

SA2620 - Infliximab

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Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

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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)

Paediatric patient has active Crohn’s disease

and

Patient has a PCDAI score of greater than or equal to 30

or

Patient has extensive small intestine disease

and

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)

PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab

or

PCDAI score is 15 or less

or

The patient has demonstrated an adequate response to treatment but PCDAI 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

Initial application — Graft vs host disease

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

Prerequisites(tick box where appropriate)

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)

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)

<input type="checkbox"/> Patient has acute, fulminant ulcerative colitis and <input type="checkbox"/> Treatment with intravenous or high dose oral corticosteroids has not been successful

Initial application — ankylosing spondylitis

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

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient has had a Special Authority approval for adalimumab or etanercept for ankylosing spondylitis and <table border="1"> <tr> <td> <input type="checkbox"/> Patient has experienced intolerable side effects or <input type="checkbox"/> Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis </td> </tr> </table> and <input type="checkbox"/> Following initial induction doses, maximum dose 5mg/kg every 6-8 weeks	<input type="checkbox"/> Patient has experienced intolerable side effects or <input type="checkbox"/> Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis
<input type="checkbox"/> Patient has experienced intolerable side effects or <input type="checkbox"/> Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis	

Renewal — ankylosing spondylitis

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

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

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> BASDAI has improved from pre-treatment baseline either by at least 4 points on a 10-point scale, or by at least 50% and <input type="checkbox"/> Maximum dose 5 mg/kg every 6-8 weeks

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Infliximab - continued

Initial application — ocular inflammation - chronic*

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

Prerequisites(tick boxes where appropriate)

Patient has had a Special Authority approval for adalimumab for chronic ocular inflammation

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for chronic ocular inflammation

or

Patient has severe uveitis with a severe risk of vision loss uncontrolled by treatment with corticosteroids and other immunosuppressants

and

Patient is 18 years or older and treatment with at least two other immunomodulatory agents has been ineffective or are contraindicated

or

Patient is under 18 years and treatment with methotrexate has been ineffective, is contraindicated or is not tolerated at a therapeutic dose

or

Patient is under 8 years and treatment with corticosteroids or methotrexate has been ineffective, is contraindicated 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

Note: Indications marked with * are unapproved indications

Renewal — ocular inflammation - chronic*

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

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

Prerequisites(tick boxes where appropriate)

Patient has received a good clinical response following 3 initial doses

or

Following each 2 year treatment period, the patient has experienced 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 2 year treatment period, the patient has a sustained corticosteroid sparing effect, allowing reduction in prednisone to < 10mg daily, or corticosteroid 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. Indications marked with * are unapproved indications

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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)

A withdrawal period has been tried and the patient has relapsed

or

A withdrawal period has been considered but would not be clinically appropriate

and

There has been a marked reduction in prednisone dose

and

There has been an improvement in MRI appearances

or

Marked improvement in other symptomology

Initial application — plaque psoriasis

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

Prerequisites(tick boxes where appropriate)

Patient had a Special Authority approval for adalimumab, etanercept or secukinumab for plaque psoriasis

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for plaque psoriasis

or

Patient has "whole body" plaque psoriasis with a PASI score of greater than 10

or

Patient has plaque psoriasis of the face, or palm of a hand or sole of a foot

or

Patient has localised genital or flexural plaque psoriasis with a DLQI score greater than 10

and

Patient has received insufficient benefit (see Note) or has experienced intolerable side effects from at least 3 of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin

and

A PASI assessment has been completed for the most recent prior treatment course within 1 month of stopping that treatment

and

The most recent PASI assessment is within 1 month before the application

Note: "Insufficient benefit" is defined as: for whole body plaque psoriasis, a PASI score of greater than 10; for 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 2 years.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient had "whole body" plaque psoriasis at the start of treatment and <input type="checkbox"/> Patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab baseline
or
<input type="checkbox"/> Patient had plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment and <input type="checkbox"/> 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 pre-infliximab baseline or <input type="checkbox"/> Patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab baseline
or
<input type="checkbox"/> Patient had localised genital or flexural plaque psoriasis at the start of treatment and <input type="checkbox"/> 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 or <input type="checkbox"/> Patient has a DLQI improvement of 5 or more, as compared to the pre-infliximab baseline
and
<input type="checkbox"/> Maximum dose 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 — arthritis - psoriatic

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

Prerequisites(tick boxes where appropriate)

Patient has had a Special Authority approval for adalimumab or etanercept or secukinumab for psoriatic arthritis

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis

and

Following initial induction doses, maximum dose 5mg/kg every 8 weeks

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Infliximab - continued

Renewal — arthritis - psoriatic

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

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

Prerequisites(tick boxes where appropriate)

- Following initial treatment, at least a 50% decrease in active joint count from baseline
or
 At least a continuing 30% improvement in active joint count from baseline

- and
 Maximum dose 5 mg/kg every 8 weeks

Initial application — arthritis - rheumatoid

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

Prerequisites(tick boxes where appropriate)

- Patient has had a Special Authority approval for adalimumab or etanercept for rheumatoid arthritis
and
 Patient has experienced intolerable side effects
or
 Patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis

- and
 Following initial induction doses, maximum dose 3mg/kg every 8 weeks

Renewal — arthritis - rheumatoid

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

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

Prerequisites(tick boxes where appropriate)

- Following initial treatment, the patient has experienced at least a 50% decrease in active joint count from baseline
or
 Patient has experienced at least a continuing 30% improvement in active joint count from baseline

- and
 Maximum dose 3 mg/kg every 8 weeks

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Infliximab - continued

Initial application — Behcet disease

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

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	Patient has severe Behcet disease which is significantly impacting their quality of life
and	
<input type="checkbox"/>	Patient has severe ocular, neurological and/or vasculitic symptoms and has received insufficient benefit from 1 or more treatment(s) appropriate for the particular symptom(s)
or	
<input type="checkbox"/>	Patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has received insufficient benefit from 2 or more treatments appropriate for the particular symptom(s)
and	
<input type="checkbox"/>	Following initial loading doses, maximum dose 5mg/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 — ocular inflammation - severe*

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

Prerequisites(tick boxes where appropriate)

Patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for severe ocular inflammation

or

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

and

Treatment with high-dose IV corticosteroids followed by high dose oral corticosteroids has been ineffective at controlling symptoms

or

Patient developed new inflammatory symptoms while receiving high dose corticosteroids

or

Patient is aged under 8 years and treatment with high dose oral corticosteroids and other immunosuppressants has been ineffective at controlling symptoms

or

High dose corticosteroids are contraindicated

Note: Indications marked with * are unapproved indications.

Renewal — ocular inflammation - severe*

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

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

Prerequisites(tick boxes where appropriate)

Patient has received a good clinical response following 3 initial doses

or

Following each 2 year treatment period, the patient has experienced 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 2 year treatment period, patient has a sustained corticosteroid sparing effect, allowing reduction in prednisone to < 10mg daily, or corticosteroid 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. Indications marked with * are unapproved indications

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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)

Patient has active ulcerative colitis

and

Patients SCCAI is greater than or equal to 4

or

Patients PUCAI score is greater than or equal to 20

and

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)

The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab

or

The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiated on infliximab

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 — pyoderma gangrenosum*

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

Prerequisites(tick boxes where appropriate)

Patient has received insufficient benefit from 3 months of conventional therapy including a minimum of 3 pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate). Where conventional pharmaceuticals are contraindicated, a 3-month trial has occurred of those that are not contraindicated

and

Maximum of 8 doses every 4 months

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

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Infliximab - continued

Initial application — inflammatory bowel arthritis – axial

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 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

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 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

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Infliximab - *continued*

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)

or	<input type="checkbox"/> 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
	<input type="checkbox"/> 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)

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

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)

and	<input type="checkbox"/> The individual has shown clinical improvement and ongoing treatment is required
	<input type="checkbox"/> 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