RS2177 - Etanercept

Still's disease - adult-onset (AOSD) - INITIATION 7
Ankylosing spondylitis - INITIATION 4
Ankylosing spondylitis - CONTINUATION 4
Arthritis - oligoarticular course juvenile idiopathic - INITIATION 2
Arthritis - oligoarticular course juvenile idiopathic - CONTINUATION 2
Arthritis - polyarticular course juvenile idiopathic - INITIATION 2
Arthritis - polyarticular course juvenile idiopathic - CONTINUATION 2
Arthritis - psoriatic - INITIATION 5
Arthritis - psoriatic - CONTINUATION 5
Arthritis - rheumatoid - INITIATION 3
Arthritis - rheumatoid - CONTINUATION 3
Plaque psoriasis - CONTINUATION 6
Plaque psoriasis, prior TNF use - INITIATION 5
Plaque psoriasis, treatment-naive - INITIATION 6
Pyoderma gangrenosum* - INITIATION 7
Undifferentiated spondyloarthritis - INITIATION 7
Undifferentiated spondyloarthritis - CONTINUATION 8

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept

INITIATION – arthritis - polyarticular course juvenile idiopathic
Re-assessment required after 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

CONTINUATION – arthritis - polyarticular course juvenile idiopathic
Re-assessment required after 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

INITIATION – arthritis - oligoarticular course juvenile idiopathic
Re-assessment required after 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

CONTINUATION – arthritis - oligoarticular course juvenile idiopathic
Re-assessment required after 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

I confirm that the above details are correct:

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

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – arthritis - rheumatoid
Re-assessment required after 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

CONTINUATION – arthritis - rheumatoid
Re-assessment required after 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

I confirm that the above details are correct:

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

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – ankylosing spondylitis
Re-assessment required after 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 NSAID (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 score 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

CONTINUATION – ankylosing spondylitis
Re-assessment required after 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

I confirm that the above details are correct:

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

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – arthritis - psoriatic
Re-assessment required after 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 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

CONTINUATION – arthritis - psoriatic
Re-assessment required after 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

INITIATION – plaque psoriasis, prior TNF use
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has had a Special Authority approval for adalimumab for plaque psoriasis

and

- ○ Patient has experienced intolerable side effects

or

- ○ Patient has received insufficient benefit to meet the renewal criteria for adalimumab for plaque psoriasis

and

- ○ Patient must be reassessed for continuation after 3 doses

I confirm that the above details are correct:

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

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – plaque psoriasis, treatment-naive
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Patient has "whole body" severe chronic plaque psoriasis with a PASI score of greater than 10
  or
- ○ Patient has plaque psoriasis of the face, or palm of a hand, or sole of a foot
  or
- ○ Patient has localised genital or flexural plaque psoriasis with a DLQI score greater than 10

and

- ○ 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

- ○ A PASI assessment or DLQI assessment has been completed for the most recent prior treatment course within 1 month of stopping that treatment

and

- ○ The most recent PASI or DLQI assessment is within 1 month of before the applicattion

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.

CONTINUATION – plaque psoriasis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Patient had "whole body" plaque psoriasis at the start of treatment
  and
  - ○ 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
  - ○ Patient has a DLQI improvement of 5 or more, compared with the pre-treatment baseline

or

- ○ Patient had plaque psoriasis of the face, or palm of a hand or sole of a foot at the start of treatment
  and
  - ○ 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
  - ○ 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

- ○ Patient had localised genital or flexural plaque psoriasis at the start of treatment
  and
  - ○ 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
  - ○ Patient has a DLQI improvement of 5 or more, compared to the pretreatment baseline

and

- ○ Maximum 50 mg every 7 days

I confirm that the above details are correct:

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

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

INITIATION – pyoderma gangrenosum*
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, ciclosporin, 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.

INITIATION – Still's disease - adult-onset (AOSD)
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 new 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

INITIATION – undifferentiated spondyloarthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ 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

- ○ Patient has received insufficient benefit from at least 3 months of each of methotrexate, sulfasalazine, and leflunomide at maximum tolerated doses, unless contraindicated

and

  - ○ Patient has a CRP level 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 currently receiving prednisone therapy greater than 5 mg per day received for more than three months

Note: Indications marked with * are unapproved indications.

I confirm that the above details are correct:

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

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Etanercept *- continued*

CONTINUATION – undifferentiated spondyloarthritis
Re-assessment required after 2 years
Prerequisites (tick boxes where appropriate)

- ○ Following initial treatment, the patient has experienced at least a 50% decrease in active joint count from baseline

or

- ○ Patient has experienced at least a continuing 30% improvement in active joint count from baseline

and

- ○ Maximum 50 mg dose every 7 days

I confirm that the above details are correct:

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