SA2050 - Infliximab

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
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Infliximab

Initial application — Crohn's disease (adults)
Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months.
Prerequisites(tick boxes where appropriate)

☐ Patient has severe active Crohn's disease

and

☐ Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300

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 had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids

and

☐ Surgery (or further surgery) is considered to be clinically inappropriate

and

☐ Patient must be reassessed for continuation after 3 months of therapy

Renewal — Crohn's disease (adults)

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

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on infliximab

or

☐ CDAI score is 150 or less

or

☐ The patient has demonstrated an adequate response to treatment but CDAI 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

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Infliximab *- continued*

Initial application — Crohn's disease (children)
Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months.
Prerequisites(tick boxes where appropriate)

- ☐ Paediatric patient has severe active Crohn's disease

and

- ☐ Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30

or

- ☐ Patient has extensive small intestine disease

and

- ☐ Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids

and

- ☐ Surgery (or further surgery) is considered to be clinically inappropriate

and

- ☐ Patient must be reassessed for continuation after 3 months of therapy

Renewal — Crohn's disease (children)

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

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

- ☐ The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept

or

- ☐ 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)

- ☐ The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation

and

- ☐ 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 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)

- ☐ 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 only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 4 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)

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 6 months.
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 neurosarcoiosis 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

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Infliximab *- continued*

Initial application — plaque psoriasis
Applications only from a dermatologist or 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 or etanercept for severe chronic plaque psoriasis

and

☐ The patient has experienced intolerable side effects from adalimumab or etanercept

or

☐ The patient has received insufficient benefit from adalimumab or etanercept to meet the renewal criteria for adalimumab or etanercept 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

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 or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and 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 only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient had "whole body" severe chronic plaque psoriasis at the start of treatment
- **and**
- ☐ 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

- ☐ Patient had severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
- **and**
- ☐ 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

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)

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

and

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

or

☐ 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)

- ☐ 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

- ☐ 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

- ☐ 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)

- ☐ The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis

and

- ☐ The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept

or

- ☐ 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

- ☐ 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)

- ☐ Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- ☐ 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

- ☐ 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

- ☐ 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)

- ☐ The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes)

and

- ☐ 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

- ☐ 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

- ☐ 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)

- ☐ Patient has had a good clinical response to initial treatment with measurably improved quality of life

and

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

Renewal — severe fulminant ulcerative colitis

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

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

Prerequisites(tick boxes where appropriate)

- ☐ Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months

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

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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)

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

and

☐ 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

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

and

☐ 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)

☐ 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 only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has histologically confirmed ulcerative colitis

and

- ☐ Patient is 18 years or older and the Simple Clinical Colitis Activity Index (SCCAI) is greater than or equal to 4

or

- ☐ Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (PUCAI) score is greater than or equal to 65

and

- ☐ Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids

and

- ☐ Surgery (or further surgery) is considered to be clinically inappropriate

Renewal — ulcerative colitis

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

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks

and

- ☐ Patient is 18 years or older and the SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab

or

- ☐ Patient is under 18 years and the PUCAI score has reduced by 30 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 only from a dermatologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has pyoderma gangrenosum*

and

- ☐ 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

- ☐ 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 Ministry of Health, 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: .....
.....	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)

☐ Patient has shown clinical improvement
and
☐ Patient continues to require treatment
and
☐ A maximum of 8 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 Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz