

Crohn's disease adult – upadacitinib – initial grandfather authority application

When to use this form

Use this form to apply for **initial grandfather** PBS-subsidised upadacitinib for patients 18 years or over with severe Crohn's disease who have received non-PBS-subsidised treatment with upadacitinib for the same condition prior to **1 December 2023**.

Important information

Initial grandfather 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.

Under no circumstances will phone approvals be granted for severe Crohn's disease **initial grandfather** authority applications.

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.

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

Continuing or extended induction treatment

This form is ONLY for **initial grandfather** treatment.

For **continuing** or **extended induction** PBS-subsidised treatment, a grandfathered patient must qualify under the **continuing** or **extended induction** treatment criteria.

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

12 The patient:

- had a Crohn's Disease Activity Index (CDAI) score ≥ 300 prior to commencing non-PBS-subsidised treatment with this drug as evidence of failure to achieve an adequate response to prior systemic therapy

CDAI score

Date of assessment (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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► **Go to 14**

or

- has a documented history of extensive intestinal inflammation affecting > 50 cm of small intestine as evidenced by radiological imaging

and

- has evidence of failure to achieve an adequate response to prior systemic therapy

and

- a CDAI score of ≥ 220 prior to commencing non-PBS-subsidised supply of this drug

CDAI score

Date of assessment (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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► **Go to 13**

or

- has a documented history of intestinal inflammation and diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy

and

- has evidence of intestinal inflammation and failure to achieve an adequate response to prior systemic therapy.

► **Go to 13**

13 The patient has failed to achieve an adequate response to prior therapy as demonstrated by:

- clinical assessment of the patient being in a high faecal output state

or

- clinical assessment that the patient is requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option in absence of this drug, if affected by short gut syndrome, extensive small intestine disease or is an ostomy patient

or

- evidence of intestinal inflammation demonstrated by at least one of the following:
- blood: higher than normal platelet count
 - blood: an elevated erythrocyte sedimentation rate (ESR) > 25 mm/hour
 - blood: a C-reactive protein (CRP) level > 15 mg/L
 - a higher than normal lactoferrin or calprotectin level in faeces
 - diagnostic imaging of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery.

14 The patient has failed to achieve an adequate response to prior systemic therapy with a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period

Name of drug

Starting dose

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg
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From (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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To (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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and

- azathioprine at a dose of at least 2 mg/kg daily for 3 or more consecutive months

Dose

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg
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From (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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To (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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or

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

Dose

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg
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From (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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To (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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or

- methotrexate at a dose of at least 15 mg weekly for 3 or more consecutive months

Dose

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	mg
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From (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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To (DD MM YYYY)

<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
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15 Contraindication or intolerance necessitating permanent treatment withdrawal

Provide details below where either:

- treatment with any of the drugs is contraindicated according to the relevant TGA-approved Product Information.
- intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal.

Include the degree of toxicity.

For details of the accepted toxicities, including severity, go to servicesaustralia.gov.au/healthprofessionals

Contraindication or toxicity and grade


Prednisolone	Grade
<input type="text"/>	<input type="text"/>

Azathioprine	Grade
<input type="text"/>	<input type="text"/>

6-mercaptopurine	Grade
<input type="text"/>	<input type="text"/>

Methotrexate	Grade
<input type="text"/>	<input type="text"/>

Checklist

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

- Details of the proposed prescription(s).
- The relevant pathology reports, diagnostic imaging test(s) and/or the completed Adult Crohn's Disease Activity Index calculation sheet.

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)

<input type="text"/>	<input type="text"/>	<input type="text"/>
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Prescriber's signature (**only** required if returning by post)



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

Week ending (DD MM YYYY)

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Each parameter in this table must be assigned a value.

		Factor	Subtotal					
Liquid stools (cumulative total over the last 7 days)	Number of liquid or soft stools over the last 7 days	sum =	x 2					
	<table border="1" style="width: 100%;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>							
Abdominal pain † (cumulative total over the last 7 days)	Daily assessment †	sum =	x 5					
	<table border="1" style="width: 100%;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>							
General well being ‡ (cumulative total over the last 7 days)	Daily assessment ‡	sum =	x 7					
	<table border="1" style="width: 100%;"><tr><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td><td style="width: 20px; height: 20px;"></td></tr></table>							
Extra-intestinal								
Arthritis/arthralgia	None = 0	score =	x 20					
	Yes = 1							
Iritis/uveitis	None = 0	score =	x 20					
	Yes = 1							
Skin/mouth lesions	None = 0	score =	x 20					
	Yes = 1							
Peri-anal disease	None = 0	score =	x 20					
	Yes = 1							
Other fistula	None = 0	score =	x 20					
	Yes = 1							
Fever > 37.8°C	None = 0	score =	x 20					
	Yes = 1							
Anti-diarrhoeals	None = 0	score =	x 30					
	Yes = 1							
Abdominal mass	None = 0	score =	x 10					
	Questionable = 2							
	Definite = 5							
Haematocrit (Hct)	Males (47 – Hct)	score =	x 6					
	Females (42 – Hct)	score =	x 6					
Weight (Maximum deduction of -10 for overweight patients)	Standard kg	kg	$100 \times \left(1 - \frac{\text{current}}{\text{standard}} \right)$					
	Current kg	kg						
TOTAL CDAI SCORE								

† Abdominal pain	None = 0
	Intermediate = 1 or 2
	Severe = 3
‡ General well being	Well = 0
	Intermediate = 1, 2 or 3
	Terrible = 4