SA2620 - Infliximab

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

- ☐ Patient has acute, fulminant ulcerative colitis

and

- ☐ 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)

- ☐ Patient has had a Special Authority approval for adalimumab or etanercept for ankylosing spondylitis

and

- ☐ Patient has experienced intolerable side effects

or

- ☐ Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis

and

- ☐ Following initial induction doses, maximum dose 5mg/kg every 6-8 weeks

Renewal — ankylosing spondylitis

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

Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- ☐ BASDAI has improved from pre-treatment baseline either by at least 4 points on a 10-point scale, or by at least 50%

and

- ☐ 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

- ☐ Patent 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 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

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)

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

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

- ☐ Patient had localised genital or flexural plaque psoriasis at the start of treatment
  - **and**
- ☐ 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**
- ☐ Patient has a DLQI improvement of 5 or more, as compared to the pre-infliximab baseline

and

- ☐ 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)

☐ Patient has severe Behcet disease which is significantly impacting their quality of life

and

☐ 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

☐ 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

☐ 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)

☐ 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 — 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)

- ☐ 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

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