

SA2399 - Etanercept

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

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..... Address:

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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.

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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)

and The patient has had an initial Special Authority approval for adalimumab for ankylosing spondylitis

or 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

and 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)

<input type="checkbox"/> Applicant is a rheumatologist
or
<input type="checkbox"/> 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
<input type="checkbox"/> 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
<input type="checkbox"/> Physician considers that the patient has benefited from treatment and that continued treatment is appropriate
and
<input type="checkbox"/> 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)

and
<input type="checkbox"/> The patient has had an initial Special Authority approval for adalimumab for polyarticular course juvenile idiopathic arthritis (JIA)
or
<input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab
or
<input type="checkbox"/> The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for polyarticular course JIA
or
<input type="checkbox"/> To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
and
<input type="checkbox"/> Patient has had polyarticular course JIA for 6 months duration or longer
and
<input type="checkbox"/> 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
<input type="checkbox"/> 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
<input type="checkbox"/> 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)

and Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance

or 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)

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

or 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)

and	<input type="checkbox"/> Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance
or	<input type="checkbox"/> 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
	<input type="checkbox"/> 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)

<input type="checkbox"/> The patient has had an initial Special Authority approval for adalimumab or secukinumab for psoriatic arthritis	and	
<input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab or secukinumab	or	
<input type="checkbox"/> The patient has received insufficient benefit from adalimumab or secukinumab to meet the renewal criteria for adalimumab or secukinumab for psoriatic arthritis		

or

<input type="checkbox"/> Patient has had severe active psoriatic arthritis for six months duration or longer	and	
<input type="checkbox"/> 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	
<input type="checkbox"/> 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	
<input type="checkbox"/> Patient has persistent symptoms of poorly controlled and active disease in at least 15 swollen, tender joints	or	
<input type="checkbox"/> 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

<input type="checkbox"/> 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	
<input type="checkbox"/> Patient has an elevated erythrocyte sedimentation rate (ESR) greater than 25 mm per hour	or	
<input type="checkbox"/> 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)

<input type="checkbox"/> Applicant is a rheumatologist
or
<input type="checkbox"/> 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
<input type="checkbox"/> 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
<input type="checkbox"/> 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
<input type="checkbox"/> 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)

<input type="checkbox"/> Patient has pyoderma gangrenosum*
and
<input type="checkbox"/> 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
<input type="checkbox"/> 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)

<input type="checkbox"/> Patient has shown clinical improvement
and
<input type="checkbox"/> Patient continues to require treatment
and
<input type="checkbox"/> 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)

<input type="checkbox"/> Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance			
and			
<table border="1"><tr><td><input type="checkbox"/> 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</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> 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</td></tr></table>	<input type="checkbox"/> 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	<input type="checkbox"/> 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
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or			
<input type="checkbox"/> 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			
<input type="checkbox"/> 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)

<input type="checkbox"/> The patient has had an initial Special Authority approval for adalimumab for severe chronic plaque psoriasis
and
<input type="checkbox"/> The patient has experienced intolerable side effects from adalimumab
or
<input type="checkbox"/> The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for severe chronic plaque psoriasis
 or
<input type="checkbox"/> 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
<input type="checkbox"/> 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
<input type="checkbox"/> 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
<input type="checkbox"/> 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
<input type="checkbox"/> 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
<input type="checkbox"/> 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)

and Patient had "whole body" severe chronic plaque psoriasis at the start of treatment
or 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)

<input type="checkbox"/> 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					
<input type="checkbox"/> 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					
<input type="checkbox"/> 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					
<input type="checkbox"/> 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					
<table border="0"><tr><td><input type="checkbox"/> 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</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> 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</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> 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</td></tr></table>	<input type="checkbox"/> 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	<input type="checkbox"/> 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	<input type="checkbox"/> 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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or					
<input type="checkbox"/> 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					
<input type="checkbox"/> 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)

<input type="checkbox"/> Applicant is a rheumatologist			
or			
<input type="checkbox"/> 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			
<table border="0"><tr><td><input type="checkbox"/> 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</td></tr><tr><td>or</td></tr><tr><td><input type="checkbox"/> 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</td></tr></table>	<input type="checkbox"/> 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	<input type="checkbox"/> 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
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or			
<input type="checkbox"/> 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			
<input type="checkbox"/> Etanercept to be administered at doses no greater than 50 mg dose every 7 days			

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