Widened access Special Authority criteria

Changing to a biosimilar adalimumab means that more New Zealanders would be able to access adalimumab.

We are proposing to widen access to Amgevita for a range of uses.

More information on each application, including relevant clinical advice records, can be found through below links to the Application Tracker:

- Ulcerative colitis first line
- Crohns disease dose escalation
- Undifferentiated spondyloarthritis
- Inflammatory bowel-disease associated arthritis
- Behçet's disease first line biologic
- Ocular inflammation – first line biologic
- Rheumatoid arthritis – Special Authority change; joint counts
- Rheumatoid arthritis – Special authority change; CRP levels

The proposed Special Authority are presented below for respective categories (links)

- Dermatology
- Gastrointestinal
- Ophthalmology
- Rheumatology

Dermatology

Behçet's disease – severe (new criteria in **bold**, deletions in ~~strikethrough~~)

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.~~

Gastrointestinal

Crohn's disease – adults (new criteria in **bold**, deletions in ~~strikethrough~~)

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~~
1. **Any of the following**:
   1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab; or
   1.2 CDAI score is 150 or less; or
~~2. Both:~~
   1.3 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed.~~; and~~
~~1.3.1 Applicant to indicate the reason that CDAI score cannot be assessed; and~~
~~2 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

Crohn's disease – children (new criteria in **bold**, deletions in ~~strikethrough~~)

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~~

1. Any of the following:

1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab; or
1.2 PCDAI score is 15 or less; or
1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed.
~~1.3.1 Applicant to indicate the reason that PCDAI score cannot be assessed; and~~
~~1.4 Adalimumab to be administered at doses no greater than 40 mg every 14 days.~~

Crohn's disease – fistulising (new criteria in **bold**, deletions in ~~strikethrough~~)

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.

Ulcerative colitis (new criteria shown only)

ADALIMUMAB (AMGEVITA)
Initial application – (ulcerative colitis - moderate to severely active)
Only from a gastroenterologist.
Approvals valid for 3 months for applications meeting the following criteria:
All of the following:

1. Patient has histologically confirmed ulcerative colitis that is moderate to severely active; 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 - moderate to severely active)
From any relevant Practitioner.
Approvals valid for 2 years for applications where:
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.

Follow this link to the proposed criteria for inflammatory bowel disease associated arthritis (IBD-A).

Ophthalmology

Ocular inflammation – chronic (new criteria in **bold**, deletions in ~~strikethrough~~)

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:~~

1. Any of the following:
   1.1 The patient has had a good clinical response following 12 weeks' initial treatment; or
   1.2 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
   1.3 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~~

~~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~~

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

Ocular inflammation – severe (new criteria in **bold**, deletions in ~~strikethrough~~)

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
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 — (~~severe~~ Ocular inflammation - severe) from any relevant practitioner.
Approvals valid for **2 years** ~~12 months~~ for applications meeting the following criteria:
~~Both:~~
1. Any of the following:
1.1 The patient has had a good clinical response following 3 initial doses; or
1.2 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
1.3 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

Inflammatory bowel arthritis – axial (new criteria shown only)

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)
Approvals 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 (new criteria shown only)

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 sulphasalazine 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; 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) Approvals from any relevant practitioner. Approvals valid for 2 years for applications where:
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.

Arthritis – rheumatoid (new critieria in **bold**, deletions in ~~strikethrough~~)
Note the same changes are proposed to be made to etanercept.

ADALIMUMAB (AMGEVITA) / ETANERCEPT
Initial application — (~~rheumatoid a~~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 [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.~~

Undifferentiated spondyloarthritis (new criteria shown only)

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, sulphasalazine and leflunomide, at maximum tolerated doses; 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.