RS2124 - Infliximab

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

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

or

- ○ 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

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

or

- ○ 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

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

or

- ○ 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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

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

or

- ○ 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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

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

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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

Name: .....

Ward: .....

PATIENT:

Name: .....

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

Name: .....

Ward: .....

PATIENT:

Name: .....

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

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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

or

- ○ Patient has severe chronic localised genital or flexural plaque psoriasis where the plaques or lesions have been present for at least 6 months from the time of initial diagnosis, and with a Dermatology Life Quality Index (DLQI) score greater than 10

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, foot, genital or flexural areas at least 2 of the 3 PASI symptom subscores for erythema, thickness and scaling are rated as severe or very severe, and for the face, palm of a hand or sole of a foot 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

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – plaque psoriasis
Re-assessment required after 3 doses
Prerequisites (tick boxes where appropriate)

- ○ 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

or

- ○ Patient had severe chronic localised genital or flexural plaque psoriasis at the start of treatment

  and

  - ○ The patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-treatment baseline value

    or

  - ○ Patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, as compared to baseline DLQI prior to commencing infliximab

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

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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

Name: .....

Ward: .....

PATIENT:

Name: .....

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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

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

INITIATION – immune checkpoint inhibitor toxicity in malignancy*
Re-assessment required after 4 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 individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy

and

- ○ The individual has received insufficient benefit from use of corticosteroids

and

- ○ Infliximab is to be administered at up to 5mg/kg for up to four doses

I confirm that the above details are correct:

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

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

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – immune checkpoint inhibitor toxicity in malignancy*
Re-assessment required after 4 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 individual has shown clinical improvement and ongoing treatment is required

and

❍ Infliximab is to be administered at up to 5mg/kg for up to a total of 8 doses

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

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