Amended Special Authority criteria

We are proposing changes to the adalimumab (Amgevita) Special Authority criteria for currently funded indications to improve access to adalimumab treatment.

- Special Authority renewal periods would be extended from 6 months to 2 years
- Special Authority renewals could be applied for by any relevant practitioner, and in some cases are not required
- There would be no dosing restrictions for people using Amgevita

These changes would be made to the current access criteria for patients from 1 February 2022. They would be specific to the Amgevita brand of adalimumab.

To dispense and claim a subsidy, the correct brand would need to be prescribed for each patient. Special Authority approvals would not be interchangeable.

Note, where adalimumab criteria are interchangeable with other biologic treatments (such as etanercept or infliximab), Pharmac would assess changes to these following a decision on adalimumab to ensure ongoing alignment of access criteria (excluding changes to Rheumatoid Arthritis detailed above).

The proposed changes are detailed below (additions in **red**, deletions in ~~strikethrough~~ for respective categories (links)

- Dermatology
- Gastrointestinal
- Ophthalmology
- Rheumatology

Dermatology

Behçet's disease – severe

ADALIMUMAB (AMGEVITA)
Initial application — (~~severe~~ Behcet's disease - severe) from any relevant practitioner.
Approvals valid **without further renewal unless notified** for ~~3 months for~~ applications meeting the following criteria:
Both ~~All of the following~~:

1. The patient has severe Behcet's disease***** that is significantly impacting the patient's quality of life ~~(see Notes)~~; and
2. Either:
   - 2.1 The patient has severe ocular, neurological, ~~gastrointestinal, rheumatological, mucocutaneous~~ and/or vasculitic symptoms and has not responded adequately to **one or more treatment(s) appropriate for the particular symptom(s)** ~~treatment with infliximab (see Notes); or~~
   - 2.2 The patient has severe ~~ocular, neurological,~~ gastrointestinal, rheumatological **and/or** mucocutaneous ~~and/or vasculitic~~ symptoms and has **not responded adequately to two or more treatments appropriate for the particular symptom(s)** ~~experienced intolerable side effects from treatment with infliximab; and~~

~~3. The patient is experiencing significant loss of quality of life; and~~
~~4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Note: Behcet's disease diagnosed according to the International Study Group for Behcet's disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al, J Rheumatol. 2004;31:931-7.~~

Note: Indications marked with * are unapproved indications.

~~**Renewal — (severe Behcet's disease)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:~~
~~Both:~~
~~1. Patient has had a good clinical response to initial treatment with measurably improved quality of life.~~
~~2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

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. ~~The~~ Patient has 3 or more active lesions (~~e.g. inflammatory nodules, abscesses, draining fistulae~~); and
4. The patient has a **DLQI** ~~Dermatology Quality of Life Index~~ of 10 or more and the assessment is no more than 1 month old at time of application~~; and~~
5. ~~Following the initial loading doses, adalimumab is to be administered at doses no greater than 40mg every 7 days.~~

ADALIMUMAB (AMGEVITA)
Renewal — (Hidradenitis suppurativa) from any relevant practitioner ~~only from a dermatologist or Practitioner on the recommendation of a dermatologist.~~
Approvals valid for **2 years** ~~6 months~~ 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** ~~Dermatology Quality of Life Index~~ improvement of 4 or more from baseline.
~~3. Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.~~

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 ~~The~~ Patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis; and
   1.2 Either:
      1.2.1 ~~The~~ Patient has experienced intolerable side effects ~~from etanercept~~; or
      1.2.2 ~~The~~ Patient has received insufficient benefit ~~from etanercept~~ 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 ~~Psoriasis Area and Severity Index~~ ~~(~~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 ~~(see Note)~~ 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 ~~Dermatology Quality of Life Index (~~DLQI~~)~~ assessment has been completed for at least the most recent prior treatment course ~~(but preferably all prior treatment courses), preferably while still on treatment~~ 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.** ~~; and~~
   ~~2.4 The most recent PASI or DLQI assessment is no more than 1 month old at the time of application.~~

~~Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.~~

ADALIMUMAB (AMGEVITA)
Renewal — (Plaque psoriasis - severe chronic) from any relevant practitioner ~~only from a dermatologist or Practitioner on the recommendation of a dermatologist.~~
Approvals valid for **2 years** ~~6 months~~ for applications meeting the following criteria:
All of the following:
~~1. Either~~
~~Applicant is a dermatologist; or~~
~~Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and~~
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 ~~Following each prior adalimumab treatment course~~ 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 ~~Following each prior adalimumab treatment course~~ The patient has a Dermatology Quality of Life Index (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 ~~Following each prior adalimumab treatment course~~ 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 ~~Following each prior adalimumab treatment course~~ he 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.

~~2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Note: A treatment course is defined as a minimum of 12 weeks adalimumab treatment~~

Pyoderma gangrenosum

ADALIMUMAB (AMGEVITA)
Initial application — (pyoderma gangrenosum) only from a dermatologist. Approvals valid **without renewal** ~~for 4 months~~ for applications meeting the following criteria:
~~All of the following:~~ **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.

~~3. A maximum of 8 doses.~~

Note: Indications marked with * are unapproved indications.

~~**Renewal — (pyoderma gangrenosum)** only from a dermatologist or Practitioner on the recommendation of a dermatologist.~~
~~Approvals valid for 4 months for applications meeting the following criteria:~~
~~All of the following:~~

~~1. Patient has shown clinical improvement; and~~
~~2. Patient continues to require treatment; and~~
~~3. A maximum of 8 doses.~~

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 severe active Crohn's disease; and
2. Any of the following:
   2.1 Patient has a ~~Crohn's Disease Activity Index~~ CDAI score of greater than or equal to 300; 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 ~~systemic~~ therapy with immunomodulators ~~at maximum tolerated doses (unless contraindicated)~~ 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** ~~only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.~~ Approvals valid for **2 years** ~~6 months~~ for applications **where** ~~meeting the following criteria~~:
~~All of the following~~ ~~**Both**~~:
~~1. Either:~~
~~1.1 Applicant is a gastroenterologist; or~~
~~1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and~~
Any of the following:
1. CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
2. CDAI score is 150 or less; or
~~2. Both:~~
3. The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed.~~; and~~
~~3.1.1 Applicant to indicate the reason that CDAI score cannot be assessed; and~~
~~4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

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 severe active Crohn's disease; and
2. Either:
   2.1 Patient has a ~~Paediatric Crohn's Disease Activity Index~~ (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 ~~systemic~~ therapy with immunomodulators ~~at maximum tolerated doses (unless contraindicated)~~ 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 ~~only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.~~
Approvals valid for **2 years** ~~6 months~~ for applications **where:** ~~meeting the following criteria~~:
~~All of the following:~~
~~Either:~~
~~1.1 Applicant is a gastroenterologist; or~~
~~1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and~~
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.
~~1.2.1 Applicant to indicate the reason that PCDAI score cannot be assessed; and~~
~~1.3 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

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. ~~Either~~ **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); ~~and~~ **or**
   2.3 **Patient has complex peri-anal fistula**
3. A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application~~; and~~
~~4. The patient will be assessed for response to treatment after 4 months' adalimumab treatment (see Note).~~

~~Note: A maximum of 4 months' adalimumab will be subsidised on an initial Special Authority approval for fistulising Crohn's disease.~~

ADALIMUMAB (AMGEVITA)
Renewal — (Crohn's disease - fistulising) from any relevant practitioner ~~only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist.~~
Approvals valid for **2 years** ~~6 months~~ for applications **where** ~~meeting the following criteria~~:
~~All of the following:~~
~~1. Either:~~
~~1.1 Applicant is a gastroenterologist; or~~
~~1.2 Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment; and~~
1. Either:
   1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
   1.2 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.

Ophthalmology

Ocular inflammation – chronic

ADALIMUMAB (AMGEVITA)
Initial application — (~~chronic~~ Ocular inflammation - chronic) from any relevant practitioner.
Approvals valid for 4 months for applications meeting the following criteria:

1. Either:
   ~~Both:~~
   ~~The~~ Patient has had an initial Special Authority approval for infliximab for chronic ocular inflammation; **or** ~~and~~
   ~~Either:~~
   ~~The patient has experienced intolerable side effects from infliximab; or~~
   ~~The patient has received insufficient benefit from infliximab to meet the renewal criteria 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 — (~~chronic~~ Ocular inflammation - chronic) from any relevant practitioner.
Approvals valid for **2 years** ~~12 months~~ for applications meeting the following criteria:
~~Both:~~
Any of the following:

1. The patient has had a good clinical response following 12 weeks' initial treatment; or
2. Following each **2 year** ~~12-month~~ 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** ~~12-month~~ 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. ~~and~~

~~1. Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Note: A trial withdrawal should be considered after every 24 months of stability, unless the~~

Ocular inflammation – severe

ADALIMUMAB (AMGEVITA)
Initial application — (~~severe~~ Ocular inflammation - severe) from any relevant practitioner.
Approvals valid for 4 months for applications meeting the following criteria:
Either:
~~Both:~~

1. ~~The~~ Patient has had an initial Special Authority approval for infliximab for severe ocular inflammation; ~~and~~ **or**
   ~~Either:~~
   ~~The patient has experienced intolerable side effects from infliximab; or~~
   ~~The patient has received insufficient benefit from infliximab to meet the renewal criteria for infliximab for severe ocular inflammation; or~~
2. Both:
   2.1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and

3. Any of the following:
   3.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
   3.2 Patient developed new inflammatory symptoms while receiving high dose steroids; or
   3.3 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 — (~~severe~~ Ocular inflammation - severe) from any relevant practitioner.
Approvals valid for **2 years** ~~12 months~~ for applications meeting the following criteria:
~~Both:~~
Any of the following:
1. The patient has had a good clinical response following 3 initial doses; or
2. Following each **2 year** ~~12-month~~ 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** ~~12-month~~ 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.

~~2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

~~Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if adalimumab is withdrawn.~~

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 ~~The~~ 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 ~~from etanercept~~; or
      1.2.2 The patient has received insufficient benefit ~~from etanercept~~ to meet the renewal criteria ~~for etanercept~~ 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** ~~plain radiographs, CT or MRI scan;~~ and
   2.4 Patient's ~~ankylosing spondylitis~~ has not responded adequately to treatment with two or more ~~non-steroidal anti-inflammatory drugs (~~NSAIDs~~)~~, ~~in combination with anti-ulcer therapy if indicated~~, 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 ~~Bath Ankylosing Spondylitis Metrology Index (~~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 ~~(see Notes)~~; and
   2.6 A ~~Bath Ankylosing Spondylitis Disease Activity Index~~ (BASDAI~~)~~ of at least 6 on a 0-10 scale.

Notes: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment **and** ~~The BASDAI measure~~ must be no more than 1 month old at the time of initial application.
~~Average normal chest expansion corrected for age and gender:~~
~~18-24 years - Male: 7.0 cm; Female: 5.5 cm~~
~~25-34 years - Male: 7.5 cm; Female: 5.5 cm~~
~~35-44 years - Male: 6.5 cm; Female: 4.5 cm~~
~~45-54 years - Male: 6.0 cm; Female: 5.0 cm~~
~~55-64 years - Male: 5.5 cm; Female: 4.0 cm~~
~~65-74 years - Male: 4.0 cm; Female: 4.0 cm~~
~~75+ years - Male: 3.0 cm; Female: 2.5 cm~~

ADALIMUMAB (AMGEVITA)
Renewal — (ankylosing spondylitis) 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 **where** ~~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~~
1. ~~Following 12 weeks' initial treatment and for subsequent renewals,~~ 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.~~; and~~
~~3 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and~~

~~4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

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 ~~The~~ Patient has experienced intolerable side effects ~~from etanercept~~; or
      1.2.2 ~~The~~ Patient has received insufficient benefit from etanercept to meet the renewal criteria ~~for etanercept~~ 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 Any of the following:
      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)~~; or~~
      ~~2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.~~

ADALIMUMAB (AMGEVITA)
~~**Renewal — (Arthritis - oligoarticular course juvenile idiopathic)**~~ **from any relevant practitioner** ~~only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist.~~ Approvals valid for **2 years** ~~6 months~~ for applications meeting the following criteria:
~~Both:~~
~~1. Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and~~
1. Either
   1.1 Following ~~3 to 4 months~~' 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
   1.2 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 ~~The~~ Patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and
   1.2 Either:
      1.2.1 ~~The~~ Patient has experienced intolerable side effects ~~from etanercept~~; or
      1.2.2 ~~The~~ Patient has received insufficient benefit ~~from etanercept~~ to meet the renewal criteria for etanercept 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 ~~only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist.~~
Approvals valid for **2 years** ~~6 months~~ for applications meeting the following criteria:
~~Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and~~
Either
1. Following ~~3 to 4 months'~~ 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 ~~The~~ Patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis; and
1.2 Either:
1.2.1 ~~The~~ Patient has experienced intolerable side effects ~~from etanercept or secukinumab~~; or
1.2.2 ~~The~~ Patient has received insufficient benefit ~~from etanercept or secukinumab~~ to meet the renewal criteria ~~for etanercept~~ for psoriatic arthritis; or
2. All of the following:
2.1 Patient has had ~~severe~~ active psoriatic arthritis for six months duration or longer; and
2.2 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; and
2.3 Patient has tried and not responded to at least three months of sulfasalazine at a ~~dose of at least 2 g per day~~ or leflunomide at ~~a dose of up to 20 mg daily (or~~ maximum tolerated doses~~)~~; and
2.4 Either:
2.4.1 Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen~~, tender~~ 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 ~~a C-reactive protein~~ **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 elevated erythrocyte sedimentation rate (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 ~~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:
~~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~~
Either:
1. Following ~~3 to 4 months'~~ initial treatment, the patient has at least a 50% decrease in ~~active~~ **swollen** 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~~ **swollen** joint count from baseline and a clinically significant response ~~to prior adalimumab treatment~~ in the opinion of the treating physician.

~~1. Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

Arthritis – rheumatoid

Note the same changes are proposed to be made to etanercept (Enbrel)

ADALIMUMAB (AMGEVITA) / ETANERCEPT
Initial application — (~~rheumatoid~~ aArthritis ~~-~~ 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 [adalimumab / 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 to meet the renewal criteria for rheumatoid arthritis; or
2. 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; 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; 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~~

~~2.1 Either:~~
~~2.1.1 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~~
~~2.1.2 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.~~

ADALIMUMAB (AMGEVITA) / 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. Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and~~
1. Either:
1.1 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
1.2 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.
~~2. Either:~~
~~2.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or~~
~~2.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.~~

Stills disease – adult onset

ADALIMUMAB (AMGEVITA)
Initial application — (Still's disease - adult-onset (AOSD)) only from a rheumatologist.
Approvals valid **without renewal** ~~for 6 months~~ for applications meeting the following criteria:
Either:
1. Either:
1.1 The patient has had an initial Special Authority approval for etanercept **and/or tocilizumab** for ~~adult-onset Still's disease (~~AOSD);~~-~~or
~~The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules; and~~
1.2 Either:
1.2.1 ~~The~~ Patient has experienced intolerable side effects from etanercept and/or tocilizumab; or
1.2.2 ~~The~~ Patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab ~~such that they do not meet the renewal criteria for AOSD~~; or
2. All of the following:
2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria ~~(J Rheumatol 1992;19:424-430)~~; 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, ~~non-steroidal anti-inflammatory drugs~~ NSAIDs and methotrexate; and
2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

~~**Renewal — (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.~~
~~Approvals valid for 6 months for applications meeting the following criteria:~~
~~Both:~~
~~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~~
~~3. The patient has a sustained improvement in inflammatory markers and functional status.~~

~~4. The patient has a sustained improvement in inflammatory markers and functional status.~~