Amgevita access criteria

From 1 March 2022, access to Amgevita will be subject to Special Authority criteria, and hospital restrictions. These criteria include widened access to the following indications:

- Ulcerative colitis first line
- Undifferentiated spondyloarthritis
- Inflammatory bowel disease-associated arthritis
- Crohn's disease dose escalation
- Rheumatoid arthritis; reduction in the number of swollen joints required for access to treatment, and removal of the requirement for CRP to be greater than 15 mg/L*
- Behçet's disease; access to funded treatment with Amgevita as a first line biologic
- Ocular inflammation; access to funded treatment with Amgevita as a first line biologic

Amgevita Special Authority will also include the following changes to improve access to treatment for all indications:

- Removal of dosing restrictions
- Extension of Special Authority renewal periods to 2 years*
- Ability for any relevant practitioner to apply for Special Authority renewals*
- Removal of the requirement for Special Authority renewal applications for some conditions

These access widenings are specific to the Amgevita brand of adalimumab.

*Note the criteria for access to etanercept for rheumatoid arthritis will also be widened to align with Amgevita.

To claim a subsidy, the correct brand will need to be prescribed and dispensed for each patient. Special Authority approvals will not be interchangeable between the Amgevita and Humira brands of adalimumab.

Follow the below links to Special Authority categorised for the different uses of adalimumab. Similar criteria would apply in hospital (Part II of Section H).

- Dermatology
- Gastrointestinal
- Ophthalmology
- Rheumatology

Dermatology

Behçet's disease – severe

ADALIMUMAB (AMGEVITA)
Initial application — (Behcet's disease - severe) from any relevant practitioner.
Approvals valid without further renewal unless notified for applications meeting the following criteria:
Both:
1. The patient has severe Behcet's disease* that is significantly impacting the patient's quality of life; and
2. Either:
   - 2.1 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
   - 2.2 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.

Hidradenitis suppurativa

ADALIMUMAB (AMGEVITA)
Initial application — (Hidradenitis suppurativa) only from a dermatologist.
Approvals valid for 4 months for applications meeting the following criteria:
All of the following:
1. Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas; and
2. 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
3. Patient has 3 or more active lesions; and
4. The patient has a DLQI of 10 or more and the assessment is no more than 1 month old at time of application.

ADALIMUMAB (AMGEVITA)
Renewal — (Hidradenitis suppurativa) from any relevant practitioner
Approvals valid for 2 years for applications meeting the following criteria:
All of the following:
1. The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline; and
2. The patient has a DLQI improvement of 4 or more from baseline.

Plaque psoriasis – severe chronic

ADALIMUMAB (AMGEVITA)
Initial application — (Plaque psoriasis - severe chronic) only from a dermatologist.
Approvals valid for 4 months for applications meeting the following criteria:
Either:
1. Both:
   - 1.1 Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
   - 1.2 Either:
     - 1.2.1 Patient has experienced intolerable side effects; or
     - 1.2.2 Patient has received insufficient benefit to meet the renewal criteria for etanercept for severe chronic plaque psoriasis; or
2. All of the following:
   - 2.1 Either:
     - 2.1.1 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
     - 2.1.2 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

2.2 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
2.3 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.

ADALIMUMAB (AMGEVITA)
Renewal — (Plaque psoriasis - severe chronic) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. Both:
   1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
   1.2 Either:
      1.2.1 The patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-adalimumab treatment baseline value; or
      1.2.2 The patient has a DLQI improvement of 5 or more, when compared with the pre-treatment baseline value; or
2. Both:
   2.1 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
   2.2 Either:
      2.2.1 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
      2.2.2 The patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-adalimumab treatment baseline value.

Pyoderma gangrenosum

ADALIMUMAB (AMGEVITA)
Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid without renewal unless notified for applications meeting the following criteria:
Both:
1. Patient has pyoderma gangrenosum*; and
2. 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.

Gastrointestinal

Crohn’s disease – adults

ADALIMUMAB (AMGEVITA)
Initial application — (Crohn's disease - adults) only from a gastroenterologist.
Approvals valid for 3 months for applications meeting the following criteria:
All of the following:
1. Patient has active Crohn's disease; and
2. Any of the following:
   2.1 Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10; or
   2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
   2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
   2.4 Patient has an ileostomy or colostomy and has intestinal inflammation; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

ADALIMUMAB (AMGEVITA)
Renewal — (Crohn's disease - adults) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. 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
2. CDAI score is 150 or less, or HBI is 4 or less; or
3. The patient has demonstrated an adequate response to treatment, but CDAI score and/or HBI score cannot be assessed.

Crohn’s disease – children

ADALIMUMAB (AMGEVITA)
Initial application — (Crohn's disease - children) only from a gastroenterologist.
Approvals valid for 3 months for applications meeting the following criteria:
All of the following:
1. Paediatric patient has active Crohn's disease; and
2. Either:
   2.1 Patient has a PCDAI score of greater than or equal to 30; or
   2.2 Patient has extensive small intestine disease; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

ADALIMUMAB (AMGEVITA)
Renewal — (Crohn's disease - children) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
2. PCDAI score is 15 or less; or
3. The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.

Crohn’s disease – fistulising

ADALIMUMAB (AMGEVITA)
Initial application — (Crohn’s disease - fistulising) only from a gastroenterologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has confirmed Crohn’s disease; and
2. Any of the following:
   2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
   2.2 Patient has one or more rectovaginal fistula(e); or
   2.3 Patient has complex peri-anal fistula; and
3. A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application.

ADALIMUMAB (AMGEVITA)
Renewal — (Crohn's disease - fistulising) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. The number of open draining fistulae have decreased from baseline by at least 50%; or
2. 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.

Ulcerative colitis

ADALIMUMAB (AMGEVITA)
Initial application – (ulcerative colitis) only from a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:
All of the following:
1. Patient has histologically confirmed active ulcerative colitis; and
2. Either:
   2.1 Patient's SCCAI score is greater than or equal to 4; or
   2.2 Patient's PUCAI score is greater than or equal to 65; and
3. Patient has tried but had an inadequate response to, or has experienced intolerable side effects from prior therapy with immunomodulators and systemic corticosteroids; and
4. Surgery (or further surgery) is considered to be clinically inappropriate.

ADALIMUMAB (AMGEVITA)
Renewal – (ulcerative colitis) from any relevant Practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. The SCCAI score has reduced by 2 points or more from the SCCAI score since initiation on adalimumab; or
2. The PUCAI score has reduced by 30 points or more from the PUCAI score since initiation on adalimumab.

Ophthalmology

Ocular inflammation – chronic

ADALIMUMAB (AMGEVITA)
Initial application — (Ocular inflammation - chronic) from any relevant practitioner.
Approvals valid for 4 months for applications meeting the following criteria:
Either:
1. Patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; or
2. Both:
   2.1 Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss; and
   2.2 Any of the following:
      2.2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
      2.2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or
      2.2.3 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.

ADALIMUMAB (AMGEVITA)
Renewal — (Ocular inflammation - chronic) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. The patient has had a good clinical response following 12 weeks' initial treatment; or
2. 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
3. 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.

Ocular inflammation – severe

ADALIMUMAB (AMGEVITA)
Initial application — (Ocular inflammation - severe) from any relevant practitioner.
Approvals valid for 4 months for applications meeting the following criteria:
Either:
1. Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; or
2. Both:
   2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
   2.2 Any of the following:
      2.2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
      2.2.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
      2.2.3 Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms.

ADALIMUMAB (AMGEVITA)
Renewal — (Ocular inflammation - severe) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Any of the following:
1. The patient has had a good clinical response following 3 initial doses; or
2. 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
3. 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.

Rheumatology

Ankylosing spondylitis

ADALIMUMAB (AMGEVITA)
Initial application — (ankylosing spondylitis) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects; or
      1.2.2 The patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis; or
2. All of the following:
   2.1 Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months; and
   2.2 Patient has low back pain and stiffness that is relieved by exercise but not by rest; and
   2.3 Patient has bilateral sacroiliitis demonstrated by radiology imaging; and
   2.4 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
   2.5 Either:
      2.5.1 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
      2.5.2 Patient has limitation of chest expansion by at least 2.5 cm below the following average normal values corrected for age and gender; and
3. 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.

ADALIMUMAB (AMGEVITA)
Renewal — (ankylosing spondylitis) from any relevant practitioner.
Approvals valid for 2 years 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.

Arthritis – oligoarticular course juvenile idiopathic

ADALIMUMAB (AMGEVITA)
Initial application — (Arthritis - oligoarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
   1.1 The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA); and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA; or
2. All of the following:
   2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
   2.2 Patient has had oligoarticular course JIA for 6 months duration or longer; and
   2.3 Either:
      2.3.1 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
      2.3.2 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).

ADALIMUMAB (AMGEVITA)
Renewal — (Arthritis - oligoarticular course juvenile idiopathic) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:

Either:
1. 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
2. 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.

Arthritis – polyarticular course juvenile idiopathic

ADALIMUMAB (AMGEVITA)
Initial application — (Arthritis - polyarticular course juvenile idiopathic) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA; or
2. All of the following:
   2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
   2.2 Patient has had polyarticular course JIA for 6 months duration or longer; and
   2.3 Any of the following:
      2.3.1 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
      2.3.2 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
      2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate.

ADALIMUMAB (AMGEVITA)
Renewal — (Arthritis - polyarticular course juvenile idiopathic) from any relevant practitioner. Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. 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
2. 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.

Arthritis – psoriatic

ADALIMUMAB (AMGEVITA)
Initial application — (Arthritis - psoriatic) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Either:
1. Both:
   1.1 Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
   1.2 Either:
      1.2.1 Patient has experienced intolerable side effects; or
      1.2.2 Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis; or
2. All of the following:
   2.1 Patient has had active psoriatic arthritis for six months duration or longer; and
   2.2 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
   2.3 Patient has tried and not responded to at least three months of sulfasalazine or leflunomide at maximum tolerated doses (unless contraindicated); and
   2.4 Either:
      2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or

2.4.2 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

2.5 Any of the following:

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

2.5.2 Patient has an ESR greater than 25 mm per hour; or

2.5.3 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.

ADALIMUMAB (AMGEVITA)
Renewal — (Arthritis - psoriatic) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:

1. 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
2. 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.

Arthritis – rheumatoid

ADALIMUMAB (AMGEVITA)
Initial application — (Arthritis - rheumatoid) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Either:

1. Both:
   1.1 The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects; or
      1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for rheumatoid arthritis; or
2. All of the following:
   2.1 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
   2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
   2.3 Patient has tried and not responded to at least three months of methotrexate at a maximum tolerated dose (unless contraindicated); and
   2.4 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
   2.5 Either:
      2.5.1 Patient has tried and not responded to at least three months of methotrexate in combination with the maximum tolerated dose of ciclosporin; or
      2.5.2 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
   2.6 Either:
      2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen joints; or
      2.6.2 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.

ADALIMUMAB (AMGEVITA)
Renewal — (Arthritis - rheumatoid) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:

1. 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
2. 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.

Inflammatory bowel arthritis – axial

ADALIMUMAB (AMGEVITA)
Initial application — (inflammatory bowel arthritis – axial) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2. Patient has axial inflammatory pain for six months or more; and
3. Patient is unable to take NSAIDs; and
4. Patient has bilateral sacroiliitis demonstrated by radiological imaging; and
5. Patient has not responded adequately to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist; and
6. 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.

ADALIMUMAB (AMGEVITA)
Renewal — (inflammatory bowel arthritis – axial) from any relevant practitioner
Approvals valid for 2 years 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.

Inflammatory bowel arthritis – peripheral

ADALIMUMAB (AMGEVITA)
Initial application — (inflammatory bowel arthritis – peripheral) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Patient has a diagnosis of active ulcerative colitis or active Crohn's disease; and
2. Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular; and
3. Patient has tried and not responded to at least three months of methotrexate or azathioprine at a maximum tolerated dose; and
4. Patient has tried and not responded to at least three months of sulfasalazine at a maximum tolerated dose; and
5. Any of the following:
   5.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
   5.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
   5.3 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.

ADALIMUMAB (AMGEVITA)
Renewal — (inflammatory bowel arthritis – peripheral) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. 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
2. Patient demonstrates at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician.

Stills disease – adult onset

ADALIMUMAB (AMGEVITA)
Initial application — (Still's disease - adult-onset (AOSD)) only from a rheumatologist.
Approvals valid without renewal unless notified for applications meeting the following criteria:
Either:
1. Both:
   1.1 The patient has had an initial Special Authority approval for etanercept and/or tocilizumab for AOSD; and
   1.2 Either:

1.2.1 Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
1.2.2 Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab; or

2. All of the following:
   2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria; and
   2.2 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
   2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

Undifferentiated spondyloarthritis

ADALIMUMAB (AMGEVITA)
Initial application — (undifferentiated spondyloarthritis) only from a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. 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
2. 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
3. Any of the following:
   3.1 Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application; or
   3.2 Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application; or
   3.3 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

ADALIMUMAB (AMGEVITA)
Renewal — (undifferentiated spondyloarthritis) from any relevant practitioner.
Approvals valid for 2 years for applications meeting the following criteria:
Either:
1. 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
2. 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.

The access criteria for etanercept in Section B and Part II of Section H of the Pharmaceutical Schedule would also change from 1 March 2022 (additions in bold, deletions in strikethrough):

ETANERCEPT
Initial application — (~~rheumatoid~~ aArthritis - rheumatoid) only from a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Either:
3. Both:
   1.1 The patient has had an initial Special Authority approval for adalimumab for rheumatoid arthritis; and
   1.2 Either:
      1.2.1 The patient has experienced intolerable side effects ~~from adalimumab~~; or
      1.2.2 The patient has received insufficient benefit ~~from adalimumab~~ to meet the renewal criteria for adalimumab for rheumatoid arthritis; or
4. All of the following:
   2.1 Patient has had ~~severe and active erosive~~ rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer; and
   2.2 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
   2.3 Patient has tried and not responded to at least three months of ~~oral or parenteral~~ methotrexate at ~~a dose of at least 20 mg weekly or~~ a maximum tolerated dose **(unless contraindicated)**; and

2.4 Patient has tried and not responded to at least three months of ~~oral or parenteral~~ methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses **unless contraindicated**); and

2.5 ~~Any of the following~~ **Either**:

2.5.1 Patient has tried and not responded to at least three months of ~~oral or parenteral~~ methotrexate in combination with the maximum tolerated dose of ciclosporin; or

~~Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or~~

2.5.2 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 ~~oral or parenteral~~ methotrexate; and

2.6 Either:

2.6.1 Patient has persistent symptoms of poorly controlled and active disease in at least ~~20~~ **15** swollen~~, tender~~ joints; or

2.6.2 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~~

~~2.7 Either:~~

~~2.7.1 Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application; or~~

~~2.7.2 C-reactive protein levels 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.~~

ETANERCEPT

Renewal — (~~rheumatoid a~~Arthritis - rheumatoid) from any relevant practitioner ~~only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.~~

Approvals valid for **2 years** ~~6 months~~ for applications meeting the following criteria:

All of the following:

~~1 Either:~~

~~1.1 Applicant is a rheumatologist; or~~

~~1.2 Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and~~

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

2.8 Either:

2.1 Following 3 to 4 months' 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

2.2 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; and

3. Etanercept to be administered at doses no greater than 50 mg every 7 days.