

SA2619 - Etanercept

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APPLICANT (stamp or sticker acceptable) **PATIENT NHI:** **REFERRER** Reg No:

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

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Fax Number: Fax Number:

Etanercept

Initial application — Stills disease - adult-onset (AOSD)

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites(tick boxes where appropriate)

Patient has had a Special Authority approval for adalimumab or tocilizumab for AOSD

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria from at least a 3-month trial of adalimumab or tocilizumab

or

Patient diagnosed with AOSD according to the Yamaguchi criteria

and

Patient has tried and received insufficient benefit from at least 6 months of corticosteroids at a dose of at least 0.5 mg/kg prednisone-equivalents, NSAIDs and methotrexate, unless contraindicated

and

Patient has persistent symptoms of disabling poorly controlled and active disease

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 from any relevant practitioner. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

Patient has had a Special Authority approval for adalimumab for ankylosing spondylitis

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for ankylosing spondylitis

or

Patient has a confirmed diagnosis of ankylosing spondylitis

and

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

and

Patient has bilateral sacroiliitis demonstrated by radiologic imaging

and

Disease has not responded adequately to treatment with two or more NSAIDs (unless contraindicated), 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 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

and

BASDAI of at least 6 on a 10-point scale completed after 3-month exercise trial before ceasing any previous pharmacological treatment and not more than 1 month before the application

Renewal — ankylosing spondylitis

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

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

Prerequisites(tick boxes where appropriate)

BASDAI has improved from pre-treatment baseline either by at least 4 points on a 10-point scale, or by at least 50%

and

Maximum dose 50 mg every 7 days

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Etanercept - continued

Initial application — arthritis - polyarticular course juvenile idiopathic

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

Prerequisites(tick boxes where appropriate)

Patient has had a Special Authority approval for adalimumab for polyarticular course juvenile idiopathic arthritis (JIA)

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for polyarticular course JIA

or

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

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, unless contraindicated

or

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

Renewal — arthritis - polyarticular course juvenile idiopathic

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

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

Prerequisites(tick boxes where appropriate)

Following initial treatment, at least a 50% decrease in active joint count from baseline

or

On subsequent reapplications, at least a continuing 30% improvement in active joint count from baseline

Initial application — arthritis - oligoarticular course juvenile idiopathic

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

Prerequisites(tick boxes where appropriate)

Patient has had a Special Authority approval for adalimumab for oligoarticular course juvenile idiopathic arthritis (JIA)

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for oligoarticular course JIA

or

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

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, unless contraindicated

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Etanercept - continued

Renewal — arthritis - oligoarticular course juvenile idiopathic

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

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

Prerequisites(tick boxes where appropriate)

Following initial treatment, at least a 50% decrease in active joint count from baseline

or

On subsequent reapplications, at least a continuing 30% improvement in active joint count from baseline

Initial application — arthritis - psoriatic

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

Prerequisites(tick boxes where appropriate)

Patient has had a Special Authority approval for adalimumab or secukinumab for psoriatic arthritis

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for psoriatic arthritis

or

Patient has received insufficient benefit from at least 3 months of methotrexate at maximum tolerated dose unless contraindicated

and

Patient received insufficient benefit from at least 3 months of sulfasalazine or leflunomide at maximum tolerated dose unless contraindicated

and

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

or

Patient has persistent symptoms of poorly controlled and active disease in at least 4 joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

and

Patient has a CRP greater than 15 mg/L measured within one month before the application

or

Patient has an ESR greater than 25 mm per hour measured within one month before the application

or

ESR and CRP not measured as patient is receiving prednisone therapy greater than 5 mg per day received for more than 3 months

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Etanercept - *continued*

Renewal — arthritis - psoriatic

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

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

Prerequisites(tick boxes where appropriate)

- Following initial treatment, at least a 50% decrease in active joint count from baseline
- or
- At least a continuing 30% improvement in active joint count from baseline

and

- Maximum dose 50 mg every 7 days

Initial application — pyoderma gangrenosum*

Applications from any relevant practitioner. Approvals valid without further renewal unless notified.

Prerequisites(tick boxes where appropriate)

- Patient has received insufficient benefit from 3 months of conventional therapy including a minimum of 3 pharmaceuticals (e.g. prednisone, ciclosporine, azathioprine, or methotrexate). Where conventional pharmaceuticals are contraindicated, a 3 month trial has occurred of those that are not contraindicated

and

- Maximum of 8 doses every 4 months

Note: Indications marked with * are unapproved indications.

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Etanercept - continued

Initial application — arthritis - rheumatoid

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

Prerequisites(tick boxes where appropriate)

Patient has had a Special Authority approval for adalimumab for rheumatoid arthritis

and

Patient has experienced intolerable side effects

or

Patient has received insufficient benefit to meet the renewal criteria for rheumatoid arthritis

or

Patient has had rheumatoid arthritis (either confirmed by radiologic imaging, or the patient is cyclic citrullinated peptide (CCP) antibody positive)

and

Patient has received insufficient benefit from at least 3 months of methotrexate at a maximum tolerated dose (unless contraindicated)

and

Patient has received insufficient benefit from at least 3 months of methotrexate in combination with sulfasalazine and hydroxychloroquine sulphate (at maximum tolerated doses unless contraindicated)

and

Patient has received insufficient benefit from at least 3 months of methotrexate in combination with the maximum tolerated dose of ciclosporin, unless contraindicated

or

Patient has received insufficient benefit from at least 3 months of therapy at the maximum tolerated dose of leflunomide alone or in combination with methotrexate, unless contraindicated

and

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

or

Patient has persistent symptoms of poorly controlled and active disease in at least 4 joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip

Renewal — arthritis - rheumatoid

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

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

Prerequisites(tick boxes where appropriate)

Following initial treatment, at least a 50% decrease in active joint count from baseline

or

On subsequent reapplications, at least a continuing 30% improvement in active joint count from baseline

and

Maximum dose 50 mg every 7 days

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Etanercept - continued

Initial application — Plaque psoriasis

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

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient has had a Special Authority approval for adalimumab for plaque psoriasis and <input type="checkbox"/> Patient has experienced intolerable side effects or <input type="checkbox"/> Patient has received insufficient benefit to meet the renewal criteria for plaque psoriasis
or <input type="checkbox"/> Patient has "whole body" plaque psoriasis with a PASI score of greater than 10 or <input type="checkbox"/> Patient has plaque psoriasis of the face, or palm of a hand or sole of a foot or <input type="checkbox"/> Patient has localised genital or flexural plaque psoriasis with a DLQI score greater than 10 and <input type="checkbox"/> Patient has received insufficient benefit from (see Note), or has experienced intolerable side effects from, at least 3 of the following at maximum tolerated doses (unless contraindicated): phototherapy, methotrexate, ciclosporin, or acitretin and <input type="checkbox"/> A PASI assessment or DLQI assessment has been completed for the most recent prior treatment course within 1 month of stopping that treatment and <input type="checkbox"/> The most recent PASI or DLQI assessment is within 1 month before the application

Note: "Insufficient benefit " is defined as: for whole body plaque psoriasis, a PASI score of greater than 10, for 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 — Plaque psoriasis

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

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

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Patient had "whole body" plaque psoriasis at the start of treatment and <table border="1"> <tr> <td> <input type="checkbox"/> Patient has a PASI score which is reduced by 75% or more, or is sustained at this level, compared with the pre-treatment baseline or <input type="checkbox"/> Patient has a DLQI improvement of 5 or more, compared with the pre-treatment baseline </td> </tr> </table>	<input type="checkbox"/> Patient has a PASI score which is reduced by 75% or more, or is sustained at this level, compared with the pre-treatment baseline or <input type="checkbox"/> Patient has a DLQI improvement of 5 or more, compared with the pre-treatment baseline
<input type="checkbox"/> Patient has a PASI score which is reduced by 75% or more, or is sustained at this level, compared with the pre-treatment baseline or <input type="checkbox"/> Patient has a DLQI improvement of 5 or more, compared with the pre-treatment baseline	
or	
<input type="checkbox"/> Patient had plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment and <table border="1"> <tr> <td> <input type="checkbox"/> 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, compared to the pre-treatment baseline or <input type="checkbox"/> Patient has a reduction of 75% or more in the skin area affected, or sustained at this level, compared to the pre-treatment baseline </td> </tr> </table>	<input type="checkbox"/> 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, compared to the pre-treatment baseline or <input type="checkbox"/> Patient has a reduction of 75% or more in the skin area affected, or sustained at this level, compared to the pre-treatment baseline
<input type="checkbox"/> 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, compared to the pre-treatment baseline or <input type="checkbox"/> Patient has a reduction of 75% or more in the skin area affected, or sustained at this level, compared to the pre-treatment baseline	
or	
<input type="checkbox"/> Patient has localised genital or flexural plaque psoriasis at the start of treatment and <table border="1"> <tr> <td> <input type="checkbox"/> Patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, compared to the pre-treatment baseline or <input type="checkbox"/> Patient has a DLQI improvement of 5 or more, compared to the pre-treatment baseline </td> </tr> </table>	<input type="checkbox"/> Patient has experienced a reduction of 75% or more in the skin area affected, or sustained at this level, compared to the pre-treatment baseline or <input type="checkbox"/> Patient has a DLQI improvement of 5 or more, compared to the pre-treatment baseline
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and	
<input type="checkbox"/> Maximum dose 50 mg every 7 days	

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Etanercept - continued

Initial application — undifferentiated spondyloarthritis*

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

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	Patient has undifferentiated peripheral spondyloarthritis with active peripheral joint arthritis in at least 4 joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip
and	
<input type="checkbox"/>	Patient has received insufficient benefit from least 3 months of each of methotrexate, sulfasalazine, and leflunomide at maximum tolerated doses, unless contraindicated
and	
<input type="checkbox"/>	Patient has a CRP level greater than 15 mg/L measured within one month before the application
or	
<input type="checkbox"/>	Patient has an ESR greater than 25 mm per hour measured within one month before the application
or	
<input type="checkbox"/>	ESR and CRP not measured as patient is currently receiving prednisone therapy greater than 5 mg per day received for more than 3 months

Note: Indications marked with * are unapproved indications.

Renewal — undifferentiated spondyloarthritis*

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

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

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	Following initial treatment, the patient has experienced at least a 50% decrease in active joint count from baseline
or	
<input type="checkbox"/>	Patient has experienced at least a continuing 30% improvement in active joint count from baseline
and	
<input type="checkbox"/>	Maximum dose 50 mg every 7 days

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

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