Alternative brand access

From 1 February 2022, patients receiving treatment with Humira would need to move to Amgevita. This change would be carefully managed by treating clinicians, working closely with primary care, the patient, their family, whānau, and caregivers.

Access to Humira after 31 August 2022 would be through Special Authority criteria. These criteria would replace the current Special Authority access criteria from 1 September 2022, and a new Special Authority application would need to be made for these patients following discussion with their doctor.

Renewal criteria would remain consistent with the renewal criteria currently in place for Humira. No changes are proposed.

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

The proposed Special Authority are presented below (new criteria shown only) for respective categories (links):

- Dermatology
- Gastrointestinal
- Ophthalmology
- Rheumatology

Dermatology

Behcet's disease - severe

ADALIMUMAB (HUMIRA)
Initial application - Behçet's' - severe disease only from any relevant Practitioner.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application - Behçet's' - severe disease only from any relevant Practitioner.
Approvals valid for 6 months for applications meeting the following criteria:
1. The patient has had a good clinical response to treatment with measurably improved quality of life; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Hidradenitis suppurativa

ADALIMUMAB (HUMIRA)
Initial application - Hidradenitis suppurativa (HUMIRA) only from a dermatologist or Practitioner on the recommendation of a dermatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:
1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered.

ADALIMUMAB (HUMIRA)
Renewal application - Hidradenitis suppurativa (HUMIRA) only from a dermatologist or Practitioner on the recommendation of a dermatologist.
Approvals valid for 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 Dermatology Quality of Life Index improvement of 4 or more from baseline; and
3 Adalimumab is to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered.

Plaque psoriasis – severe chronic

ADALIMUMAB (HUMIRA)
Initial application - (Psoriasis - severe chronic plaque)only from a dermatologist or Practitioner on the recommendation of a dermatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application (Psoriasis - severe chronic plaque) only from a dermatologist or Practitioner on the recommendation of a dermatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Both

1. Either:
   - 1.1 Both:
     - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
     - 1.1.2 Either:
       - 1.1.2.1 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
       - 1.1.2.2 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
   - 1.2 Both:
     - 1.2.1 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
     - 1.2.2 Either:
     - 1.2.3 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
     - 1.2.4 Following each prior adalimumab treatment course 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; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Pyoderma gangrenosum

ADALIMUMAB (HUMIRA)
Initial application - Pyoderma gangrenosum only from a dermatologist
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. A maximum of 8 doses.

ADALIMUMAB (HUMIRA)
Renewal application - Pyoderma gangrenosum only from a dermatologist
Approvals valid for 6 months for applications meeting the following criteria:
Both:

1. The patient has demonstrated clinical improvement requiring retreatment; and
2. A maximum of 8 doses.

Gastrointestinal

Crohn's disease – adult

ADALIMUMAB (HUMIRA)
Initial application - Crohn's disease (Adult) from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following
1. Any of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   1.3 Patient has severe Crohn's and is considered to be at risk of severe disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal - Crohn's disease (Adult) from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:
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
   1.3 The patient has demonstrated an adequate response to treatment, but 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

ADALIMUMAB (HUMIRA)
Initial application – Crohn's disease (Children) from a gastroenterologist or any relevant practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following
1. Any of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   1.3 Patient has severe Crohn's and is considered to be at risk of severe disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal – Crohn's disease (Children) from a gastroenterologist or any relevant Practitioner on the recommendation of a gastroenterologist.

Approvals valid for 6 months for applications meeting the following criteria:
Both:

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

Crohn's disease – fistulising

ADALIMUMAB (HUMIRA)
Initial application - Crohn's disease (Adult) from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
All of the following

1. Any of the following:
   - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   - 1.3 Patient has severe Crohn's and is considered to be at risk of severe disease destabilisation if there were to be a change to current treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal – Crohn's disease (Fistulising) from a gastroenterologist or any relevant Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:
Both:

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

Ophthalmology

Ocular inflammation – chronic

ADALIMUMAB (HUMIRA)
Initial application - (Ocular inflammation – chronic) from any relevant Practitioner.
Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. Any of the following:
   - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   - 1.3 Patient has severe uveitis and is considered to be at risk of vision loss if they were to change treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application (Ocular inflammation – chronic) from any relevant Practitioner.
Approvals valid for 12 months for applications meeting the following criteria:
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 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 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 is to be administered at doses no greater than 40 mg every 14 days.

Ocular inflammation – severe

ADALIMUMAB (HUMIRA)
Initial application (Ocular inflammation – severe) from any relevant Practitioner.
Approvals valid for 12 months for applications meeting the following criteria:
All of the following:
1. Any of the following:
   - 1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment, and a maximum of 6 months treatment with Amgevita; or
   - 1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with Amgevita, and a maximum of 6 months treatment with Amgevita and clinician attributes this loss of disease response to a change in treatment regimen; or
   - 1.3 Patient has severe uveitis and is considered to be at risk of vision loss if they were to change treatment; and
2. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
3. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application – (Ocular inflammation – severe) from any relevant Practitioner.

Approvals valid for 12 months for applications meeting the following criteria:

1. Any of the following
   - 1.1 The patient has had a good clinical response following 3 initial doses; or
   - 1.2 Following each 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 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 is to be administered at doses no greater than 40 mg every 14 days.

Rheumatology

Ankylosing spondylitis

ADALIMUMAB (HUMIRA)
Initial application- Ankylosing spondylitis only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita); and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application- Ankylosing spondylitis only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:

1. Both:
   1.1 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
   1.2 Adalimumab is to be administered at doses no greater than 40 mg every 14 days.

Arthritis – oligoarticular course juvenile idiopathic

ADALIMUMAB (HUMIRA)
Initial application (Arthritis – oligoarticular course juvenile idiopathic) only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Renewal application (Arthritis – oligoarticular course juvenile idiopathic) only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist.

Approvals valid for 6 months for applications where 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 (HUMIRA)
Initial application (Arthritis - **polyarticular course juvenile idiopathic)** only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Renewal application (Arthritis - **polyarticular course juvenile idiopathic)**only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist.

Approvals valid for 6 months for applications where 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 (HUMIRA)
Initial application – (Arthritis - **psoriatic)** only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Either
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

ADALIMUMAB (HUMIRA)
Renewal application - (Arthritis - **psoriatic** only from a named specialist, rheumatologist, or Practitioner on the recommendation of a named specialist or rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
Both:

1. The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
2. Adalimumab to be administered at doses no greater than 40 mg every 14 days.

Arthritis – rheumatoid

ADALIMUMAB (HUMIRA)

Initial application – (Arthritis – rheumatoid) only from a rheumatologist, or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. One of the following:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication; and
4. Either
   4.1 Adalimumab to be administered at doses no greater than 40 mg every 14 days; or
   4.2 Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response.

ADALIMUMAB (HUMIRA)
Renewal application – (Arthritis – rheumatoid) only from a rheumatologist, or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior adalimumab treatment in the opinion of the treating physician; and
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 (HUMIRA)
Initial application - Still's disease – Adult onset only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.
Approvals valid for 6 months for applications meeting the following criteria:
All of the following:

1. Both:
   1.1 The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment; or
   1.2 Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita) and clinician attributes this loss of disease response to a change in treatment regimen; and
2. Patient has received a maximum of 6 months treatment with Amgevita; and
3. Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication.

ADALIMUMAB (HUMIRA)
Renewal application - Still's disease – Adult onset only from a rheumatologist or Practitioner on the recommendation of a rheumatologist.

Approvals valid for 6 months for applications where the patient has demonstrated a sustained improvement in inflammatory markers and functional status.