Australian Government
Services Australia

medicare

PBS

Crohn's disease paediatric – initial authority application

When to use this form

Use this form to apply for **initial** PBS-subsidised biological medicines for paediatric patients 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.

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.

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

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

The assessment of the patient's response to the course of treatment must be conducted within the time frame specified in the restriction. Where a demonstration of response is not conducted within the required time frame, the patient will be deemed to have failed treatment with that particular PBS-subsidised biological medicine.

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 particular PBS-subsidised biological medicine.

For more information

Go to **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 (DD MM YYYY)

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 (including area code)

Alternative phone number (including area code)

Hospital details

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 The patient, between 6 and 17 years, is being treated by a:

☐ gastroenterologist

☐ consultant physician (internal medicine specialising in gastroenterology)

☐ consultant physician (general medicine specialising in gastroenterology)

☐ paediatrician

☐ specialist paediatric gastroenterologist.

12 This application is for:

☐ adalimumab

☐ infliximab

MCA0PB085 2407

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/m^2 weekly for 3 or more months

Dose mg

From (DD MM YYYY)

To (DD MM YYYY)

14 If applicable, 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 ≥ 30 (infliximab only)

or

☐ severe disease defined by a PCDAI score ≥ 40 (adalimumab).

PCDAI score

Date of assessment (DD MM YYYY)

Checklist

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

☐ Details of the proposed prescription(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 details of the proposed prescription(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)

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

If returning by post, print and sign by hand.

Returning this form

Return this form, details of the proposed prescription(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

Australian Government
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Paediatric Crohn's Disease Activity Index

Week ending (DD MM YYYY) ☐☐ ☐☐ ☐☐☐☐

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		
	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 > 38.5ºC over 3 days over last week, arthritis, uveitis, Erythema nodosum or Pyoderma gangrenosum

Reset form