

## RS1941 - Infliximab

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

**Infliximab**

**INITIATION – Graft vs host disease**

Prerequisites (tick box where appropriate)

- Patient has steroid-refractory acute graft vs. host disease of the gut

**INITIATION – rheumatoid arthritis**

Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

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

and

- The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis

and

- The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept
- Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept

or

and

- Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

**CONTINUATION – rheumatoid arthritis**

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

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

and

- Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

and

- Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
- The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

and

- Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks

**INITIATION – ankylosing spondylitis**

Re-assessment required after 3 months

Prerequisites (tick boxes where appropriate)

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

and

- The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis

and

- The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept
- Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis

or

I confirm that the above details are correct:

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

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**PRESCRIBER**

**PATIENT:**

Name: .....

Ward: ..... NHI: .....

**Infliximab - continued**

**CONTINUATION – ankylosing spondylitis**

Re-assessment required after 6 months

**Prerequisites** (tick boxes where appropriate)

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

and

Following 12 weeks of infliximab treatment, BASDAI has improved by 4 or more points from pre-infliximab baseline on a 10 point scale, or by 50%, whichever is less

and

Physician considers that the patient has benefited from treatment and that continued treatment is appropriate

and

Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks

**INITIATION – psoriatic arthritis**

Re-assessment required after 4 months

**Prerequisites** (tick boxes where appropriate)

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

and

The patient has had an initial Special Authority approval for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis

and

- The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept and/or secukinumab
- Following 3-4 months' initial treatment with adalimumab and/or etanercept and/or secukinumab, the patient did not meet the renewal criteria for adalimumab and/or etanercept and/or secukinumab for psoriatic arthritis.

**CONTINUATION – psoriatic arthritis**

Re-assessment required after 6 months

**Prerequisites** (tick boxes where appropriate)

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

and

Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

or

The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician

and

Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

I confirm that the above details are correct:

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**PRESCRIBER**

**PATIENT:**

Name: .....

Name: .....

Ward: .....

NHI: .....

**Infliximab - continued**

**INITIATION – severe ocular inflammation**

Re-assessment required after 4 months

**Prerequisites** (tick boxes where appropriate)

The patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation

and

The patient has experienced intolerable side effects from adalimumab

or

The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe ocular inflammation

or

Patient has severe, vision-threatening ocular inflammation requiring rapid control

and

Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms

or

Patient developed new inflammatory symptoms while receiving high dose steroids

or

Patient is aged under 8 years and treatment with high dose oral steroids and other immunosuppressants has proven ineffective at controlling symptoms

**CONTINUATION – severe ocular inflammation**

Re-assessment required after 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

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

**Infliximab - continued**

**INITIATION – chronic ocular inflammation**

Re-assessment required after 4 months

**Prerequisites** (tick boxes where appropriate)

The patient has had an initial Special Authority approval for adalimumab for chronic ocular inflammation

and

The patient has experienced intolerable side effects from adalimumab

or

The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for chronic ocular inflammation

or

Patient has severe uveitis uncontrolled with treatment of steroids and other immunosuppressants with a severe risk of vision loss

and

Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective

or

Patient is under 18 years and treatment with methotrexate has proven ineffective or is not tolerated at therapeutic dose

or

Patient is under 8 years and treatment with steroids or methotrexate has proven ineffective or is not tolerated at a therapeutic dose; or disease requires control to prevent irreversible vision loss prior to achieving a therapeutic dose of methotrexate

**CONTINUATION – chronic ocular inflammation**

Re-assessment required after 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

Note: A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

**INITIATION – Pulmonary sarcoidosis**

**Prerequisites** (tick boxes where appropriate)

Patient has life-threatening pulmonary sarcoidosis that is refractory to other treatments

and

Treatment is to be prescribed by, or has been recommended by, a physician with expertise in the treatment of pulmonary sarcoidosis

I confirm that the above details are correct:

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

**Infliximab - continued**

**INITIATION – Crohn’s disease (adults)**

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

Patient has active Crohn’s disease

and

Patient has a CDAI score of greater than or equal to 300, or HBI score of greater than or equal to 10

or

Patient has extensive small intestine disease affecting more than 50 cm of the small intestine

or

Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection

or

Patient has an ileostomy or colostomy, and has intestinal inflammation

and

Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior therapy with immunomodulators and corticosteroids

**CONTINUATION – Crohn’s disease (adults)**

Re-assessment required after 2 years

**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

CDAI score has reduced by 100 points from the CDAI score, or HBI score has reduced by 3 points, from when the patient was initiated on infliximab

or

CDAI score is 150 or less, or HBI is 4 or less

or

The patient has demonstrated an adequate response to treatment but CDAI score and/or HBI score cannot be assessed

and

Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

**INITIATION – Crohn’s disease (children)**

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

Paediatric patient has active Crohn’s disease

and

Patient has a PCDAI score of greater than or equal to 30

or

Patient has extensive small intestine disease

and

Patient has tried but experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and corticosteroids

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**PRESCRIBER**

**PATIENT:**

Name: .....

Ward: ..... NHI: .....

**Infliximab - continued**

**CONTINUATION – Crohn’s disease (children)**

Re-assessment required after 2 years

**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

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

and

Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

**INITIATION – fistulising Crohn’s disease**

Re-assessment required after 6 months

**Prerequisites** (tick boxes where appropriate)

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

and

Patient has confirmed Crohn’s disease

and

- Patient has one or more complex externally draining enterocutaneous fistula(e)
- or
- Patient has one or more rectovaginal fistula(e)
- or
- Patient has complete peri-anal fistula

**CONTINUATION – fistulising Crohn’s disease**

Re-assessment required after 2 years

**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 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 (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain

and

Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

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**PRESCRIBER**

**PATIENT:**

Name: .....

Ward: ..... NHI: .....

**Infliximab - continued**

**INITIATION – acute fulminant ulcerative colitis**

Re-assessment required after 6 weeks

**Prerequisites** (tick boxes where appropriate)

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

and

Patient has acute, fulminant ulcerative colitis

and

Treatment with intravenous or high dose oral corticosteroids has not been successful

**CONTINUATION – fulminant ulcerative colitis**

Re-assessment required after 2 years

**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

Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months

and

Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

**INITIATION – ulcerative colitis**

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

Patient has active ulcerative colitis

and

Patients SCCAI is greater than or equal to 4

or

Patients PUCAI score is greater than or equal to 20

and

Patient has experienced an inadequate response to, or intolerable side effects from, prior therapy with immunomodulators and systemic corticosteroids

I confirm that the above details are correct:

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



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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

**Infliximab - continued**

**CONTINUATION – ulcerative colitis**

Re-assessment required after 2 years

**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 SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab  
or  
 The PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on infliximab

and

- Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle

**INITIATION – plaque psoriasis**

Re-assessment required after 3 doses

**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

- Patient has had an initial Special Authority approval for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis  
and  
 Patient has experienced intolerable side effects from adalimumab, etanercept or secukinumab  
or  
 Patient has received insufficient benefit from adalimumab, etanercept or secukinumab to meet the renewal criteria for adalimumab, etanercept or secukinumab for severe chronic plaque psoriasis

or

- Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 10, where lesions have been present for at least 6 months from the time of initial diagnosis  
or  
 Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis

and

- Patient has tried, but had an inadequate response (see Note) to, or has experienced intolerable side effects from, at least three of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, cyclosporin, or acitretin

and

- A PASI assessment has been completed for at least the most recent prior treatment course (but preferably all prior treatment courses), preferably while still on treatment but no longer than 1 month following cessation of each prior treatment course

and

- The most recent PASI assessment is no more than 1 month old at the time of initiation

Note: "Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 10, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment; for severe chronic plaque psoriasis of the face, hand or foot, at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and the skin area affected is 30% or more of the face, palm of a hand or sole of a foot, as assessed preferably while still on treatment but no longer than 1 month following cessation of the most recent prior treatment.

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**PRESCRIBER**

**PATIENT:**

Name: .....

Ward: ..... NHI: .....

**Infliximab - continued**

**CONTINUATION – plaque psoriasis**

Re-assessment required after 3 doses

**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

Patient had "whole body" severe chronic plaque psoriasis at the start of treatment  
and  
 Following each prior infliximab 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-infliximab 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 infliximab 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 infliximab 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-infliximab treatment baseline value

and

Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

**INITIATION – neurosarcoidosis**

Re-assessment required after 18 months

**Prerequisites** (tick boxes where appropriate)

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

and

Biopsy consistent with diagnosis of neurosarcoidosis

and

Patient has CNS involvement

and

Patient has steroid-refractory disease

and

IV cyclophosphamide has been tried  
or  
 Treatment with IV cyclophosphamide is clinically inappropriate

I confirm that the above details are correct:

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

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**PRESCRIBER**

Name: .....

Ward: .....

**PATIENT:**

Name: .....

NHI: .....

**Infliximab - continued**

**CONTINUATION – neurosarcoidosis**

Re-assessment required after 18 months

**Prerequisites** (tick boxes where appropriate)

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

and

A withdrawal period has been tried and the patient has relapsed

or

A withdrawal period has been considered but would not be clinically appropriate

and

There has been a marked reduction in prednisone dose

and

There has been an improvement in MRI appearances

or

Marked improvement in other symptomology

**INITIATION – severe Behcet’s disease**

Re-assessment required after 4 months

**Prerequisites** (tick boxes where appropriate)

The patient has severe Behcet’s disease which is significantly impacting the patient’s quality of life (see Notes)

and

The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes)

or

The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes)

and

The patient is experiencing significant loss of quality of life

Note:

- a) Behcet’s disease diagnosed according to the International Study Group for Behcet’s Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7.
- b) Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.

**CONTINUATION – severe Behcet’s disease**

Re-assessment required after 6 months

**Prerequisites** (tick boxes where appropriate)

Patient has had a good clinical response to initial treatment with measurably improved quality of life

and

Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks

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**PRESCRIBER**

**PATIENT:**

Name: .....

Name: .....

Ward: .....

NHI: .....

**Infliximab - continued**

**INITIATION – pyoderma gangrenosum**

**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

- Patient has pyoderma gangrenosum\*  
and  
 Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate) and not received an adequate response  
and  
 A maximum of 8 doses

Note: Indications marked with \* are unapproved indications.

**CONTINUATION – pyoderma gangrenosum**

**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

- Patient has shown clinical improvement  
and  
 Patient continues to require treatment  
and  
 A maximum of 8 doses

**INITIATION – Inflammatory bowel arthritis (axial)**

Re-assessment required after 6 months

**Prerequisites** (tick boxes where appropriate)

- Patient has a diagnosis of active ulcerative colitis or active Crohn's disease  
and  
 Patient has had axial inflammatory pain for six months or more  
and  
 Patient is unable to take NSAIDs  
and  
 Patient has unequivocal sacroiliitis demonstrated by radiological imaging or MRI  
and  
 Patient has not experienced an adequate response to prior treatment consisting of at least 3 months of an exercise regime supervised by a physiotherapist  
and  
 Patient has a BASDAI of at least 6 on a 0-10 scale completed after the 3 month exercise trial, but prior to ceasing any previous pharmacological treatment

**CONTINUATION – Inflammatory bowel arthritis (axial)**

Re-assessment required after 2 years

**Prerequisites** (tick box where appropriate)

- Where 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

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

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**PRESCRIBER**

**PATIENT:**

Name: .....

Name: .....

Ward: .....

NHI: .....

**Infliximab - continued**

**INITIATION – Inflammatory bowel arthritis (peripheral)**

Re-assessment required after 6 months

**Prerequisites** (tick boxes where appropriate)

- Patient has a diagnosis of active ulcerative colitis or active Crohn's disease
- and  Patient has active arthritis in at least four joints from the following: hip, knee, ankle, subtalar, tarsus, forefoot, wrist, elbow, shoulder, sternoclavicular
- and  Patient has tried and not experienced a response to at least three months of methotrexate or azathioprine at a maximum tolerated dose (unless contraindicated)
- and  Patient has tried and not experienced a response to at least three months of sulfasalazine at a maximum tolerated dose (unless contraindicated)
- and
  - Patient has a CRP level greater than 15 mg/L measured no more than one month prior to the date of this application
  - or  Patient has an ESR greater than 25 mm per hour measured no more than one month prior to the date of this application
  - or  ESR and CRP not measured as patient is currently receiving prednisone therapy at a dose of greater than 5 mg per day and has done so for more than three months

**CONTINUATION – Inflammatory bowel arthritis (peripheral)**

Re-assessment required after 2 years

**Prerequisites** (tick boxes where appropriate)

- Following initial treatment, patient has experienced at least a 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician
- or  Patient has experienced at least a continuing 30% improvement in active joint count from baseline in the opinion of the treating physician

I confirm that the above details are correct:

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