## SA2487 - Infliximab

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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

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

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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.

**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) | **PATIENT** NHI: ..... | **REFERRER** Reg No: ..... |
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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**

- ☐ Patients SCCAI is greater than or equal to 4

**or**

- ☐ 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)

- ☐ 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 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.

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## 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

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## 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

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## 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.

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