RS2140 - Adalimumab (Amgevita)

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita)

INITIATION – Behcet's disease - severe

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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.

INITIATION – Hidradenitis suppurativa

Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 patient 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

CONTINUATION – Hidradenitis suppurativa

Re-assessment required after 2 years

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Plaque psoriasis - severe chronic
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ 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 that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

CONTINUATION – Plaque psoriasis - severe chronic
Re-assessment required after 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 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 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 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

INITIATION – pyoderma gangrenosum
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 not received an adequate response

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Crohn's disease - adults
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has severe 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

CONTINUATION – Crohn's disease - adults
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced 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

INITIATION – Crohn's disease - children
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

CONTINUATION – Crohn's disease - children
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

INITIATION – Crohn's disease - fistulising
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION – Crohn's disease - fistulising
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Ocular inflammation - chronic
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION – Ocular inflammation - chronic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Ocular inflammation - severe
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION – Ocular inflammation - severe
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – ankylosing spondylitis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION – ankylosing spondylitis
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ For applications where 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 that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Arthritis - oligoarticular course juvenile idiopathic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ 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)

CONTINUATION – Arthritis - oligoarticular course juvenile idiopathic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ 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 that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Arthritis - polyarticular course juvenile idiopathic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ 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

CONTINUATION – Arthritis - polyarticular course juvenile idiopathic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ 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 that the above details are correct:

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Arthritis - psoriatic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis

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 CRP level greater than 15 mg/L measured no more than one month prior to the date of this application

or

- ○ Patient has an elevated 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

CONTINUATION – Arthritis - psoriatic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Arthritis - rheumatoid
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 cyclic citrullinated peptide (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 leflunomid (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

CONTINUATION – Arthritis - rheumatoid
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – Still's disease - adult-onset (AOSD)

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

INITIATION – ulcerative colitis

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION – ulcerative colitis

Re-assessment required after 2 years

Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 initiated on biologic therapy

I confirm that the above details are correct:

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

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

INITIATION – undifferentiated spondyloarthiritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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, sulphasalazine 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.

CONTINUATION – undifferentiated spondyloarthiritis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

INITIATION – inflammatory bowel arthritis – axial
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

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

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Adalimumab (Amgevita) *- continued*

CONTINUATION – inflammatory bowel arthritis – axial
Re-assessment required after 2 years
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ Where 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

INITIATION – inflammatory bowel arthritis – peripheral
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 sulphasalazine 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

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

CONTINUATION – inflammatory bowel arthritis – peripheral
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

- ○ Patient demonstrates at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician

I confirm that the above details are correct:

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