

SA2487 - Infliximab

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.....
Fax Number:	Fax Number:

Infliximab

Initial application — Crohn's disease (adults)

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Patient has active Crohn's disease
and

Patient has a CDAI score of greater than or equal to 300 or HBI score of greater than or equal to 10
or
 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine
or
 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection
or
 Patient has an ileostomy or colostomy, and has intestinal inflammation

and Patient has tried but has experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids

Renewal — Crohn's disease (adults)

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on infliximab
or
 CDAI score is 150 or less, or HBI is 4 or less
or
 The patient has demonstrated an adequate response to treatment but CDAI score and/or HBI score cannot be assessed
and Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

I confirm the above details are correct and that in signing this form I understand I may be audited.

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Infliximab - *continued*

Initial application — Crohn's disease (children)

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Paediatric patient has active Crohn's disease			
and			
<table border="1"><tr><td><input type="checkbox"/> Patient has a PCDAI score of greater than or equal to 30</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> Patient has extensive small intestine disease</td></tr></table>	<input type="checkbox"/> Patient has a PCDAI score of greater than or equal to 30	or	<input type="checkbox"/> Patient has extensive small intestine disease
<input type="checkbox"/> Patient has a PCDAI score of greater than or equal to 30			
or			
<input type="checkbox"/> Patient has extensive small intestine disease			
and			
<input type="checkbox"/> Patient has tried but experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids			

Renewal — Crohn's disease (children)

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

<table border="1"><tr><td><input type="checkbox"/> PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> PCDAI score is 15 or less</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed</td></tr></table>	<input type="checkbox"/> PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab	or	<input type="checkbox"/> PCDAI score is 15 or less	or	<input type="checkbox"/> The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed
<input type="checkbox"/> PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab					
or					
<input type="checkbox"/> PCDAI score is 15 or less					
or					
<input type="checkbox"/> The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed					
and					
<input type="checkbox"/> Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019					

Initial application — Graft vs host disease

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites(tick box where appropriate)

<input type="checkbox"/> Patient has steroid-refractory acute graft vs. host disease of the gut

Initial application — Pulmonary sarcoidosis

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites(tick box where appropriate)

<input type="checkbox"/> Patient has life-threatening pulmonary sarcoidosis diagnosed by a multidisciplinary team that is refractory to other treatments
--

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Infliximab - *continued*

Initial application — acute fulminant ulcerative colitis

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks.

Prerequisites(tick boxes where appropriate)

Patient has acute, fulminant ulcerative colitis
and
 Treatment with intravenous or high dose oral corticosteroids has not been successful

Initial application — ankylosing spondylitis

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis
and
or
 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept
 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis

Renewal — ankylosing spondylitis

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Following 12 weeks of infliximab treatment, BASDAI has improved by 4 or more points from pre-infliximab baseline on a 10 point scale, or by 50%, whichever is less
and
 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate
and
 Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks

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Infliximab - *continued*

Initial application — chronic ocular inflammation

Applications from any relevant practitioner. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

and The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation
or The patient has experienced intolerable side effects from adalimumab
 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for chronic ocular inflammation

or Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss
and Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective
or Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose
or Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate

Renewal — chronic ocular inflammation

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

or The patient has had a good clinical response following 3 initial doses
or Following each 12 month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)
or Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

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Infliximab - *continued*

Initial application — fistulising Crohn's disease

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Patient has confirmed Crohn's disease
and
 Patient has one or more complex externally draining enterocutaneous fistula(e)
or
 Patient has one or more rectovaginal fistula(e)
or
 Patient has complex peri-anal fistula

Renewal — fistulising Crohn's disease

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

The number of open draining fistulae have decreased from baseline by at least 50%
or
 There has been a marked reduction in drainage of all fistula(e) from baseline (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain
and
 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

Initial application — neurosarcoidosis

Applications only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months.

Prerequisites(tick boxes where appropriate)

Patient has been diagnosed with neurosarcoidosis by a multidisciplinary team
and
 Patient has CNS involvement
and
 Patient has steroid-refractory disease
and
 IV cyclophosphamide has been tried
or
 Treatment with IV cyclophosphamide is clinically inappropriate

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Infliximab - *continued*

Renewal — neurosarcoidosis

Current approval Number (if known):.....

Applications only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> A withdrawal period has been tried and the patient has relapsed
or
<input type="checkbox"/> A withdrawal period has been considered but would not be clinically appropriate
and
<input type="checkbox"/> There has been a marked reduction in prednisone dose
and
<input type="checkbox"/> There has been an improvement in MRI appearances
or
<input type="checkbox"/> Marked improvement in other symptomology

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Infliximab - *continued*

Initial application — plaque psoriasis

Applications only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

The patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis

and

Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab

or

Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis

or

Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis

or

Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis

or

Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10

and

Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin

and

A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

The most recent PASI assessment is no more than 1 month old at the time of initiation

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand, foot, genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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Infliximab - *continued*

Renewal — plaque psoriasis

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

and Patient had "whole body" severe chronic plaque psoriasis at the start of treatment
 Following each prior infliximab treatment course the patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab treatment baseline value

or

and Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
 Following each prior infliximab treatment course the patient has a reduction in the PASI symptom subscores for all 3 of erythema, thickness and scaling, to slight or better, or sustained at this level, as compared to the treatment course baseline values
or Following each prior infliximab treatment course the patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab treatment baseline value

or

and Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment
 The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value
or Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab

and

Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

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Infliximab - *continued*

Initial application — previous use

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Patient was being treated with infliximab prior to 1 February 2019

and

- Rheumatoid arthritis
- or
- Ankylosing spondylitis
- or
- Psoriatic arthritis
- or
- Severe ocular inflammation
- or
- Chronic ocular inflammation
- or
- Crohn's disease (adults)
- or
- Crohn's disease (children)
- or
- Fistulising Crohn's disease
- or
- Severe fulminant ulcerative colitis
- or
- Severe ulcerative colitis
- or
- Plaque psoriasis
- or
- Neurosarcoidosis
- or
- Severe Behcet's disease

Initial application — psoriatic arthritis

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

and

The patient has had an initial Special Authority approval for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis

or

The patient has experienced intolerable side effects from adalimumab and/or etanercept and/or secukinumab

Following 3-4 months' initial treatment with adalimumab and/or etanercept and/or secukinumab, the patient did not meet the renewal criteria for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis

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Infliximab - *continued*

Renewal — psoriatic arthritis

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

and

<input type="checkbox"/> Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
or
<input type="checkbox"/> The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician

and

<input type="checkbox"/> Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

Initial application — rheumatoid arthritis

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

and

<input type="checkbox"/> The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis
or
<input type="checkbox"/> The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept
<input type="checkbox"/> Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept

and

<input type="checkbox"/> Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

Renewal — rheumatoid arthritis

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

and

<input type="checkbox"/> Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
or
<input type="checkbox"/> Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
<input type="checkbox"/> The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

and

<input type="checkbox"/> Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks

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Infliximab - *continued*

Initial application — severe Behcet's disease

Applications from any relevant practitioner. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes)			
and			
<table border="0"><tr><td><input type="checkbox"/> The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes)</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes)</td></tr></table>	<input type="checkbox"/> The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes)	or	<input type="checkbox"/> The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes)
<input type="checkbox"/> The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes)			
or			
<input type="checkbox"/> The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes)			
and			
<input type="checkbox"/> The patient is experiencing significant loss of quality of life			

Note: Behcet's disease diagnosed according to the International Study Group for Behcet's Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7.

Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.

Renewal — severe Behcet's disease

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient has had a good clinical response to initial treatment with measurably improved quality of life
and
<input type="checkbox"/> Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

Renewal — fulminant ulcerative colitis

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months
and
<input type="checkbox"/> Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

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Infliximab - *continued*

Initial application — severe ocular inflammation

Applications from any relevant practitioner. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

and The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation

or The patient has experienced intolerable side effects from adalimumab

or The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe ocular inflammation

or

and Patient has severe, vision-threatening ocular inflammation requiring rapid control

or Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms

or Patient developed new inflammatory symptoms while receiving high dose steroids

or Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms

Renewal — severe ocular inflammation

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

Prerequisites(tick boxes where appropriate)

or The patient has had a good clinical response following 3 initial doses

or Following each 12 month treatment period, the patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema)

or Following each 12 month treatment period, the patient has a sustained steroid sparing effect, allowing reduction in prednisone to < 10mg daily, or steroid drops less than twice daily if under 18 years old

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

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Infliximab - *continued*

Initial application — ulcerative colitis

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient has active ulcerative colitis			
and			
<table border="1"><tr><td><input type="checkbox"/> Patients SCCAI is greater than or equal to 4</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> Patients PUCAI score is greater than or equal to 20</td></tr></table>	<input type="checkbox"/> Patients SCCAI is greater than or equal to 4	or	<input type="checkbox"/> Patients PUCAI score is greater than or equal to 20
<input type="checkbox"/> Patients SCCAI is greater than or equal to 4			
or			
<input type="checkbox"/> Patients PUCAI score is greater than or equal to 20			
and			
<input type="checkbox"/> Patient has tried but has experienced an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids			

Renewal — ulcerative colitis

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

<table border="1"><tr><td><input type="checkbox"/> The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on infliximab</td></tr></table>	<input type="checkbox"/> The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab	or	<input type="checkbox"/> The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on infliximab
<input type="checkbox"/> The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab			
or			
<input type="checkbox"/> The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on infliximab			
and			
<input type="checkbox"/> Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019			

Initial application — pyoderma gangrenosum

Applications only from a dermatologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient has pyoderma gangrenosum*
and
<input type="checkbox"/> Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response
and
<input type="checkbox"/> A maximum of 8 doses

Note: Note: Indications marked with * are unapproved indications.

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
.....
Fax Number:	Fax Number:

Infliximab - *continued*

Renewal — pyoderma gangrenosum

Current approval Number (if known):.....

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

and Patient has shown clinical improvement
and Patient continues to require treatment
and A maximum of 8 doses

Initial application — inflammatory bowel arthritis – axial

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

and Patient has a diagnosis of active ulcerative colitis or active Crohn's disease
and Patient has had axial inflammatory pain for six months or more
and Patient is unable to take NSAIDs
and Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI
and Patient's disease has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist
and Patient has a BASDAI of at least 6 on a 0 - 10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment

Renewal — inflammatory bowel arthritis – axial

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick box where appropriate)

Treatment has resulted in an improvement in BASDAI of 4 or more points from pre-treatment baseline on a 10-point scale, or an improvement in BASDAI of 50%, whichever is less

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Signed: Date:

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APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
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Address:	DOB:	Address:
.....
Fax Number:	Fax Number:	

Infliximab - *continued*

Initial application — inflammatory bowel arthritis – peripheral

Applications from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Patient has a diagnosis of active ulcerative colitis or active Crohn's disease
and
 Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular
and
 Patient has tried and not experienced a response to at least three months of methotrexate or azathioprine at a maximum tolerated dose (unless contraindicated)
and
 Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated)
and
 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application
or
or
 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application
or
 ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

Renewal — inflammatory bowel arthritis – peripheral

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 2 years.

Prerequisites(tick boxes where appropriate)

Following initial treatment, patient has experienced at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
or
 Patient has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician

Initial application — immune checkpoint inhibitor toxicity in malignancy*

Applications from any relevant practitioner. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy
and
 The individual has received insufficient benefit from use of corticosteroids
and
 Infliximab is to be administered at up to 5mg/kg for up to four doses

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)	PATIENT NHI:	REFERRER Reg No:
Reg No:	First Names:	First Names:
Name:	Surname:	Surname:
Address:	DOB:	Address:
.....
Fax Number:	Fax Number:	

Infliximab - *continued*

Renewal — immune checkpoint inhibitor toxicity in malignancy*

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

The individual has shown clinical improvement and ongoing treatment is required
and
 Infliximab is to be administered at up to 5mg/kg for up to a total of 8 doses

Note: Indications marked with * are unapproved indications.

I confirm the above details are correct and that in signing this form I understand I may be audited.

Signed: Date:

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz