SA2487 - Infliximab

APPLICANT (stamp or sticker acceptable)
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Infliximab

Initial application — Crohn's disease (adults)
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

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

Renewal — Crohn's disease (adults)

Current approval Number (if known):..........

Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- ☐ 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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

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Infliximab *- continued*

Initial application — Crohn's disease (children)
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- [ ] 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

Renewal — Crohn's disease (children)

Current approval Number (if known):..

Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- [ ] 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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

Initial application — Graft vs host disease
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick box where appropriate)

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

Initial application — Pulmonary sarcoidosis
Applications from any relevant practitioner. Approvals valid without further renewal unless notified.
Prerequisites(tick box where appropriate)

- [ ] Patient has life-threatening pulmonary sarcoidosis diagnosed by a multidisciplinary team that is refractory to other treatments

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Infliximab *- continued*

Initial application — acute fulminant ulcerative colitis
Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has acute, fulminant ulcerative colitis

and

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

Initial application — ankylosing spondylitis
Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

Renewal — ankylosing spondylitis

Current approval Number (if known):..

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

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Infliximab *- continued*

Initial application — chronic ocular inflammation
Applications from any relevant practitioner. Approvals valid for 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 a 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

Renewal — chronic ocular inflammation

Current approval Number (if known):..

Applications from any relevant practitioner. Approvals valid for 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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Infliximab *- continued*

Initial application — fistulising Crohn's disease
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

- ☐ Patent has complex peri-anal fistula

Renewal — fistulising Crohn's disease

Current approval Number (if known):..

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- ☐ 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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

Initial application — neurosarcoidosis
Applications only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has been diagnosed with neurosarcoiosis by a multidisciplinary team

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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Infliximab *- continued*

Renewal — neurosarcoidosis

Current approval Number (if known):...

Applications only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months.

Prerequisites(tick boxes where appropriate)

- ☐ 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

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Infliximab *- continued*

Initial application — plaque psoriasis

Applications only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

- ☐ The 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, ciclosporin, 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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Infliximab *- continued*

Renewal — plaque psoriasis

Current approval Number (if known):...

Applications from any relevant practitioner. Approvals valid for 6 months.

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

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Infliximab *- continued*

Initial application — previous use
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient was being treated with infliximab prior to 1 February 2019

and

- ☐ Rheumatoid arthritis
- **or** ☐ Ankylosing spondylitis
- **or** ☐ Psoriatic arthritis
- **or** ☐ Severe ocular inflammation
- **or** ☐ Chronic ocular inflammation
- **or** ☐ Crohn's disease (adults)
- **or** ☐ Crohn's disease (children)
- **or** ☐ Fistulising Crohn's disease
- **or** ☐ Severe fulminant ulcerative colitis
- **or** ☐ Severe ulcerative colitis
- **or** ☐ Plaque psoriasis
- **or** ☐ Neurosarcoidosis
- **or** ☐ Severe Behcet's disease

Initial application — psoriatic arthritis
Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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 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

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Infliximab *- continued*

Renewal — psoriatic arthritis

Current approval Number (if known):..

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

Initial application — rheumatoid arthritis
Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

Renewal — rheumatoid arthritis

Current approval Number (if known):..

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ 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

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Infliximab *- continued*

Initial application — severe Behcet's disease
Applications from any relevant practitioner. Approvals valid for 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: 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.
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.

Renewal — severe Behcet's disease

Current approval Number (if known):..........

Applications from any relevant practitioner. Approvals valid for 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

Renewal — fulminant ulcerative colitis

Current approval Number (if known):..........

Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- ☐ 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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

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Infliximab *- continued*

Initial application — severe ocular inflammation
Applications from any relevant practitioner. Approvals valid for 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

Renewal — severe ocular inflammation

Current approval Number (if known):..

Applications from any relevant practitioner. Approvals valid for 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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Infliximab *- continued*

Initial application — ulcerative colitis
Applications from any relevant practitioner. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has active ulcerative colitis

and

- **or**
  - ☐ Patients SCCAI is greater than or equal to 4
  - ☐ Patients PUCAI score is greater than or equal to 20

and

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

Renewal — ulcerative colitis

Current approval Number (if known):..

Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick boxes where appropriate)

- **or**
  - ☐ The SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab
  - ☐ The PUCAI score has reduced by 10 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. Up to 10 mg/kg every 8 weeks (or equivalent) may be used for patients treated with this dose prior to 1 February 2019

Initial application — pyoderma gangrenosum
Applications only from a dermatologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has pyoderma gangrenosum*

and

- ☐ Patient has received three months of conventional therapy including a minimum of three pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate) and not received an adequate response

and

- ☐ A maximum of 8 doses

Note: Note: Indications marked with * are unapproved indications.

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

APPLICANT (stamp or sticker acceptable)

Reg No: ....

Name: ....

Address: ....

....

....

Fax Number: ....

PATIENT NHI: ....

First Names: ....

Surname: ....

DOB: ....

Address: ....

....

....

REFERRER Reg No: ....

First Names: ....

Surname: ....

Address: ....

....

....

Fax Number: ....

Infliximab *- continued*

Renewal — pyoderma gangrenosum

Current approval Number (if known):...

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- ☐ Patient has shown clinical improvement

and
- ☐ Patient continues to require treatment

and
- ☐ A maximum of 8 doses

Initial application — inflammatory bowel arthritis – axial
Applications from any relevant practitioner. Approvals valid for 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's disease has not responded adequately 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

Renewal — inflammatory bowel arthritis – axial

Current approval Number (if known):...

Applications from any relevant practitioner. Approvals valid for 2 years.
Prerequisites(tick box where appropriate)

- ☐ 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

I confirm the above details are correct and that in signing this form I understand I may be audited.

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

**APPLICATION FOR SUBSIDY
BY SPECIAL AUTHORITY**

APPLICANT (stamp or sticker acceptable)

Reg No: ....

Name: ....

Address: ....

....

....

Fax Number: ....

PATIENT NHI: ....

First Names: ....

Surname: ....

DOB: ....

Address: ....

....

....

REFERRER Reg No: ....

First Names: ....

Surname: ....

Address: ....

....

....

Fax Number: ....

Infliximab *- continued*

Initial application — inflammatory bowel arthritis – peripheral
Applications from any relevant practitioner. Approvals valid for 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

Renewal — inflammatory bowel arthritis – peripheral

Current approval Number (if known):..

Applications from any relevant practitioner. Approvals valid for 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

Initial application — immune checkpoint inhibitor toxicity in malignancy*
Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

- [ ] 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 the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

APPLICANT (stamp or sticker acceptable)

Reg No: ....

Name: ....

Address: ....

....

....

Fax Number: ....

PATIENT NHI: ....

First Names: ....

Surname: ....

DOB: ....

Address: ....

....

....

REFERRER Reg No: ....

First Names: ....

Surname: ....

Address: ....

....

....

Fax Number: ....

Infliximab *- continued*

Renewal — immune checkpoint inhibitor toxicity in malignancy*

Current approval Number (if known):..

Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ 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 the above details are correct and that in signing this form I understand I may be audited.

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

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz