SA2525 - Adalimumab (Amgevita)

Arthritis - oligoarticular course juvenile idiopathic - Initial application 9
Arthritis - oligoarticular course juvenile idiopathic - Renewal 9
Arthritis - polyarticular course juvenile idiopathic - Initial application 10
Arthritis - polyarticular course juvenile idiopathic - Renewal 10
Arthritis - psoriatic - Initial application 11
Arthritis - psoriatic - Renewal 11
Arthritis - rheumatoid - Initial application 12
Arthritis - rheumatoid - Renewal 12
Behcet's disease - severe - Initial application 2
Crohn's disease - adults - Initial application 5
Crohn's disease - adults - Renewal 5
Crohn's disease - children - Initial application 5
Crohn's disease - children - Renewal 6
Crohn's disease - fistulising - Initial application 6
Crohn's disease - fistulising - Renewal 6
Hidradenitis suppurativa - Initial application 2
Hidradenitis suppurativa - Renewal 2
Ocular inflammation - chronic - Initial application 7
Ocular inflammation - chronic - Renewal 7
Ocular inflammation - severe - Initial application 7
Ocular inflammation - severe - Renewal 8
Plaque psoriasis - severe chronic - Initial application 3
Plaque psoriasis - severe chronic - Renewal 4
Still's disease - adult-onset (AOSD) - Initial application 13
Ankylosing spondylitis - Initial application 8
Ankylosing spondylitis - Renewal 9
Inflammatory bowel arthritis – axial - Initial application 14
Inflammatory bowel arthritis – axial - Renewal 15
Inflammatory bowel arthritis – peripheral - Initial application 15
Inflammatory bowel arthritis – peripheral - Renewal 15
Pyoderma gangrenosum - Initial application 4
Ulcerative colitis - Initial application 13
Ulcerative colitis - Renewal 13
Undifferentiated spondyloarthritis - Initial application 14
Undifferentiated spondyloarthritis - Renewal 14

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: .....

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

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

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

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

Adalimumab (Amgevita) *- continued*

Initial application — Plaque psoriasis - severe chronic
Applications only from a dermatologist or any relevant practitioner on the recommendation of 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

or

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

and

☐ Patient has tried, but had an inadequate response 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

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

Signed: ..... Date: .....

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

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

Adalimumab (Amgevita) *- continued*

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

or

☐ Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment

and

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

or

☐ Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing adalimumab

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.

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

Signed: ..... Date: .....

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

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

Adalimumab (Amgevita) *- continued*

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

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

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

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

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

Adalimumab (Amgevita) *- continued*

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

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

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

Signed: ..... Date: .....

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

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

Adalimumab (Amgevita) *- continued*

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

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

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

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

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

Adalimumab (Amgevita) *- continued*

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

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

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

Signed: ..... Date: .....

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

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

Adalimumab (Amgevita) *- continued*

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

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

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

Signed: ..... Date: .....

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

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

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

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

Signed: ..... Date: .....

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

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

Adalimumab (Amgevita) *- continued*

Initial application — Arthritis - psoriatic
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 or secukinumab for psoriatic arthritis
- **and**
  - **or**
    - ☐ The patient has experienced intolerable side effects
    - ☐ The patient has received insufficient benefit from to meet the renewal criteria for psoriatic arthritis

or

- ☐ Patient has had active psoriatic arthritis for six months duration or longer
- **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 sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated)
- **and**
  - **or**
    - ☐ Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints
    - ☐ 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**
  - **or**
    - ☐ Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application
    - ☐ Patient has an ESR greater than 25 mm per hour
    - **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 — 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, 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**
- ☐ 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

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

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

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

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 (unless contraindicated)

or

☐ Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide (unless contraindicated) 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

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

Signed: ..... Date: .....

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

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

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

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

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

APPLICANT (stamp or sticker acceptable)

Reg No: .....

Name: .....

Address: .....

.....

.....

Fax Number: .....

PATIENT NHI: .....

First Names: .....

Surname: .....

DOB: .....

Address: .....

.....

.....

REFERRER Reg No: .....

First Names: .....

Surname: .....

Address: .....

.....

.....

Fax Number: .....

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

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

Signed: ..... Date: .....

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

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

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