

SA2178 - 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 | 4 |
| Crohn's disease - adults - Renewal | 4 |
| Crohn's disease - children - Initial application | 5 |
| Crohn's disease - children - Renewal | 5 |
| Crohn's disease - fistulising - Initial application | 5 |
| Crohn's disease - fistulising - Renewal | 6 |
| Hidradenitis suppurativa - Initial application | 2 |
| Hidradenitis suppurativa - Renewal | 2 |
| Ocular inflammation - chronic - Initial application | 6 |
| Ocular inflammation - chronic - Renewal | 6 |
| Ocular inflammation - severe - Initial application | 7 |
| Ocular inflammation - severe - Renewal | 7 |
| Plaque psoriasis - severe chronic - Initial application | 3 |
| Plaque psoriasis - severe chronic - Renewal | 3 |
| Still's disease - adult-onset (AOSD) - Initial application | 13 |
| Ankylosing spondylitis - Initial application | 8 |
| Ankylosing spondylitis - Renewal | 8 |
| 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 Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

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

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

Signed: Date:

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

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

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

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

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

Signed: Date:

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

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

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

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

Signed: Date:

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

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

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

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

Signed: Date:

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

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

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

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

Signed: Date:

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

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

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

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

Signed: Date:

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

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

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

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

Signed: Date:

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

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

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 Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

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

☐ The patient has experienced intolerable side effects

or

☐ 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

☐ 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

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

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 Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

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

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

Signed: Date:

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

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

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 Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

.....

Fax Number: Fax Number:

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 Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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

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