

## **INFLIXIMAB**

**August 2008**

### **NOTE:**

Any queries concerning the arrangements to prescribe infliximab may be directed to Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Written applications for authority to prescribe infliximab should be forwarded to:  
Medicare Australia  
Prior Written Approval of Specialised Drugs  
Reply Paid 9826  
GPO Box 9826  
HOBART TAS 7001

Further prescribing information is on the Medicare Australia website at <http://www.medicareaustralia.gov.au/provider/pbs/drugs1/crohns.jsp>

### **TREATMENT OF ADULT PATIENTS WITH SEVERE REFRACTORY CROHN DISEASE**

The following information applies to the prescribing under the Pharmaceutical Benefits Scheme (PBS) of adalimumab and infliximab for adult patients with severe refractory Crohn disease. Where the term 'tumour necrosis factor (TNF) alfa antagonist' appears in the following NOTES and restrictions, it refers to adalimumab and infliximab only.

A patient is eligible for PBS-subsidised treatment with only 1 of the 2 TNF-alfa antagonists at any 1 time.

From 1 August 2008, under the PBS, all patients will be able to commence a treatment cycle where they may trial each PBS-subsidised TNF-alfa antagonist without having to experience a disease flare when swapping to the alternate agent. Under these interchangeability arrangements, within a single treatment cycle, a patient may continue to receive long-term treatment with a TNF-alfa antagonist while they continue to show a response to therapy.

A patient who received PBS-subsidised TNF-alfa antagonist treatment prior to 1 August 2008 is considered to be in their first cycle as of 1 August 2008.

Within the same treatment cycle, a patient cannot trial and fail, or cease to respond to, the same PBS-subsidised TNF-alfa antagonist more than twice.

Once a patient has either failed or ceased to respond to treatment 3 times, they are deemed to have completed a treatment cycle and they must have, at a minimum, a 5-year break in PBS-subsidised TNF-alfa antagonist therapy before they are eligible to commence the next cycle. The 5-year break is measured from the date of the last approval for PBS-subsidised TNF-alfa antagonist treatment in the most recent cycle to the date of the first application for initial treatment with a TNF-alfa antagonist under the new treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of less than 5 years, may commence a further course of treatment within the same treatment cycle.

A patient who has failed fewer than 3 trials of TNF-alfa antagonists in a treatment cycle and who has a break in therapy of more than 5 years, may commence a new treatment cycle.

There is no limit to the number of treatment cycles a patient may undertake in their lifetime.

#### **(1) How to prescribe PBS-subsidised TNF-alfa antagonist therapy after 1 August 2008.**

(a) Initial treatment.

Applications for initial treatment should be made where:

(i) a patient has received no prior PBS-subsidised TNF-alfa antagonist treatment in this treatment cycle and wishes to commence such therapy (Initial 1); or  
(ii) a patient has received prior PBS-subsidised (initial or continuing) TNF-alfa antagonist therapy and wishes to trial an alternate agent (Initial 2) [further details are under 'Swapping therapy' below]; or

(iii) a patient wishes to re-commence treatment with a specific TNF-alfa antagonist following a break in PBS-subsidised therapy with that agent (Initial 2). Initial treatment authorisations will be limited to provide for a maximum of 16 weeks of therapy for adalimumab and 14 weeks of therapy for infliximab.

From 1 August 2008, a patient must be assessed for response to any course of initial PBS-subsidised treatment 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, and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

For second and subsequent courses of PBS-subsidised TNF-alfa antagonist treatment, it is recommended that a patient is reviewed in the month prior to completing their current course of treatment and that an application is posted to Medicare Australia no later than 2 weeks prior to the patient completing their current treatment course.

Adalimumab only: Two completed authority prescriptions must be submitted with every initial application for adalimumab. One prescription must be for the induction pack containing a quantity of 6 doses of 40 mg and no repeats.

The second prescription must be written for 2 doses of 40 mg and 2 repeats.

(b) Continuing treatment. Following the completion of an initial treatment course with a specific TNF-alfa antagonist, a patient may qualify to receive up to 24 weeks of continuing treatment with that drug providing they have demonstrated an adequate response to treatment. The patient remains eligible to receive continuing TNF-alfa antagonist treatment with the same drug in courses of up to 24 weeks providing they continue to sustain the response.

It is recommended that a patient be reviewed in the month prior to completing their current course of treatment to ensure uninterrupted TNF-alfa antagonist supply.

Assessments of response to a course of PBS-subsidised therapy must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

Where a response assessment is not submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with that TNF-alfa antagonist.

## **(2) Swapping therapy.**

Once initial treatment with the first PBS-subsidised TNF-alfa antagonist is approved, a patient may swap if eligible to the alternate TNF-alfa antagonist within the same treatment cycle without having to requalify with respect to the indices of disease severity (i.e. Crohn Disease Activity Index (CDAI) Score, evidence of intestinal inflammation,), or the prior corticosteroid therapy and immunosuppressive therapy.

A patient may trial the alternate TNF-alfa antagonist at any time, regardless of whether they are receiving therapy (initial or continuing) with a TNF-alfa antagonist at the time of the application. However, they cannot swap to a particular TNF-alfa antagonist if they have failed to respond to prior treatment with that drug two times within the same treatment cycle.

To ensure a patient receives the maximum treatment opportunities allowed under the interchangeability arrangements, it is important that they are assessed for response to every course of treatment approved, within the timeframes specified

in the relevant restriction.

To avoid confusion, an application for a patient who wishes to swap to the alternate TNF-alfa antagonist should be accompanied by the approved authority prescription or remaining repeats for the TNF-alfa antagonist the patient is ceasing.

**(3) Baseline measurements to determine response.**

Medicare Australia will determine whether a response to treatment has been demonstrated based on the baseline measurements of the CDAI or evidence of intestinal inflammation submitted with the first authority application for a TNF-alfa antagonist. However, prescribers may provide new baseline measurements any time that an initial treatment authority application is submitted within a treatment cycle and Medicare Australia will assess response according to these revised baseline measurements.

To ensure consistency in determining response, the same indices of disease severity used to establish baseline at the commencement of treatment with each initial treatment application must be provided for all subsequent continuing treatment applications.

**(4) Re-commencement of treatment after a 5-year break in PBS-subsidised therapy.**

A patient who wishes to trial a second or subsequent treatment cycle following a break in PBS-subsidised TNF-alfa antagonist therapy of at least 5 years, must requalify for initial treatment with respect to the indices of disease severity. Patients must have received treatment with a corticosteroid and at least 1 immunosuppressive agent, at an adequate dose, for a minimum of 3 consecutive months immediately prior to the time the CDAI score or the indices of intestinal inflammation are measured.

**(5) Patients 'grandfathered' onto PBS-subsidised treatment with adalimumab or infliximab.**

A patient who commenced treatment with adalimumab for severe refractory Crohn disease prior to 9 November 2007 or infliximab prior to 7 March 2007 and who continues to receive treatment at the time of application, may qualify for treatment under the initial 'grandfather' treatment restriction.

A patient may only qualify for PBS-subsidised treatment under this criterion once. A maximum of 24 weeks of treatment with adalimumab or infliximab will be authorised under this criterion.

Following completion of the initial PBS-subsidised course, further applications for treatment with adalimumab or infliximab will be assessed under the continuing treatment restriction.

'Grandfather' arrangements will only apply for the first treatment cycle. For the second and subsequent cycles, a 'grandfather' patient must requalify for initial treatment under the criteria that apply to a new patient. See 'Re-commencement of treatment after a 5-year break in PBS-subsidised therapy' above for further details.

**Public hospital authority required**

Initial 1 (new patients)

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or a consultant physician as specified in the NOTE below; and
- (b) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the

predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(c) has failed to achieve an adequate response to prior systemic therapy including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and

(ii) immunosuppressive therapy including:

- azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
- 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months; or
- methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application. .

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) ).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) have a severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 300 as assessed.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

The most recent CDAI assessment must be no more than 1 month old at the time of application.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) )] which includes the following:

(i) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated. This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised adalimumab treatment.

### **Public hospital authority required**

#### **Initial 2**

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course 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 and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:
  - (i) the completed current Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
  - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority

applications, or for treatment that would otherwise extend the initial treatment period.

A CDAI assessment of the patient's response to this initial course of treatment must be made 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, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

### **Public hospital authority required**

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to a level no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) )] which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition.

The CDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a CDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **Public hospital authority required**

#### Initial 1

Initial PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below of a patient who satisfies the following criteria:

- (a) has confirmed Crohn disease defined by standard clinical, endoscopic and/or imaging features, including histological evidence with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
  - (b) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy; and
  - (c) has evidence of intestinal inflammation; and
  - (d) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
  - (e) has failed to achieve an adequate response to prior systemic drug therapy including:
    - (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
    - (ii) immunosuppressive therapy including:
      - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
      - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months;
- or
- methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have evidence of intestinal inflammation, including:
  - (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
  - (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
  - (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; AND/OR
- (b) be assessed clinically as being in a high faecal output state; AND/OR
- (c) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) )] which includes the following:
  - (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (ii) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; and
  - (iii) date of the most recent clinical assessment; and
  - (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

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

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

### **Public hospital authority required**

Initial 2

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below of a patient who:

- (a) has a documented history of severe refractory Crohn disease; and
- (b) in this treatment cycle, has received prior PBS-subsidised treatment with infliximab or adalimumab for this condition; and
- (c) has not failed PBS-subsidised therapy with infliximab for this condition more than once in the current treatment cycle.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

To demonstrate a response to treatment the application must be accompanied by the results of the most recent course of TNF-alfa antagonist therapy within the timeframes specified in the relevant restriction.

Where the most recent course of PBS-subsidised TNF-alfa antagonist treatment was approved under an initial treatment restriction, the patient must have been assessed for response to that course 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 and this assessment must be submitted to Medicare Australia no later than 4 weeks from the date that course was ceased.

If the response assessment to the previous course of TNF-alfa antagonist treatment is not submitted as detailed above, the patient will be deemed to have failed therapy with that particular course of TNF-alfa antagonist.

Authority applications must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) )] which includes the following:
  - (i) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criteria, if relevant; and
  - (ii) details of prior TNF alfa antagonist treatment including details of date and duration of treatment.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 16 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

The assessment of the patient's response to this initial course of treatment must be made following a minimum of 12 weeks of therapy so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

### **Public hospital authority required**

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease with intestinal inflammation and with short gut syndrome or with an ileostomy or colostomy; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) improvement of intestinal inflammation as demonstrated by:

- (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
  - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
  - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
- (b) reversal of high faecal output state; or
- (c) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) )] which includes the following:

- (i) the reports and dates of the pathology or diagnostic imaging test(s) used to assess response to therapy or the date of clinical assessment.

The patient's assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **Public hospital authority required**

Initial 1

Initial PBS-subsidised treatment with infliximab by a gastroenterologist or a consultant physician as specified in the NOTE below, of a patient with severe refractory Crohn disease who satisfies the following criteria:

- (a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and
- (b) has extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; and
- (c) has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has failed to achieve an adequate response to prior systemic therapy including:

- (i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period; and
- (ii) immunosuppressive therapy including:
  - azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or
  - 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months;or
- methotrexate at a dose of at least 15 mg weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) ).

The following initiation criteria indicate failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

- (a) have severity of disease activity which results in a Crohn Disease Activity Index (CDAI) Score greater than or equal to 220; AND/OR
- (b) have evidence of active intestinal inflammation, including:
  - (i) blood: higher than normal platelet count, or, an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour, or, a C-reactive protein (CRP) level greater than 15 mg per L; AND/OR
  - (ii) faeces: higher than normal lactoferrin or calprotectin level; AND/OR
  - (iii) diagnostic imaging: demonstration of increased uptake of intravenous contrast with thickening of the bowel wall or mesenteric lymphadenopathy or fat streaking in the mesentery; AND/OR
- (c) be assessed clinically as being in a high faecal output state; AND/OR
- (d) be assessed clinically as requiring surgery or total parenteral nutrition (TPN) as the next therapeutic option, in the absence of infliximab.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Any one of the baseline criteria may be used to determine response to an initial course of treatment and eligibility for continued therapy, according to the criteria included in the continuing treatment restriction. However, the same criterion must be used for any subsequent determination of response to treatment, for the purpose of eligibility for continuing PBS-subsidised therapy.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) )] which includes the following:
  - (i) details of prior systemic drug therapy [dosage, date of commencement and duration of therapy]; and
  - (ii) (1) reports and dates of the pathology or diagnostic imaging test(s) nominated as the response criterion, if relevant; or
  - (2) the completed current Crohn Disease Activity Index (CDAI) calculation sheet including the dates of assessment of the patient's condition, if relevant; and
  - (iii) date of the most recent clinical assessment; and
  - (iv) the signed patient acknowledgement.

All assessments, pathology tests and diagnostic imaging studies must be made within 1 month of the date of application.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 1, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

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

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

#### **Public hospital authority required**

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, or consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease with extensive intestinal inflammation affecting more than 50 cm of the small intestine; and
- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as:

- (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
- (b) improvement of intestinal inflammation as demonstrated by:
  - (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
  - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
  - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
- (c) reversal of high faecal output state; or
- (d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:
  - (i) the completed Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; or
  - (ii) the reports and dates of the pathology test or diagnostic imaging test(s) used to assess response to therapy; or

(iii) the date of clinical assessment.

All assessments must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, an assessment of the patient's response must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **Public hospital authority required**

Initial 3 (grandfather)

Initial PBS-subsidised supply with infliximab for continuing treatment by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist of a patient who:

- (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
- (b) had a Crohn Disease Activity Index (CDAI) Score of greater than or equal to 300 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) )] which includes the following:

- (i) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet including the date of the assessment of the patient's condition; and
- (ii) the signed patient acknowledgement.

The current CDAI assessment must be no more than 1 month old at the time of application. The baseline CDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.

### **Public hospital authority required**

Initial 3

Initial PBS-subsidised supply for continuing treatment with infliximab by a gastroenterologist, a consultant physician as specified in the NOTE below, or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of severe refractory Crohn disease and was receiving treatment with infliximab prior to 7 March 2007; and
- (b) (1) has a history of extensive small intestinal disease with radiological evidence of intestinal inflammation affecting more than 50 cm of the small intestine; or
- (2) has diagnostic imaging or surgical evidence of short gut syndrome or has an ileostomy or colostomy with a documented history of intestinal inflammation; and
- (c) has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and
- (d) has demonstrated or sustained an adequate response to treatment with infliximab according to the criteria included in the relevant continuation restriction. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

The same criteria used to determine an inadequate response to prior treatment at baseline must be used to determine response to treatment and eligibility for continuing therapy, according to the criteria included in the continuing treatment restriction.

An adequate response to infliximab treatment is defined as:

- (a) a reduction in Crohn Disease Activity Index (CDAI) Score to no greater than 150; or
- (b) improvement of intestinal inflammation as demonstrated by:
  - (i) blood: normalisation of the platelet count, or an erythrocyte sedimentation rate (ESR) level no greater than 25 mm per hour, or a C-reactive protein (CRP) level no greater than 15 mg per L; AND/OR
  - (ii) faeces: normalisation of lactoferrin or calprotectin level; AND/OR
  - (iii) evidence of mucosal healing, as demonstrated by diagnostic imaging findings, compared to the baseline assessment; or
- (c) reversal of high faecal output state; or
- (d) avoidance of the need for surgery or total parenteral nutrition (TPN).

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and
- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ( [www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au) ) ] which includes the following:
  - (i) (1) the completed current and baseline Crohn Disease Activity Index (CDAI) Score calculation sheet, where relevant, including the date of the assessment of the patient's condition; or
  - (2) the reports and dates of the current and baseline pathology or diagnostic imaging test(s) in order to assess response to therapy; or
  - (3) the date of clinical assessment(s); and
  - (ii) the signed patient acknowledgement.

The patient's assessment must be no more than 1 month old at the time of application. The baseline CDAI assessments must be from immediately prior to commencing treatment with infliximab. Where a baseline assessment is not available, please call Medicare Australia on 1800 700 270 to discuss.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Patients may qualify for PBS-subsidised treatment under this restriction once only.

## **TREATMENT OF PATIENTS AGED 6 to 17 YEARS WITH SEVERE REFRACTORY CROHN DISEASE**

### **Public hospital authority required**

Initial PBS-subsidised treatment by a gastroenterologist, paediatrician or consultant physician as specified in the NOTE below, of a patient aged 6 to 17 years inclusive with moderate to severe refractory Crohn disease who satisfies

the following criteria:

(a) has confirmed Crohn disease, defined by standard clinical, endoscopic and/or imaging features, including histological evidence, with the diagnosis confirmed by a gastroenterologist or consultant physician as specified in the NOTE below; and  
(b) whose parent or authorised guardian has signed a patient acknowledgement indicating they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and  
(c) has failed to achieve an adequate response to 2 of the following 3 conventional prior therapies including:

(i) a tapered course of steroids, starting at a dose of at least 40 mg prednisolone (or equivalent), over a 6 week period;

(ii) an 8 week course of enteral nutrition;

(iii) immunosuppressive therapy including:

- azathioprine at a dose of at least 2 mg per kg daily for 3 or more months; or  
- 6-mercaptopurine at a dose of at least 1 mg per kg daily for 3 or more months;

or

- methotrexate at a dose of at least 10 mg per square metre weekly for 3 or more months.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

If treatment with any of the above-mentioned drugs is contraindicated according to the relevant TGA-approved Product Information, please provide details at the time of application.

If intolerance to treatment develops during the relevant period of use, which is of a severity necessitating permanent treatment withdrawal, please provide details of the degree of this toxicity at the time of application. Details of the accepted toxicities including severity can be found on the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au)).

The following initiation criterion indicates failure to achieve an adequate response and must be demonstrated in all patients at the time of the application:

(a) severity of disease activity which results in a Paediatric Crohn Disease Activity Index (PCDAI) Score greater than or equal to 30 as assessed, preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

(b) The most recent PCDAI assessment must be no more than 1 month old at the time of application.

All tests and assessments should be performed preferably whilst still on treatment, but no longer than 1 month following cessation of the most recent prior treatment.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:

(i) the completed current Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet including the date of assessment of the patient's condition; and

(ii) details of previous systemic drug therapy [dosage, date of commencement and duration of therapy], or dates of enteral nutrition; and

(iii) the signed patient acknowledgement.

A maximum quantity and number of repeats to provide for an initial course of infliximab consisting of 3 doses at 5 mg per kg body weight per dose to be administered at weeks 0, 2 and 6, will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete the 3 doses of infliximab may be requested by telephone by contacting Medicare Australia on 1800 700

270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday). Under no circumstances will telephone approvals be granted for initial authority applications, or for treatment that would otherwise extend the initial treatment period.

A PCDAI assessment of the patient's response to this initial course of treatment must be made up to 12 weeks after the first dose (6 weeks following the third dose) so that there is adequate time for a response to be demonstrated.

This assessment, which will be used to determine eligibility for continuing treatment, must be submitted to Medicare Australia no later than 1 month from the date of completion of this initial course of treatment. Where a response assessment is not undertaken and submitted to Medicare Australia within these timeframes, the patient will be deemed to have failed to respond to treatment with infliximab.

It is recommended that an application for continuing treatment is posted to Medicare Australia at the time of the 12 week assessment, to ensure continuity of treatment for those patients who meet the continuation criterion for PBS-subsidised infliximab treatment.

### **Public hospital authority required**

Continuing PBS-subsidised treatment with infliximab by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient who:

- (a) has a documented history of moderate to severe refractory Crohn disease;

and

- (b) has demonstrated or sustained an adequate response to treatment with infliximab.

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

- (a) a completed authority prescription form; and

- (b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:

- (i) the completed Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition.

The PCDAI assessment must be no more than 1 month old at the time of application.

If the application is the first application for continuing treatment with infliximab, a PCDAI assessment of the patient's response must be made up to 12 weeks after the first dose so that there is adequate time for a response to be demonstrated. The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

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Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to receive PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

### **Public hospital authority required**

Initial PBS-subsidised supply with infliximab for continuing treatment by a gastroenterologist, paediatrician, consultant physician as specified in the NOTE below or other consultant physician in consultation with a gastroenterologist, of a patient aged 6 to 17 years inclusive who:

(a) has a documented history of moderate to severe refractory Crohn disease and was receiving treatment with infliximab prior to 4 July 2007; and

(b) had a Paediatric Crohn Disease Activity Index (PCDAI) Score of greater than 30 prior to commencing treatment with infliximab. Where a baseline CDAI assessment is not available, please call Medicare Australia on 1800 700 270 to discuss; and

(c) whose parent or authorised guardian has signed a patient acknowledgement indicating that they understand and acknowledge that PBS-subsidised treatment will cease if they do not meet the predetermined response criterion for ongoing PBS-subsidised treatment, as outlined in the restriction for continuing treatment; and

(d) has demonstrated or sustained an adequate response to treatment with infliximab. For advice please contact Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

NOTE: Prescribers must be gastroenterologists (code 87), consultant physicians [internal medicine specialising in gastroenterology (code 81)] or consultant physicians [general medicine specialising in gastroenterology (code 82)].

An adequate response to infliximab treatment is defined as a reduction in Paediatric Crohn Disease Activity Index (PCDAI) Score by at least 15 points as compared to baseline AND a total PCDAI score of 30 points or less.

Applications for authorisation must be made in writing and must include:

(a) a completed authority prescription form; and

(b) a completed Crohn Disease PBS Authority Application - Supporting Information Form [may be downloaded from the Medicare Australia website ([www.medicareaustralia.gov.au](http://www.medicareaustralia.gov.au))] which includes the following:

(i) the completed current and baseline Paediatric Crohn Disease Activity Index (PCDAI) calculation sheet along with the date of the assessment of the patient's condition; and

(ii) the signed patient acknowledgement.

The current PCDAI assessment must be no more than 1 month old at the time of application. The baseline PCDAI assessment must be from immediately prior to commencing treatment with infliximab.

The assessment of the patient's response to a continuing course of therapy must be made within the 4 weeks prior to completion of that course and posted to Medicare Australia no less than 2 weeks prior to the date the next dose is scheduled, in order to ensure continuity of treatment for those patients who meet the continuation criterion.

Where an assessment is not submitted to Medicare Australia within these timeframes, patients will be deemed to have failed to respond, or to have failed to sustain a response, to treatment with infliximab.

Patients are eligible to receive continuing infliximab treatment in courses of up to 24 weeks providing they continue to sustain the response.

Patients who fail to demonstrate or sustain a response to treatment with infliximab for Crohn disease as specified in the criteria for continuing treatment with infliximab, will not be eligible to recommence PBS-subsidised treatment with this drug within 12 months of the date on which treatment was ceased.

At the time of the authority application, medical practitioners should request the appropriate number of vials, based on the weight of the patient, to provide sufficient for a single infusion at a dose of 5 mg per kg. Up to a maximum of 2 repeats will be authorised. No applications for increased repeats will be authorised.

Where fewer than 2 repeats are requested at the time of the application, authority approvals for sufficient repeats to complete a maximum of 24 weeks of treatment may be requested by telephone by contacting Medicare Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. EST Monday to Friday).

Patients may qualify for PBS-subsidised treatment under this restriction once only.