

RS1922 - Adalimumab (Humira - Alternative brand)

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PRESCRIBER

Name:

Ward:

PATIENT:

Name:

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

or

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

or

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

Name:

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:

Ward:

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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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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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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Name:

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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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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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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

Name:

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PATIENT:

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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

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