RS2178 - 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 – arthritis - rheumatoid

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has had a Special Authority approval for adalimumab or etanercept for rheumatoid arthritis

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis

and

- ○ Following initial induction doses, maximum dose 3mg/kg every 8 weeks

CONTINUATION – arthritis - rheumatoid

Re-assessment required after 2 years

Prerequisites (tick boxes where appropriate)

- ○ Following initial treatment, the patient has experienced at least a 50% decrease in active joint count from baseline

or

- ○ Patient has experienced at least a continuing 30% improvement in active joint count from baseline

and

- ○ Maximum dose 3 mg/kg every 8 weeks

INITIATION – ankylosing spondylitis

Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ○ Patient has had a Special Authority approval for adalimumab or etanercept for ankylosing spondylitis

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis

and

- ○ Following initial induction doses, maximum dose 5mg/kg every 6-8 weeks

CONTINUATION – ankylosing spondylitis

Re-assessment required after 2 years

Prerequisites (tick boxes where appropriate)

- ○ BASDAI has improved from pre-treatment baseline either by at least 4 points on a 10-point scale, or by at least 50%

and

- ○ Maximum dose 5 mg/kg every 6-8 weeks

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Name: .....

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PATIENT:

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NHI: .....

Infliximab *- continued*

INITIATION – arthritis - psoriatic
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has had a Special Authority approval for adalimumab or etanercept or secukinumab for psoriatic arthritis

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis

and

- ○ Following initial induction doses, maximum dose 5mg/kg every 8 weeks

CONTINUATION – arthritis - psoriatic
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Following initial treatment, at least a 50% decrease in active joint count from baseline

or

- ○ At least a continuing 30% improvement in active joint count from baseline

and

- ○ Maximum dose 5 mg/kg every 8 weeks

INITIATION – ocular inflammation - severe*
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has had an initial Special Authority approval for adalimumab for severe ocular inflammation

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for severe ocular inflammation

or

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

and

- ○ Treatment with high-dose IV corticosteroids followed by high dose oral corticosteroids has been ineffective at controlling symptoms

or

- ○ Patient developed new inflammatory symptoms while receiving high dose corticosteroids

or

- ○ Patient is aged under 8 years and treatment with high dose oral corticosteroids and other immunosuppressants has been ineffective at controlling symptoms

or

- ○ High dose corticosteroids are contraindicated

Note: Indications marked with * are unapproved indications.

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Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – ocular inflammation - severe*
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ❍ Patient has received a good clinical response following 3 initial doses

or

- ❍ Following each 2 year treatment period, the patient has experienced 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 2 year treatment period, the patient has a sustained corticosteroid sparing effect, allowing reduction in prednisone to < 10mg daily, or corticosteroid 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.
Indications marked with * are unapproved indications.

INITIATION – ocular inflammation - chronic*
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ❍ Patient has had a Special Authority approval for adalimumab for chronic ocular inflammation

and

- ❍ Patient has experienced intolerable side effects

or

- ❍ Patient has received insufficient benefit to meet the renewal criteria for chronic ocular inflammation

or

- ❍ Patient has severe uveitis with a severe risk of vision loss uncontrolled by treatment with corticosteroids and other immunosuppressants

and

- ❍ Patient is 18 years or older and treatment with at least two other immunomodulatory agents has been ineffective or are contraindicated

or

- ❍ Patient is under 18 years and treatment with methotrexate has been ineffective, is contraindicated or is not tolerated at a therapeutic dose

or

- ❍ Patient is under 8 years and treatment with corticosteroids or methotrexate has been ineffective, is contraindicated 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

Note: Indications marked with * are unapproved indications.

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – ocular inflammation - chronic*
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Patient has received a good clinical response following 3 initial doses

or

- ○ Following each 2 year treatment period, the patient has experienced 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 2 year treatment period, the patient has a sustained corticosteroid sparing effect, allowing reduction in prednisone to < 10mg daily, or corticosteroid 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.
Indications marked with * are unapproved indications.

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

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

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Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

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

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

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

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

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

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

INITIATION – plaque psoriasis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient had a Special Authority approval for adalimumab, etanercept or secukinumab for plaque psoriasis

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for plaque psoriasis

or

- ○ Patient has "whole body" plaque psoriasis with a PASI score of greater than 10

or

- ○ Patient has plaque psoriasis of the face, or palm of a hand or sole of a foot

or

- ○ Patient has localised genital or flexural plaque psoriasis with a DLQI score greater than 10

and

- ○ Patient has received insufficient benefit (see Note) or has experienced intolerable side effects from at least 3 of the following (at maximum tolerated doses unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin

and

- ○ A PASI assessment has been completed for the most recent prior treatment course within 1 month of stopping that treatment

and

- ○ The most recent PASI assessment is within 1 month before the application

Note: "Insufficient benefit" is defined as: for whole body plaque psoriasis, a PASI score of greater than 10, for 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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Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

CONTINUATION – plaque psoriasis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Patient had "whole body" plaque psoriasis at the start of treatment
  and
- ○ Patient has a PASI score which is reduced by 75% or more, or is sustained at this level, when compared with the pre-infliximab baseline

or

- ○ Patient had plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
  and
  - ○ 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 pre-infliximab baseline
    or
  - ○ Patient has a reduction of 75% or more in the skin area affected, or sustained at this level, as compared to the pre-infliximab baseline

or

- ○ Patient had localised genital or flexural plaque psoriasis at the start of treatment
  and
  - ○ 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
    or
  - ○ Patient has a DLQI improvement of 5 or more, as compared to the pre-infliximab baseline

and

- ○ Maximum dose 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 – Behcet disease
Prerequisites (tick boxes where appropriate)

- ○ Patient has severe Behcet disease which is significantly impacting their quality of life

and

- ○ Patient has severe ocular, neurological and/or vasculitic symptoms and has received insufficient benefit from 1 or more treatment(s) appropriate for the particular symptom(s)

or

- ○ Patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has received insufficient benefit from 2 or more treatments appropriate for the particular symptom(s)

and

- ○ Following initial loading doses, maximum dose 5mg/kg every 8 weeks

INITIATION – pyoderma gangrenosum*
Prerequisites (tick boxes where appropriate)

- ○ Patient has received insufficient benefit from 3 months of conventional therapy including a minimum of 3 pharmaceuticals (e.g. prednisone, ciclosporin, azathioprine, or methotrexate). Where conventional pharmaceuticals are contraindicated, a 3-month trial has occurred of those that are not contraindicated

and

- ○ Maximum of 8 doses every 4 months

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

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

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

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Infliximab *- continued*

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

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.

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