SA2048 - Etanercept

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APPLICANT (stamp or sticker acceptable)

Reg No: .....

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Fax Number: .....

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First Names: .....

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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 DHB hospital in accordance with the HML rules

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: .....

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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

- ☐ 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 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

- ☐ 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 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

☐ 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

or

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

☐ 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

or

☐ 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 — 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 adalimumab for rheumatoid arthritis

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 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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Etanercept *- 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 etanercept 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

- ☐ 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. 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

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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Etanercept *- 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 etanercept treatment

and

☐ 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

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

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