

SA2178 - Adalimumab (Amgevita)

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Adalimumab (Amgevita)

Initial application — Behcet’s disease - severe

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

Prerequisites(tick boxes where appropriate)

The patient has severe Behcet’s disease* that is significantly impacting the patient’s quality of life

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)

or

The patient has severe gastrointestinal, rheumatological, and/or mucocutaneous symptoms and has not responded adequately to two or more treatments appropriate for the particular symptom(s)

Note: Indications marked with * are unapproved indications.

Initial application — Hidradenitis suppurativa

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

Prerequisites(tick boxes where appropriate)

Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas

and

Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or has demonstrated intolerance to or has contraindications for systemic antibiotics

and

Patient has 3 or more active lesions

and

The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application

Renewal — Hidradenitis suppurativa

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

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

Prerequisites(tick boxes where appropriate)

The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline

and

The patient has a DLQI improvement of 4 or more from baseline

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Adalimumab (Amgevita) - continued

Initial application — Plaque psoriasis - severe chronic

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

Prerequisites(tick boxes where appropriate)

Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis

and

Patient has experienced intolerable side effects

or

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

or

Patient has "whole body" severe chronic plaque psoriasis with a 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 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 or DLQI assessment has been completed for at least the most recent prior treatment course but no longer than 1 month following cessation of each prior treatment course and is no more than 1 month old at the time of application

Renewal — Plaque psoriasis - severe chronic

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

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

Prerequisites(tick boxes where appropriate)

Patient had "whole body" severe chronic plaque psoriasis at the start of treatment

and

The patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre treatment baseline value

or

The patient has a DLQI improvement of 5 or more, when compared with the pre-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

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

The patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre treatment baseline value

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Adalimumab (Amgevita) - continued

Initial application — pyoderma gangrenosum

Applications only from a dermatologist. Approvals valid without further renewal unless notified.

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, ciclosporin, azathioprine, or methotrexate) and has not received an adequate response

Note: Indications marked with * are unapproved indications.

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 had an inadequate response to, or has experienced 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 adalimumab

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

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Adalimumab (Amgevita) - 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 had an inadequate response to, or has experienced 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 adalimumab

or

PCDAI score is 15 or less

or

The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed

Initial application — Crohn’s disease - fistulising

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

and

A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application

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Adalimumab (Amgevita) - continued

Renewal — Crohn’s disease - fistulising

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

Applications from any relevant practitioner. 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 as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain

Initial application — Ocular inflammation - chronic

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 infliximab 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 — Ocular inflammation - chronic

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

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

Prerequisites(tick boxes where appropriate)

The patient has had a good clinical response following 12 weeks’ initial treatment

or

Following each 2 year 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 2 year 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

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Adalimumab (Amgevita) - 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 infliximab 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 — Ocular inflammation - severe

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

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

Prerequisites(tick boxes where appropriate)

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

or

Following each 2 year 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 2 year 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

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Adalimumab (Amgevita) - continued

Initial application — ankylosing spondylitis

Applications only from a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis

and

The patient has experienced intolerable side effects

or

The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis

or

Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months

and

Patient has low back pain and stiffness that is relieved by exercise but not by rest

and

Patient has bilateral sacroiliitis demonstrated by radiology imaging

and

Patient has not responded adequately to treatment with two or more NSAIDs, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis

and

Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following BASMI measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right)

or

Patient has limitation of chest expansion by at least 2.5 cm below the average normal values corrected for age and gender

and

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 and is no more than 1 month old at the time of application

Renewal — ankylosing spondylitis

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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Adalimumab (Amgevita) - continued

Initial application — Arthritis - oligoarticular course juvenile idiopathic
Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA)

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA

or

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

and

Patient has had oligoarticular course JIA for 6 months duration or longer

and

At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose)

Renewal — Arthritis - oligoarticular course juvenile idiopathic

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 at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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Adalimumab (Amgevita) - continued

Initial application — Arthritis - polyarticular course juvenile idiopathic
Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA)

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA

or

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

and

Patient has had polyarticular course JIA for 6 months duration or longer

and

At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate

Renewal — Arthritis - polyarticular course juvenile idiopathic

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 at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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Adalimumab (Amgevita) - continued

Initial application — Arthritis - psoriatic

Applications only from a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis and <input type="checkbox"/> The patient has experienced intolerable side effects or <input type="checkbox"/> The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis
or
<input type="checkbox"/> Patient has had active psoriatic arthritis for six months duration or longer and <input type="checkbox"/> Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated) and <input type="checkbox"/> Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated) and <input type="checkbox"/> Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints or <input type="checkbox"/> Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip and <input type="checkbox"/> Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application or <input type="checkbox"/> Patient has an ESR greater than 25 mm per hour or <input type="checkbox"/> 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 — Arthritis - psoriatic

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

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

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Following initial treatment, the patient has at least a 50% decrease in swollen joint count from baseline and a clinically significant response in the opinion of the physician or <input type="checkbox"/> Patient demonstrates at least a continuing 30% improvement in swollen joint count from baseline and a clinically significant response in the opinion of the treating physician
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Adalimumab (Amgevita) - continued

Initial application — Arthritis - rheumatoid

Applications only from a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis

and

The patient has experienced intolerable side effects

or

The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis

or

Patient has had rheumatoid arthritis (either confirmed by radiology imaging, or the patient is CCP antibody positive) for six months duration or longer

and

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

and

Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated)

and

Patient has tried and not responded to at least three months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate at maximum tolerated doses (unless contraindicated)

and

Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin

or

Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate

and

Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints

or

Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

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 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

On subsequent reapplications, 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

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Adalimumab (Amgevita) - continued

Initial application — Still's disease - adult-onset (AOSD)

Applications only from a rheumatologist. Approvals valid without further renewal unless notified.

Prerequisites(tick boxes where appropriate)

The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD

and

Patient has experienced intolerable side effects from etanercept and/or tocilizumab

or

Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab

or

Patient diagnosed with AOSD according to the Yamaguchi criteria

and

Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, NSAIDs and methotrexate

and

Patient has persistent symptoms of disabling poorly controlled and active disease

Initial application — ulcerative colitis

Applications from any relevant practitioner. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

Patient has active ulcerative colitis

and

Patient's SCCAI score is greater than or equal to 4

or

Patient's PUCAI score is greater than or equal to 20

and

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

and

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

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 biologic therapy

or

The PUCAI score has reduced by 10 points or more from the PUCAI score when the patient was initiation on biologic therapy

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Adalimumab (Amgevita) - continued

Initial application — undifferentiated spondyloarthritis

Applications only from a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

Patient has tried and not responded to at least three months of each of methotrexate, sulfasalazine and leflunomide, at maximum tolerated doses (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

Note: Indications marked with * are unapproved indications

Renewal — undifferentiated spondyloarthritis

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 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 in the opinion of the treating physician

Initial application — inflammatory bowel arthritis – axial

Applications only from a rheumatologist. 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 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 has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist

and

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

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Adalimumab (Amgevita) - continued

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 only from a rheumatologist. 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

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 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

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