

medicare



Fistulising Crohn's disease – continuing authority application

| When to use this form | Use this form to apply for continuing PBS-subsidised biological medicines for patients with complex refractory fistulising Crohn's disease. |
|--------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Important information | Continuing 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 complex refractory fistulising Crohn's disease continuing authority applications. |
| | Where the term 'biological medicine' appears, it refers to adalimumab, infliximab or ustekinumab. |
| | 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. |
| | 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 | This item is available to a patient who is attending: |
| for infliximab i.v. | 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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| Pa | Patient's details Hospital details | | |
|----|------------------------------------------------|----|-------------------------------------------------------------------------------------------------------------------------|
| 1 | Medicare card number | 8 | Hospital name |
| | Ref no. | | |
| | or | | This hospital is a: |
| | Department of Veterans' Affairs card number | | public hospital |
| | | | private hospital |
| _ | | 9 | Hospital provider number |
| 2 | Dr Mr Mrs Miss Ms Other | | |
| | Family name | | |
| | | Co | nditions and criteria |
| | First given name | То | qualify for PBS authority approval, the following conditions |
| | | | ust be met. |
| 3 | Date of birth (DD MM YYYY) | 10 | The patient is being treated by a: |
| | | | gastroenterologist |
| 4 | Patient's weight | | consultant physician specialising in gastroenterology (either |
| | kg | | internal or general medicine) |
| | | 11 | This application is for: |
| Pr | escriber's details | | adalimumab |
| 5 | Prescriber number | | infliximab i.v. |
| 0 | | | infliximab s.c. |
| | | 10 | ustekinumab s.c. |
| 6 | Dr 🗌 Mr 🗌 Mrs 🗌 Miss 🗌 Ms 🗌 Other 📃 | 12 | Has the patient previously received this biological medicine (regardless of formulation) as their most recent course of |
| | Family name | | PBS-subsidised treatment? |
| | | | No 🛄 |
| | First given name | | Yes Dates of the most recent treatment course |
| | | | From (DD MM YYYY) |
| 7 | Business phone number (including area code) | | |
| | | | To (DD MM YYYY) |
| | Alternative phone number (including area code) | | |
| | | 13 | The patient has demonstrated an adequate response to |
| | | | treatment with this drug evidenced by: |
| | | | a decrease from baseline in the number of open draining fistulae of greater than or equal to 50% |
| | | | and/or |
| | | | a marked reduction in drainage of all fistula(e) from |
| | | | baseline, together with less pain and induration as reported by the patient. |
| | | | by the patient. |
| | | | |
| | | | |

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Checklist

| U | le | C | K | | 5 |
|---|----|---|---|---|---|
| | | | | _ | _ |

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

Details of the proposed prescription(s).

The completed **Fistula assessment form** on page 4 of this form.

Privacy notice

15 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**

16 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:



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)

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

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Fistula assessment form

| PRINT IN BLOCK LETTERS | | |
|------------------------------------------------|--|--|
| Patient's full name | | |
| Date of assessment (DD MM YYYY) | | |
| Number of externally draining complex fistulae | | |

Number of externally draining complex fistulae

Fistulae symptom grading table

Note: Each parameter in this table must be assigned a value

| Symptom | Descriptions | Score | Subtotal |
|----------------------|---------------------------------------|---------------------------|----------|
| Discharge | no discharge | 0 | |
| | minimal mucous discharge | 1 | |
| | moderate mucous or purulent discharge | 2 | |
| | substantial discharge | 3 | |
| | gross faecal soiling | 4 | |
| | | | |
| Pain | no pain | 0 | |
| | mild discomfort | 1 | |
| | moderate discomfort | 2 | |
| | marked discomfort | 3 | |
| | severe pain | 4 | |
| | | | |
| Degree of induration | no induration | 0 | |
| | minimal induration | 1 | |
| | moderate induration | 2 | |
| | substantial induration | 3 | |
| | gross fluctuance/abscess | 4 | |
| | · | matom grading total agora | |

Fistulae symptom grading total score