [servicesaustralia.gov.au/privacy](https://servicesaustralia.gov.au/privacy)

## Prescriber's declaration

### 17 I declare that:

- I am aware that this patient must meet the criteria listed in the current Schedule of Pharmaceutical Benefits to be eligible for this medicine.
- I have informed the patient that their personal information (including health information) will be disclosed to Services Australia for the purposes of assessing and processing this authority application.
- I have provided the completed authority prescription form(s) and the relevant attachments as specified in the Pharmaceutical Benefits Scheme restriction.
- the information I have provided in this form is complete and correct.

### I understand that:

- giving false or misleading information is a serious offence.

Prescriber's signature

Date

## Returning this form

Return this form and any supporting documents:

- **online**, upload this form, the authority prescription form(s) and any relevant attachments through Health Professional Online Services (HPOS) at [servicesaustralia.gov.au/hpos](https://servicesaustralia.gov.au/hpos)
- **or**
- by post, send this form, the authority prescription form(s) and any relevant attachments to:

Services Australia  
Complex Drugs Programs  
Reply Paid 9826  
HOBART TAS 7001

Week ending  /  /

Patient's full name

Age  years

Gender  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	
<b>or</b>			
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		
	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		
	M/F 6–10 years: < 28	5	
	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	

**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