

Below are the changes to the adalimumab, etanercept and tocilizumab criteria, effective 1 December 2020. Additions in bold, deletions in strikethrough. Changes made following consultation feedback are shown in red. Changes also include separating the polyarticular and oligoarticular course JIA criteria.

ADALIMUMAB

Initial application – (polyarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

1.1 The patient has had an initial Special Authority approval for etanercept for polyarticular course juvenile idiopathic arthritis (JIA); and

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from etanercept; or

1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for polyarticular course JIA; or

2 All of the following:

~~2.1 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and~~

2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2.2 Patient has polyarticular course JIA for 6 months duration or longer; and

2.3 Any of the following:

2.3.1 At least 5 ~~active swollen~~ joints and at least 3 joints with ~~swelling or~~ limited range of motion, pain or tenderness ~~after a 3-month trial of methotrexate (at the maximum tolerated dose); or~~

2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (~~at a dose of 10-20 mg/m² weekly or~~ at the maximum tolerated dose); or

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

~~2.4 Patient has tried and not responded to a therapeutic trial of oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose).~~

2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and

2.5 Both:

2.5.1 Either:

2.5.1.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or

2.5.1.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and

2.5.2 Physician's global assessment indicating severe disease.

ADALIMUMAB

Initial application – (oligoarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

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

1.2 Either:

- 1.2.1 The patient has experienced intolerable side effects from etanercept; or
- 1.2.2 The patient has received insufficient benefit from etanercept to meet the renewal criteria for etanercept for oligoarticular course JIA; or
- 2 All of the following:
 - 2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and
 - 2.2 Patient has oligoarticular course JIA for 6 months duration or longer; and
 - 2.3 Any of the following:
 - 2.3.1 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
 - 2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose); or
 - 2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.

ADALIMUMAB

Renewal – (polyarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both: All of the following:

1 Either:

- 1.1 Applicant is a named specialist or rheumatologist; or
- 1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with [adalimumab/ etanercept] treatment; and

1 2 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2 3 Either:

- 2.1 3.1 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
- 2.2 3.2 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.

ADALIMUMAB

Renewal – (oligoarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Both: All of the following:

1 Either:

- 1.1 Applicant is a named specialist or rheumatologist; or
- 1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with [adalimumab/ etanercept] treatment; and

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

2 Either:

- 2.1 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

2.2 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.

ETANCERCEPT

Initial application – (polyarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

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

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from adalimumab; or

1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for polyarticular course JIA; or

2 All of the following:

~~2.1 Patient diagnosed with Juvenile Idiopathic Arthritis (JIA); and~~

~~2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and~~

~~2.2 Patient has polyarticular course JIA for 6 months duration or longer; and~~

~~2.3 Either:~~

~~2.3.1 At least 5 active swollen joints and at least 3 joints with swelling or limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose); or~~

~~2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose); or~~

~~2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate; and~~

~~2.4 Patient has tried and not responded to a therapeutic trial of oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose).~~

~~2.4 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and~~

~~2.5 Both:~~

~~2.5.1 Either:~~

~~2.5.1.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or~~

~~2.5.1.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and~~

~~2.5.2 Physician's global assessment indicating severe disease.~~

ETANERCEPT

Initial application – (oligoarticular course juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

1 Both:

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

1.2 Either:

1.2.1 The patient has experienced intolerable side effects from adalimumab; or

1.2.2 The patient has received insufficient benefit from adalimumab to meet the renewal criteria for adalimumab for oligoarticular course JIA; or

2 All of the following:

2.1 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2.2 Patient has oligoarticular course JIA for 6 months duration or longer; and

2.3 Any of the following:

2.3.1 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

2.3.2 Moderate or high disease activity (cJADAS10 score greater than 1.5) with poor prognostic features after a 3-month trial of methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose); or

2.3.3 High disease activity (cJADAS10 score greater than 4) after a 6-month trial of methotrexate.

ETANCERCEPT

Renewal – (polyarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both: All of the following:

1 Either:

1.1 Applicant is a named specialist or rheumatologist; or

1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with [adalimumab/etanercept] treatment; and

1 2 Subsidised as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2 3 Either:

2.1 3.1 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

2.2 3.2 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.

ETANCERCEPT

Renewal – (oligoarticular course juvenile idiopathic arthritis) only from a named specialist, rheumatologist or Practitioner on the recommendation of a named specialist or rheumatologist.

Approvals valid for 6 months for applications meeting the following criteria:

Both: All of the following:

1 Either:

1.1 Applicant is a named specialist or rheumatologist; or

1.2 Applicant is a Practitioner and confirms that a named specialist or rheumatologist has provided a letter, email or fax recommending that the patient continues with [adalimumab/etanercept] treatment; and

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

2 Either:

2.1 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

2.2 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.

TOCILIZUMAB

Initial application – (polyarticular juvenile idiopathic arthritis) only from a named specialist or rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

Either:

1 Both:

- 1.1 The patient has had an initial Special Authority approval for both etanercept and adalimumab for polyarticular course juvenile idiopathic arthritis (JIA); and
- 1.2 The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab; or

2 All of the following:

- 2.1 Treatment with a tumour necrosis factor alpha inhibitor is contraindicated; and
- 2.2 Patient has had **severe active** polyarticular course JIA for 6 months duration or longer; and
- 2.3 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2.4 Any of the following:

- 2.4.1 At least 5 **active swollen** joints and at least 3 joints with **swelling or** limited range of motion, pain or tenderness **after a 3-month trial of methotrexate (at the maximum tolerated dose)**; or
- 2.3.2 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (~~at a dose of 10-20 mg/m² weekly or~~ at the maximum tolerated dose); or
- 2.3.3 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate

~~2.5 Patient has tried and not responded to a therapeutic trial of oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose).~~

~~2.3 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m² weekly or at the maximum tolerated dose) in combination with either oral corticosteroids (prednisone 0.25 mg/kg or at the maximum tolerated dose) or a full trial of serial intra-articular corticosteroid injections; and~~

~~2.5 Both:~~

~~2.5.1 Either:~~

~~2.5.1.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or~~

~~2.5.1.2 Patient has persistent symptoms of poorly controlled and active disease in at least four joints from the following: wrist, elbow, knee, ankle, shoulder, cervical spine, hip; and~~

~~2.5.2 Physician's global assessment indicating severe disease.~~

TOCILIZUMAB

Renewal — (polyarticular juvenile idiopathic arthritis) only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

1 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; and

2 Either:

2.1 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

2.2 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.