

**SA2157 - Adalimumab (Humira - Alternative brand)**

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**Adalimumab (Humira - Alternative brand)**

**Initial application — Behcet’s disease – severe**

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- or
- 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

- Patient has received a maximum of 6 months treatment with Amgevita

and

- Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Renewal — Behcet’s disease – severe**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has had a good clinical response to treatment with measurably improved quality of life

and

- Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Initial application — Hidradenitis suppurativa**

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- or
- 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

- Patient has received a maximum of 6 months treatment with Amgevita

and

- Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- Adalimumab to be administered at doses no greater than 40 mg every 7 days. Fortnightly dosing has been considered

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Hidradenitis suppurativa**

Current approval Number (if known):.....

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline
- and
- The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline
- and
- Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered

**Initial application — Psoriasis - severe chronic plaque**

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- or
- 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
- Patient has received a maximum of 6 months treatment with Amgevita
- and
- Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication
- and
- Adalimumab to be administered at doses no greater than 40 mg every 14 days

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Psoriasis - severe chronic plaque**

Current approval Number (if known):.....

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

Patient had "whole body" severe chronic plaque psoriasis at the start of treatment

**and**

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**

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**

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**

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**

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**

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

**Initial application — Pyoderma gangrenosum**

Applications only from a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

**or**

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**

Patient has received a maximum of 6 months treatment with Amgevita

**and**

Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

**and**

A maximum of 8 doses

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Pyoderma gangrenosum**

Current approval Number (if known):.....

Applications only from a dermatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

The patient has demonstrated clinical improvement and continues to require treatment  
**and**  
 A maximum of 8 doses

**Initial application — Crohn’s disease - adult**

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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**  
 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**  
 Patient has Crohn’s and is considered to be at risk of disease destabilisation if there were to be a change to current treatment  
**and**  
 Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication  
**and**  
 Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Renewal — Crohn’s disease - adult**

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab  
**or**  
 CDAI score is 150 or less  
**or**  
 The patient has demonstrated an adequate response to treatment, but CDAI score cannot be assessed  
**and**  
 Adalimumab to be administered at doses no greater than 40 mg every 14 days

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**Adalimumab (Humira - Alternative brand) - continued**

**Initial application — Crohn's disease - children**

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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
- 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
- Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment

- and
- Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication
- and
- Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Renewal — Crohn's disease - children**

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab
- or
- PCDAI score is 15 or less
- or
- The patient has demonstrated an adequate response to treatment, but PCDAI score cannot be assessed

- and
- Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Initial application — Crohn's disease - fistulising**

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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
- 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
- Patient has Crohn's and is considered to be at risk of disease destabilisation if there were to be a change to current treatment

- and
- Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication
- and
- Adalimumab to be administered at doses no greater than 40 mg every 14 days

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Crohn’s disease - fistulising**

Current approval Number (if known):.....

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

The number of open draining fistulae have decreased from baseline by at least 50%

or

There has been a marked reduction in drainage of all fistula(e) from baseline as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain

and

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

**Initial application — Ocular inflammation – chronic**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

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

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

Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment

and

Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

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

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Ocular inflammation – chronic**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has had a good clinical response following 12 weeks' initial treatment
- or
- 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
- 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

- Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Initial application — Ocular inflammation – severe**

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- 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
- 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
- Patient has uveitis and is considered to be at risk of vision loss if they were to change treatment

and

- Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

and

- Adalimumab to be administered at doses no greater than 40 mg every 14 days

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Ocular inflammation – severe**

Current approval Number (if known):.....

Applications from any relevant practitioner. Approvals valid for 12 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has had a good clinical response following 3 initial doses
- or
- 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
- 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  Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Initial application — ankylosing spondylitis**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- or
- Patient has developed symptoms of loss of disease control following a minimum of 4 weeks treatment with adalimumab (Amgevita)

and  Patient has received a maximum of 6 months treatment with Amgevita

and  Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

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

**Renewal — ankylosing spondylitis**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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  Adalimumab to be administered at doses no greater than 40 mg every 14 days

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**Adalimumab (Humira - Alternative brand) - continued**

**Initial application — Arthritis – oligoarticular course juvenile idiopathic**

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- or
- 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

- Patient has received a maximum of 6 months treatment with Amgevita

and

- Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

**Renewal — Arthritis – oligoarticular course juvenile idiopathic**

Current approval Number (if known):.....

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

- The patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

**Initial application — Arthritis - polyarticular course juvenile idiopathic**

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- or
- 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

- Patient has received a maximum of 6 months treatment with Amgevita

and

- Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

**Renewal — Arthritis - polyarticular course juvenile idiopathic**

Current approval Number (if known):.....

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

- The patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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**Adalimumab (Humira - Alternative brand) - continued**

**Initial application — Arthritis - psoriatic**  
Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- or
- 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  Patient has received a maximum of 6 months treatment with Amgevita
- and  Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication
- and  Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Renewal — Arthritis - psoriatic**

Current approval Number (if known):.....

Applications only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- 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  Adalimumab to be administered at doses no greater than 40 mg every 14 days

**Initial application — Arthritis – rheumatoid**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

- The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment
- or
- 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  Patient has received a maximum of 6 months treatment with Amgevita
- and  Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

- and  Adalimumab to be administered at doses no greater than 40 mg every 14 days
- or
- Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response

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**Adalimumab (Humira - Alternative brand) - continued**

**Renewal — Arthritis – rheumatoid**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

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**

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

**or**

Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response

**Initial application — Still's disease – adult-onset (AOSD)**

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick boxes where appropriate)

The patient has experienced intolerable side effects from adalimumab (Amgevita) following a minimum of 4 weeks treatment

**or**

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**

Patient has received a maximum of 6 months treatment with Amgevita

**and**

Patient has previously had a Special Authority approval for the Humira brand of adalimumab for this indication

**Renewal — Still's disease – adult-onset (AOSD)**

Current approval Number (if known):.....

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

**Prerequisites**(tick box where appropriate)

The patient has demonstrated a sustained improvement in inflammatory markers and functional status

**I confirm the above details are correct and that in signing this form I understand I may be audited.**

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

Post application to Health New Zealand, Private Bag 3015, Wanganui – email: [customerservice@health.govt.nz](mailto:customerservice@health.govt.nz)