Australian Government
Services Australia

medicare

PBS

Crohn's disease paediatric – change or recommencement or demonstration of response authority application

When to use this form

Use this form for **changing or recommencing** PBS-subsidised biological medicines for paediatric patients 6 to 17 years inclusive, with Crohn's disease.

This form can also be used for **demonstrating a response** to the current PBS-subsidised treatment before temporarily stopping treatment.

Important information

Authority 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** 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 **change or recommencement** 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 **changing or recommencing** treatment or **demonstrating** a response to treatment before temporarily stopping 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 Has the patient received prior PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle?

No ☐

Yes ☐ Provide details

Most recent biological medicine

Dates of the most recent treatment course

From (DD MM YYYY)

To (DD MM YYYY)

13 This application for:

☐ adalimumab

☐ infliximab

MCA0PB239 2407

14 The patient is:

☐ **changing** to an alternate PBS-subsidised biological medicine

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

▶ ***Go to 15***

or

☐ **recommencing** PBS-subsidised biological medicine treatment after a break **< 5 years** from the most recent PBS-subsidised biological medicine for this condition

and

☐ will be submitting a new baseline

or

☐ will be using the previous baseline

▶ ***Go to 15***

or

☐ **recommencing** PBS-subsidised biological medicine treatment after a break **> 5 years** from the most recent PBS-subsidised biological medicine for this condition

and

☐ will be submitting a new baseline

and

☐ has previously received PBS-subsidised biological medicine treatment for this condition

and

☐ the patient has confirmed severe Crohn's disease defined by standard clinical, endoscopic and/or imaging features including histological evidence

▶ ***Go to 18***

15 The patient:

☐ has previously received PBS-subsidised treatment with a biological medicine for this condition in this treatment cycle

and

☐ has not failed or ceased to respond to PBS-subsidised treatment more than once with this drug (the biological medicine this application is for) for this condition in this treatment cycle

16 The patient:

☐ has **failed** to demonstrate or sustain a response with the previous biological medicine

or

☐ has experienced a **serious adverse reaction** of a severity resulting in the necessity for permanent withdrawal of the previous PBS-subsidised biological medicine.

Give details of treatment and adverse reaction

or

☐ has demonstrated or sustained a response to current PBS-subsidised biological treatment

If the patient is demonstrating a response ▶ ***Go to 17***

If new baselines are being provided ▶ ***Go to 18***

Demonstration of response

17 The patient:

☐ has demonstrated or sustained a response to current PBS-subsidised biological treatment by:

☐ a reduction in Paediatric Crohn's Disease Activity Index (PCDAI) score by at least 15 points from baseline

and

☐ a PCDAI score ≤ 30 for moderate to severe disease (infliximab only)

or

☐ a PCDAI score ≤ 40 for severe disease (adalimumab only)

Patient's baseline

18 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

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

☐ Details of the proposed prescription(s).

Privacy notice

20 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**

21 **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
Services Australia

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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	

† 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

TOTAL PCDAI SCORE ☐

Reset form