

RS1922 - Adalimumab (Humira - Alternative brand)

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PRESCRIBER

PATIENT:

Name:

Ward: NHI:

Adalimumab (Humira - Alternative brand)

INITIATION – Behcet’s disease – severe

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION – Behcet’s disease – severe

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

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

INITIATION – Hidradenitis suppurativa

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a dermatologist or Practitioner on the recommendation of a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

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Name:

Ward:

PATIENT:

Name:

NHI:

Adalimumab (Humira - Alternative brand) - continued

CONTINUATION – Hidradenitis suppurativa

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a dermatologist or Practitioner on the recommendation of a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

INITIATION – Psoriasis - severe chronic plaque

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a dermatologist or Practitioner on the recommendation of a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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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Name:

Ward:

PATIENT:

Name:

NHI:

Adalimumab (Humira - Alternative brand) - continued

CONTINUATION – Psoriasis - severe chronic plaque

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a dermatologist or Practitioner on the recommendation of a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

INITIATION – Pyoderma gangrenosum

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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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PRESCRIBER

PATIENT:

Name:

Ward: NHI:

Adalimumab (Humira - Alternative brand) - continued

CONTINUATION – Pyoderma gangrenosum

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a dermatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

The patient has demonstrated clinical improvement and continues to require treatment

and

A maximum of 8 doses

INITIATION – Crohn’s disease - adult

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

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

CONTINUATION – Crohn’s disease - adult

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

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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Name:

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PATIENT:

Name:

NHI:

Adalimumab (Humira - Alternative brand) - continued

INITIATION – Crohn’s disease - children

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION – Crohn’s disease - children

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

INITIATION – Crohn’s disease - fistulising

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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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Name:

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PATIENT:

Name:

NHI:

Adalimumab (Humira - Alternative brand) - continued

CONTINUATION – Crohn’s disease - fistulising

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a gastroenterologist or Practitioner on the recommendation of a gastroenterologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

INITIATION – Ocular inflammation – chronic

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION – Ocular inflammation – chronic

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

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PRESCRIBER

Name:

Ward:

PATIENT:

Name:

NHI:

Adalimumab (Humira - Alternative brand) - continued

INITIATION – Ocular inflammation – severe

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION – Ocular inflammation – severe

Re-assessment required after 12 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

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PRESCRIBER

Name:

Ward:

PATIENT:

Name:

NHI:

Adalimumab (Humira - Alternative brand) - continued

INITIATION – ankylosing spondylitis

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION – ankylosing spondylitis

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

INITIATION – Arthritis – oligoarticular course juvenile idiopathic

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

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Name:

Ward:

PATIENT:

Name:

NHI:

Adalimumab (Humira - Alternative brand) - continued

CONTINUATION – Arthritis – oligoarticular course juvenile idiopathic

Re-assessment required after 6 months

Prerequisites (tick box where appropriate)

Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

For patients that demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

INITIATION – Arthritis - polyarticular course juvenile idiopathic

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION – Arthritis - polyarticular course juvenile idiopathic

Re-assessment required after 6 months

Prerequisites (tick box where appropriate)

Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

For patients that demonstrate at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

INITIATION – Arthritis - psoriatic

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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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Name:

Ward:

PATIENT:

Name:

NHI:

Adalimumab (Humira - Alternative brand) - continued

CONTINUATION – Arthritis - psoriatic

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a named specialist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

INITIATION – Arthritis – rheumatoid

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION – Arthritis – rheumatoid

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

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PRESCRIBER

PATIENT:

Name:

Name:

Ward:

NHI:

Adalimumab (Humira - Alternative brand) - continued

INITIATION – Still's disease – adult-onset (AOSD)

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- 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

CONTINUATION – Still's disease – adult-onset (AOSD)

Re-assessment required after 6 months

Prerequisites (tick box where appropriate)

- Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

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

I confirm that the above details are correct:

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