## SA2399 - Etanercept

| **APPLICANT** (stamp or sticker acceptable) | **PATIENT** NHI: ..... | **REFERRER** Reg No: ..... |
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## Etanercept

**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 adalimumab for adult-onset Still's disease (AOSD)
  **or**
- ☐ The patient has been started on tocilizumab for AOSD in a Health NZ Hospital

**and**

- ☐ The patient has experienced intolerable side effects from adalimumab and/or tocilizumab
  **or**
- ☐ The patient has received insufficient benefit from at least a three-month trial of adalimumab 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 etanercept 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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## Etanercept *- 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 adalimumab for ankylosing spondylitis

**and**

**or**

☐ The patient has experienced intolerable side effects from adalimumab

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

**or**

☐ Patient has a confirmed diagnosis of ankylosing spondylitis present 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**

**or**

☐ 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)

☐ Patient has limitation of chest expansion by at least 2.5 cm below the 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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## Etanercept *- 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 etanercept 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**

- ☐ Etanercept to be administered at doses no greater than 50 mg every 7 days

**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 adalimumab for polyarticular course juvenile idiopathic arthritis (JIA)

**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 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

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## Etanercept *- continued*

**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

**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 adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA)

**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 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

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## Etanercept *- continued*

**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

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## Etanercept *- 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 adalimumab or secukinumab for psoriatic arthritis

**and**

**or**

☐ The patient has experienced intolerable side effects from adalimumab or secukinumab

**or**

☐ The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab 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

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## Etanercept *- 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 etanercept 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 etanercept treatment in the opinion of the treating physician

**and**

- ☐ Etanercept to be administered at doses no greater than 50 mg every 7 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, ciclosporine, azathioprine, or methotrexate) and not received an adequate response

**and**

- ☐ A maximum of 8 doses

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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## Etanercept *- continued*

**Initial application — Arthritis - rheumatoid**
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 adalimumab for rheumatoid arthritis

**and**

☐ The patient has experienced intolerable side effects

**or**

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

**or**

☐ Patient has had 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 methotrexate at a maximum tolerated dose (unless contraindicated)

**and**

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

**and**

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

**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 methotrexate

**and**

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

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## Etanercept *- continued*

**Renewal — Arthritis - rheumatoid**

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

Applications from any relevant practitioner. Approvals valid for 2 years.

**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 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**

☐ Etanercept to be administered at doses no greater than 50 mg every 7 days

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## Etanercept *- continued*

**Initial application — severe chronic plaque psoriasis**
Applications only from a dermatologist or any relevant practitioner on the recommendation of a dermatologist. Approvals valid for 4 months.

**Prerequisites**(tick boxes where appropriate)

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

**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 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 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, 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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## Etanercept *- continued*

**Renewal — severe chronic 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 etanercept 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-treatment baseline value

**or**

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

**and**

☐ Etanercept to be administered at doses no greater than 50 mg every 7 days

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

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## Etanercept *- continued*

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

- ☐ Patient has undifferentiated peripheral spondyloarthritis* with active peripheral joint arthritis in at least four joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

**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 maximum tolerated dose)

**and**

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

**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 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

Note: Indications marked with * are unapproved indications.

**Renewal — undifferentiated spondyloarthritis**

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 etanercept 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 etanercept treatment in the opinion of the treating physician

**and**

- ☐ Etanercept to be administered at doses no greater than 50 mg dose every 7 days

**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**