SA2049 - Adalimumab

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
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Adalimumab

Initial application — adult-onset Still's disease
Applications only from a rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has had an initial Special Authority approval for etanercept for adult-onset Still's disease (AOSD)
  or
- ☐ The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the HML rules

and

- ☐ The patient has experienced intolerable side effects from etanercept and/or tocilizumab
  or
- ☐ The patient has received insufficient benefit from at least a three-month trial of etanercept and/or tocilizumab such that they do not meet the renewal criteria for AOSD

or

- ☐ Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430)

and

- ☐ Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal anti-inflammatory drugs (NSAIDs) and methotrexate

and

- ☐ Patient has persistent symptoms of disabling poorly controlled and active disease

Renewal — adult-onset Still's disease

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)

- ☐ Applicant is a rheumatologist
  or
- ☐ Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

- ☐ The patient has a sustained improvement in inflammatory markers and functional status

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

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Adalimumab *- continued*

Initial application — ankylosing spondylitis
Applications only from a rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has had an initial Special Authority approval for etanercept for ankylosing spondylitis

and

☐ The patient has experienced intolerable side effects from etanercept

or

☐ The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for ankylosing spondylitis

or

☐ Patient has a confirmed diagnosis of ankylosing spondylitis for more than six months

and

☐ Patient has low back pain and stiffness that is relieved by exercise but not by rest

and

☐ Patient has bilateral sacroiliitis demonstrated by plain radiographs, CT or MRI scan

and

☐ Patient's ankylosing spondylitis has not responded adequately to treatment with two or more non-steroidal anti-inflammatory drugs (NSAIDs), in combination with anti-ulcer therapy if indicated, while patient was undergoing at least 3 months of a regular exercise regimen for ankylosing spondylitis

and

☐ Patient has limitation of motion of the lumbar spine in the sagittal and the frontal planes as determined by the following Bath Ankylosing Spondylitis Metrology Index (BASMI) measures: a modified Schober's test of less than or equal to 4 cm and lumbar side flexion measurement of less than or equal to 10 cm (mean of left and right)

or

☐ Patient has limitation of chest expansion by at least 2.5 cm below the following average normal values corrected for age and gender (see Notes)

and

☐ A Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) of at least 6 on a 0-10 scale

Note: The BASDAI must have been determined at the completion of the 3 month exercise trial, but prior to ceasing NSAID treatment. The BASDAI measure must be no more than 1 month old at the time of initial application.
Average normal chest expansion corrected for age and gender:
18-24 years - Male: 7.0 cm; Female: 5.5 cm
25-34 years - Male: 7.5 cm; Female: 5.5 cm
35-44 years - Male: 6.5 cm; Female: 4.5 cm
45-54 years - Male: 6.0 cm; Female: 5.0 cm
55-64 years - Male: 5.5 cm; Female: 4.0 cm
65-74 years - Male: 4.0 cm; Female: 4.0 cm
75+ years - Male: 3.0 cm; Female: 2.5 cm

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Adalimumab *- continued*

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)

- ☐ Applicant is a rheumatologist

or

- ☐ Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

- ☐ Following 12 weeks' initial treatment and for subsequent renewals, 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

and

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

and

- ☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

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 infliximab for chronic ocular inflammation

and

- ☐ The patient has experienced intolerable side effects from infliximab

or

- ☐ The patient has received insufficient benefit from infliximab to meet the renewal criteria for infliximab 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

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Adalimumab *- continued*

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 12 weeks' initial treatment

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

and

- ☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

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 adalimumab is withdrawn.

Initial application — Crohn's disease - adults

Applications only from a gastroenterologist. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient has severe active Crohn's disease

and

- ☐ Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300

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 systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids

and

- ☐ Surgery (or further surgery) is considered to be clinically inappropriate

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Adalimumab *- continued*

Renewal — Crohn's disease - adults

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

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

Prerequisites(tick boxes, and write the data requested in the space provided where appropriate)

☐ Applicant is a gastroenterologist

or

☐ Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

☐ CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on adalimumab

or

☐ CDAI score is 150 or less

or

☐ The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed

and

Applicant to indicate the reason that CDAI score cannot be assessed.....

and

☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

Initial application — Crohn's disease - children

Applications only from a gastroenterologist. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

☐ Paediatric patient has severe active Crohn's disease

and

☐ Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30

or

☐ Patient has extensive small intestine disease

and

☐ Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids

and

☐ Surgery (or further surgery) is considered to be clinically inappropriate

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Adalimumab *- continued*

Renewal — Crohn's disease - children

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

Applications only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months.

Prerequisites(tick boxes, and write the data requested in the space provided where appropriate)

- ☐ Applicant is a gastroenterologist

or

- ☐ Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

- ☐ PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on adalimumab

or

- ☐ PCDAI score is 15 or less

or

- ☐ The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed

and

Applicant to indicate the reason that PCDAI score cannot be assessed.....

and

☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

Initial application — fistulising Crohn's disease

Applications only from a gastroenterologist. 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)

and

☐ A Baseline Fistula Assessment has been completed and is no more than 1 month old at the time of application

and

☐ The patient will be assessed for response to treatment after 4 months' adalimumab treatment (see Note)

Note: A maximum of 4 months' adalimumab will be subsidised on an initial Special Authority approval for fistulising Crohn's disease.

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Adalimumab *- continued*

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 6 months.

Prerequisites(tick boxes where appropriate)

- ☐ Applicant is a gastroenterologist

or

- ☐ Applicant is a Practitioner and confirms that a gastroenterologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

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 as demonstrated by a reduction in the Fistula Assessment score, together with less induration and patient-reported pain

Initial application — hidradenitis suppurativa

Applications only from a dermatologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ Patient has hidradenitis suppurativa Hurley Stage II or Hurley Stage III lesions in distinct anatomic areas

and

- ☐ Patient has tried, but had an inadequate response to at least a 90 day trial of systemic antibiotics or patient has demonstrated intolerance to or has contraindications for systemic antibiotics

and

- ☐ The patient has 3 or more active lesions (e.g. inflammatory nodules, abscesses, draining fistulae)

and

- ☐ The patient has a Dermatology Quality of Life Index of 10 or more and the assessment is no more than 1 month old at time of application

and

- ☐ Following the initial loading doses, adalimumab is to be administered at doses no greater than 40mg every 7 days

Renewal — hidradenitis suppurativa

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

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has a reduction in active lesions (e.g. inflammatory nodules, abscesses, draining fistulae) of 25% or more from baseline

and

- ☐ The patient has a Dermatology Quality of Life Index improvement of 4 or more from baseline

and

- ☐ Adalimumab is to be administered at doses no greater than 40mg every 7 days. Fortnightly dosing has been considered

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Adalimumab *- continued*

Initial application — polyarticular course juvenile idiopathic arthritis
Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA)

and

or

☐ The patient has experienced intolerable side effects from etanercept

or

☐ The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for polyarticular course JIA

or

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

and

☐ Patient has had polyarticular course JIA for 6 months duration or longer

and

☐ At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

☐ Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

☐ Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate

Renewal — polyarticular course juvenile idiopathic arthritis

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

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

☐ Subsidised 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 and an improvement in physician's global assessment from baseline

or

☐ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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Adalimumab *- continued*

Initial application — oligoarticular course juvenile idiopathic arthritis
Applications only from a named specialist or rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has had an initial Special Authority approval for etanercept for oligoarticular course juvenile idiopathic arthritis (JIA)

and

☐ The patient has experienced intolerable side effects from etanercept

or

☐ The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for oligoarticular course JIA

or

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

and

☐ Patient has had oligoarticular course JIA for 6 months duration or longer

and

☐ At least 2 active joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

☐ Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at the maximum tolerated dose)

or

☐ High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate

Renewal — oligoarticular course juvenile idiopathic arthritis

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

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

☐ Subsidised 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 and an improvement in physician's global assessment from baseline

or

☐ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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

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Adalimumab *- continued*

Initial application — psoriatic arthritis
Applications only from a rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

- ☐ The patient has had an initial Special Authority approval for etanercept or secukinumab for psoriatic arthritis

and

  - ☐ The patient has experienced intolerable side effects from etanercept or secukinumab

  or

  - ☐ The patient has received insufficient benefit from etanercept or secukinumab to meet the renewal criteria for etanercept or secukinumab for psoriatic arthritis

or

- ☐ Patient has had severe active psoriatic arthritis for six months duration or longer

and

- ☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose

and

- ☐ Patient has tried and not responded to at least three months of sulfasalazine at a dose of at least 2 g per day or leflunomide at a dose of up to 20 mg daily (or maximum tolerated doses)

and

  - ☐ Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints

  or

  - ☐ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

  - ☐ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application

  or

  - ☐ Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour

  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

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

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APPLICANT (stamp or sticker acceptable)

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Adalimumab *- 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)

☐ Applicant is a rheumatologist

or

☐ Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

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 adalimumab treatment in the opinion of the treating physician

and

☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

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, ciclosporin, azathioprine, or methotrexate) and not received an adequate response

and

☐ A maximum of 8 doses

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

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

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Adalimumab *- continued*

Initial application — rheumatoid arthritis
Applications only from a rheumatologist. Approvals valid for 6 months.
Prerequisites(tick boxes where appropriate)

☐ The patient has had an initial Special Authority approval for etanercept for rheumatoid arthritis

and

☐ The patient has experienced intolerable side effects from etanercept

or

☐ The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for rheumatoid arthritis

or

☐ Patient has had severe and active erosive rheumatoid arthritis (either confirmed by radiology imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive) for six months duration or longer

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

☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate at a dose of at least 20 mg weekly or a maximum tolerated dose

and

☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses)

and

☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with the maximum tolerated dose of ciclosporin

or

☐ Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold

or

☐ Patient has tried and not responded to at least three months of therapy at the maximum tolerated dose of leflunomide alone or in combination with oral or parenteral methotrexate

and

☐ Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints

or

☐ Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

☐ Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application

or

☐ C-reactive protein levels 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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Adalimumab *- continued*

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)

- ☐ Applicant is a rheumatologist

or

- ☐ Applicant is a Practitioner and confirms that a rheumatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

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

- ☐ On subsequent reapplications, 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

- ☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

or

- ☐ Patient cannot take concomitant methotrexate and requires doses of adalimumab higher than 40 mg every 14 days to maintain an adequate response

Initial application — severe Behcet's disease

Applications from any relevant practitioner. Approvals valid for 3 months.

Prerequisites(tick boxes where appropriate)

☐ The patient has severe Behcet's disease that is significantly impacting the patient's quality of life (see Notes)

and

- ☐ The patient has severe ocular, neurological, gastrointestinal, rheumatological, mucocutaneous and/or vasculitic symptoms and has not responded adequately to treatment with infliximab (see Notes)

or

- ☐ The patient has severe ocular, neurological, gastrointestinal, rheumatological, mucocutaneous and/or vasculitic symptoms and has experienced intolerable side effects from treatment with infliximab

and

☐ The patient is experiencing significant loss of quality of life

and

☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

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.

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: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
.....	Address:	.....
.....	.....	.....
Fax Number:	.....	Fax Number: .....

Adalimumab *- continued*

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

- ☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

Initial application — severe chronic plaque psoriasis

Applications only from a dermatologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

- ☐ The patient has had an initial Special Authority approval for etanercept for severe chronic plaque psoriasis

and

- ☐ The patient has experienced intolerable side effects from etanercept

or

- ☐ The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for severe chronic plaque psoriasis

or

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

or

- ☐ Patient has severe chronic plaque psoriasis of the face, or palm of a hand or sole of a foot, where the plaque or plaques have been present for at least 6 months from the time of initial diagnosis

and

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

and

- ☐ A PASI assessment or Dermatology Quality of Life Index (DLQI) 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 or DLQI assessment is no more than 1 month old at the time of application

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

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Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
.....	Address:	.....
.....	.....	.....
Fax Number:	.....	Fax Number: .....

Adalimumab *- continued*

Renewal — severe chronic plaque psoriasis

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

Applications only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

- ☐ Applicant is a dermatologist

or

- ☐ Applicant is a Practitioner and confirms that a dermatologist has provided a letter, email or fax recommending that the patient continues with adalimumab treatment

and

- ☐ Patient had "whole body" severe chronic plaque psoriasis at the start of treatment

and

- ☐ Following each prior adalimumab 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-adalimumab treatment baseline value

or

- ☐ Following each prior adalimumab treatment course the patient has a Dermatology Quality of Life Index (DLQI) improvement of 5 or more, when compared with the pre-treatment baseline valuee

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 adalimumab 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 adalimumab 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-adalimumab treatment baseline value

and

- ☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

Note: A treatment course is defined as a minimum of 12 weeks adalimumab treatment

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

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Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
.....	Address:	.....
.....	.....	.....
Fax Number:	.....	Fax Number: .....

Adalimumab *- 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 infliximab for severe ocular inflammation

and

- ☐ The patient has experienced intolerable side effects from infliximab

or

- ☐ The patient has received insufficient benefit from infliximab to meet the renewal criteria for infliximab 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

and

- ☐ Adalimumab to be administered at doses no greater than 40 mg every 14 days

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 adalimumab is withdrawn.

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

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