

When to use this form

Use this form to apply for **initial** PBS-subsidised biological medicines for a paediatric patient aged 6 to 17 years inclusive, with Crohn's disease.

Important information

Initial applications to start PBS-subsidised treatment 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** can 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 paediatric Crohn's disease **initial** authority applications.

Where the term 'biological medicine' 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 **initial** treatment.

The assessment of the patient's response to the course of treatment must be made following a **minimum of 12 weeks** of therapy for adalimumab and **up to 12 weeks** after the first dose (6 weeks following the third dose) for infliximab so that there is adequate time for a response to be demonstrated.

This assessment will be used to determine eligibility for continuing treatment and must be conducted **no later than 4 weeks** from the date of completion of the initial course of treatment.

After a written authority application for the **first continuing** treatment has been approved, **subsequent continuing** treatments with PBS-subsidised biosimilar brands of biological medicines 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, **or**
- a public hospital

and is a:

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

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

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

Treatment specifics

A patient who has experienced a serious adverse reaction of a severity necessitating permanent treatment withdrawal is not considered to have failed treatment with that PBS-subsidised biological medicine.

For more information

Go to servicesaustralia.gov.au/healthprofessionals

13 The patient:

- has confirmed paediatric Crohn's disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence

and

- has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:
- a tapered course of steroids starting at a dose of at least 1 mg/kg or 40 mg (whichever is the lesser) of prednisolone (or equivalent) over a 6 week period

Name of drug

Starting dose mg

From (DD MM YYYY)

To (DD MM YYYY)

and/or

- an 8 week course of enteral nutrition

From (DD MM YYYY)

To (DD MM YYYY)

and/or

- immunosuppressive therapy
- azathioprine at a dose of at least 2 mg/kg per day for 3 or more months

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

or

- 6-mercaptopurine at a dose of at least 1 mg/kg per day for 3 or more months

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

or

- methotrexate at a dose of at least 10 mg/m² weekly for 3 or more months

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

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

For details of the toxicity criteria, go to servicesaustralia.gov.au/healthprofessionals

Intolerance must be of a severity to necessitate permanent treatment withdrawal.

Contraindication or toxicity and grade

Prednisolone (or equivalent)

Azathioprine

6-mercaptopurine

Methotrexate

15 The patient has:

- moderate to severe disease defined by a Paediatric Crohn's Disease Activity Index (PCDAI) score \geq 30 (infliximab only)

or

- severe disease defined by a PCDAI score \geq 40 (adalimumab).

PCDAI score

Date of assessment (DD MM YYYY)

Checklist

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

- The completed authority prescription form(s).

Privacy notice

17 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/privacypolicy

Prescriber's declaration

You do not need to **sign** the declaration if you complete this form using Adobe Acrobat Reader and return this form through Health Professional Online Services (HPOS) at servicesaustralia.gov.au/hpos

18 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.

I have read, understood and agree to the above.

Date (DD MM YYYY) (you **must** date this declaration)

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Prescriber's signature (**only** required if returning by post)



Returning this form

Return this form, the authority prescription form(s) and any relevant attachments:

- **online** (no signature required), upload through HPOS at servicesaustralia.gov.au/hpos
- **or**
- by post (signature required) to
Services Australia
Complex Drugs Programs
Reply Paid 9826
HOBART TAS 7001

Week ending (DD MM YYYY)

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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 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**

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