

**RS1922 - Adalimumab (Humira - Alternative brand)**

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Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to [Section H](#) of the Pharmaceutical Schedule. For community funding, see the [Special Authority Criteria](#).

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

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**PRESCRIBER**

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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**PRESCRIBER**

**PATIENT:**

Name: .....

Ward: ..... 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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**PRESCRIBER**

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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**PRESCRIBER**

Name: .....

Ward: .....

**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**

**PATIENT:**

Name: .....

Ward: ..... 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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**PRESCRIBER**

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

I confirm that the above details are correct:

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

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**PRESCRIBER**

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

I confirm that the above details are correct:

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

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

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:

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