

# Proposed Special Authority criteria for infliximab, rituximab and tocilizumab

## Infliximab

Special Authority for Subsidy

**Initial application - (Graft vs host disease)** from any relevant practitioner. Approvals valid without further renewal unless notified where patient has steroid-refractory acute graft vs. host disease of the gut

**Initial application - (Pulmonary sarcoidosis)** from any relevant practitioner. Approvals valid without further renewal unless notified for applications meeting the following criteria:

Both:

- 1 Patient has life-threatening pulmonary sarcoidosis that is refractory to other treatments; and
- 2 Treatment is to be prescribed by, or has been recommended by, a physician with expertise in the treatment of pulmonary sarcoidosis.

**Initial application – (previous use)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient was being treated with infliximab prior to 1 February 2019; and
- 2 Either:
  - 2.1 Rheumatoid arthritis; or
  - 2.2 Ankylosing spondylitis; or
  - 2.3 Psoriatic arthritis; or
  - 2.4 Severe ocular inflammation; or
  - 2.5 Chronic ocular inflammation; or
  - 2.6 Chron's disease (adults); or
  - 2.7 Chron's disease (children); or
  - 2.8 Fistulising Chron's disease; or
  - 2.9 Severe fulminant ulcerative colitis; or
  - 2.10 Severe ulcerative colitis; or
  - 2.11 Plaque psoriasis; or
  - 2.12 Neurosarcoidosis; or
  - 2.13 Severe Behcet's disease.

**Initial application - (rheumatoid arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did

- not meet the renewal criteria for adalimumab and/or etanercept; and
- 3 Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance.

**Renewal - (rheumatoid arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 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 from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 2.2 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
- 3 Infliximab to be administered at doses no greater than 3 mg/kg every 8 weeks.

**Initial application - (ankylosing spondylitis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for ankylosing spondylitis; and
- 2 Either:
  - 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
  - 2.2 Following 12 weeks of adalimumab and/or etanercept treatment, the patient did not meet the renewal criteria for adalimumab and/or etanercept for ankylosing spondylitis.

**Renewal - (ankylosing spondylitis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Following 12 weeks of infliximab treatment, BASDAI has improved by 4 or more points from pre-infliximab baseline on a 10 point scale, or by 50%, whichever is less; and
- 2 Physician considers that the patient has benefited from treatment and that continued treatment is appropriate; and
- 3 Infliximab to be administered at doses no greater than 5 mg/kg every 6-8 weeks.

**Initial application - (psoriatic arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for psoriatic arthritis; and
- 2 Either:

- 2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
- 2.2 Following 3-4 months' initial treatment with adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for psoriatic arthritis.

**Renewal - (psoriatic 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 Either:
  - 1.1 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
  - 1.2 The patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to prior infliximab treatment in the opinion of the treating physician; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

**Initial application - (severe ocular inflammation)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient has severe, vision-threatening ocular inflammation requiring rapid control; and
- 2 Either:
  - 2.1 Treatment with high-dose steroids (intravenous methylprednisolone) followed by high dose oral steroids has proven ineffective at controlling symptoms; or
  - 2.2 Patient developed new inflammatory symptoms while receiving high dose steroids.

**Renewal - (severe ocular inflammation)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses; or
- 2 The patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema), following 12 months' treatment; or
- 3 The patient has a sustained steroid sparing effect, allowing reduction in prednisone to <10mg daily, or steroid drops less than twice daily if under 18 years old, following 12 months' treatment.

Note

A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

**Initial application - (chronic ocular inflammation)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient has severe uveitis uncontrolled with treatment of steroids and other

immunosuppressants with a severe risk of vision loss; and

2 Either:

- 2.1 Patient is 18 years or older and treatment with at least two other immunomodulatory agents has proven ineffective; or
- 2.2 Patient is under 18 years and treatment with methotrexate has proven ineffective.

**Renewal - (chronic ocular inflammation)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Any of the following:

- 1 The patient has had a good clinical response following 3 initial doses; or
- 2 The patient has had a sustained reduction in inflammation (Standardisation of Uveitis Nomenclature (SUN) criteria < ½+ anterior chamber or vitreous cells, absence of active vitreous or retinal lesions, or resolution of uveitic cystoid macular oedema), following 12 months' treatment; or
- 3 The patient has a sustained steroid sparing effect, allowing reduction in prednisone to <10mg daily, or steroid drops less than twice daily if under 18 years old, following 12 months' treatment.

Note

A trial withdrawal should be considered after every 24 months of stability, unless the patient is deemed to have extremely high risk of irreversible vision loss if infliximab is withdrawn.

**Initial application - (Crohn's disease (adults))** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe active Crohn's disease; and
- 2 Any of the following:
  - 2.1 Patient has a Crohn's Disease Activity Index (CDAI) score of greater than or equal to 300; or
  - 2.2 Patient has extensive small intestine disease affecting more than 50 cm of the small intestine; or
  - 2.3 Patient has evidence of short gut syndrome or would be at risk of short gut syndrome with further bowel resection; or
  - 2.4 Patient has an ileostomy or colostomy, and has intestinal inflammation; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate; and
- 5 Patient must be reassessed for continuation after 3 months of therapy.

**Renewal - (Crohn's disease (adults))** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 CDAI score has reduced by 100 points from the CDAI score when the patient was initiated on infliximab; or

- 1.2 CDAI score is 150 or less; or
- 1.3 The patient has demonstrated an adequate response to treatment but CDAI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

**Initial application - (Crohn's disease (children))** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Paediatric patient has severe active Crohn's disease; and
- 2 Either:
  - 2.1 Patient has a Paediatric Crohn's Disease Activity Index (PCDAI) score of greater than or equal to 30; or
  - 2.2 Patient has extensive small intestine disease; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate; and
- 5 Patient must be reassessed for continuation after 3 months of therapy.

**Renewal - (Crohn's disease (children))** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Any of the following:
  - 1.1 PCDAI score has reduced by 10 points from the PCDAI score when the patient was initiated on infliximab; or
  - 1.2 PCDAI score is 15 or less; or
  - 1.3 The patient has demonstrated an adequate response to treatment but PCDAI score cannot be assessed; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

**Initial application - (fistulising Crohn's disease)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 4 months for applications meeting the following criteria:

Both:

- 1 Patient has confirmed Crohn's disease; and
- 2 Either:
  - 2.1 Patient has one or more complex externally draining enterocutaneous fistula(e); or
  - 2.2 Patient has one or more rectovaginal fistula(e).

**Renewal - (fistulising Crohn's disease)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
  - 1.1 The number of open draining fistulae have decreased from baseline by at least 50%; or
  - 1.2 There has been a marked reduction in drainage of all fistula(e) from baseline (in the case of adult patients, as demonstrated by a reduction in the Fistula Assessment score), together with less induration and patient reported pain; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

**Initial application - (acute severe fulminant ulcerative colitis)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 weeks for applications meeting the following criteria:

Both:

- 1 Patient has acute, severe fulminant ulcerative colitis; and
- 2 Treatment with intravenous or high dose oral corticosteroids has not been successful.

**Renewal - (severe fulminant ulcerative colitis)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Where maintenance treatment is considered appropriate, infliximab should be used in combination with immunomodulators and reassessed every 6 months; and
- 2 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

**Initial application - (severe ulcerative colitis)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 3 months for applications meeting the following criteria:

All of the following:

- 1 Patient has histologically confirmed ulcerative colitis; and
- 2 Either:
  - 2.1 Patient is 18 years or older and the Simple Clinical Colitis Activity Index (SCCAI) is greater than or equal to 4; or
  - 2.2 Patient is under 18 years and the Paediatric Ulcerative Colitis Activity Index (PUCAI) score is greater than or equal to 65; and
- 3 Patient has tried but had an inadequate response to, or has experienced intolerable side effects from, prior systemic therapy with immunomodulators at maximum tolerated doses for an adequate duration (unless contraindicated) and corticosteroids; and
- 4 Surgery (or further surgery) is considered to be clinically inappropriate.

**Renewal - (severe ulcerative colitis)** only from a gastroenterologist or Practitioner on the recommendation of a gastroenterologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient is continuing to maintain remission and the benefit of continuing infliximab outweighs the risks; and
- 2 Either:
  - 2.1 Patient is 18 years or older and the SCCAI score has reduced by 2 points or more from the SCCAI score when the patient was initiated on infliximab; or
  - 2.2 Patient is under 18 years and the PUCAI score has reduced by 30 points or more from the PUCAI score when the patient was initiated on infliximab; and
- 3 Infliximab to be administered at doses up to 5 mg/kg every 8 weeks. Up to 10 mg/kg every 8 weeks (or equivalent) can be used for up to 3 doses if required for secondary non-response to treatment for re-induction. Another re-induction may be considered sixteen weeks after completing the last re-induction cycle.

**Initial application - (plaque psoriasis)** only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 3 months for applications meeting the following criteria:

Either:

- 1 Both:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab or etanercept for severe chronic plaque psoriasis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab or etanercept; or
    - 1.2.2 The patient has received insufficient benefit from adalimumab or etanercept to meet the renewal criteria for adalimumab or etanercept for severe chronic plaque psoriasis; or
- 2 All of the following:
  - 2.1 Either:
    - 2.1.1 Patient has "whole body" severe chronic plaque psoriasis with a Psoriasis Area and Severity Index (PASI) score of greater than 15, where lesions have been present for at least 6 months from the time of initial diagnosis; or
    - 2.1.2 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
  - 2.2 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
  - 2.3 A PASI 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
  - 2.4 The most recent PASI assessment is no more than 1 month old at the time of initiation.

Note

"Inadequate response" is defined as: for whole body severe chronic plaque psoriasis, a PASI score of greater than 15, 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.

**Renewal - (plaque psoriasis)** only from a dermatologist or Practitioner on the recommendation of a dermatologist. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Either:
  - 1.1 Both:
    - 1.1.1 Patient had "whole body" severe chronic plaque psoriasis at the start of treatment; and
    - 1.1.2 Following each prior infliximab 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-infliximab treatment baseline value; or
  - 1.2 Both:
    - 1.2.1 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
    - 1.2.2 Either:
      - 1.2.2.1 Following each prior infliximab 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
      - 1.2.2.2 Following each prior infliximab 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-infliximab treatment baseline value; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

**Initial application - (neurosarcoidosis)** only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months for applications meeting the following criteria:

All of the following:

- 1 Biopsy consistent with diagnosis of neurosarcoidosis; and
- 2 Patient has CNS involvement; and
- 3 Patient has steroid-refractory disease; and
- 4 Either:
  - 4.1 IV cyclophosphamide has been tried; or
  - 4.2 Treatment with IV cyclophosphamide is clinically inappropriate.

**Renewal - (neurosarcoidosis)** only from a neurologist or Practitioner on the recommendation of a neurologist. Approvals valid for 18 months for applications meeting the following criteria:

Either:

- 1 A withdrawal period has been tried and the patient has relapsed; or
- 2 All of the following:
  - 2.1 A withdrawal period has been considered but would not be clinically appropriate; and
  - 2.2 There has been a marked reduction in prednisone dose; and
  - 2.3 Either:
    - 2.3.1 There has been an improvement in MRI appearances; or
    - 2.3.2 Marked improvement in other symptomology.

**Initial application - (severe Behcet's disease)** from any relevant practitioner. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe Behcet's disease which is significantly impacting the patient's quality of life (see Notes); and
- 2 Either:
  - 2.1 The patient has severe ocular, neurological and/or vasculitic symptoms and has not responded adequately to one or more treatment(s) appropriate for the particular symptom(s) (see Notes); or
  - 2.2 The patient has severe gastrointestinal, rheumatologic and/or mucocutaneous symptoms and has not responded adequately to two or more treatment appropriate for the particular symptom(s) (see Notes); and
- 3 The patient is experiencing significant loss of quality of life.

Note

- 1 Behcet's disease diagnosed according to the International Study Group for Behcet's Disease. Lancet 1990;335(8697):1078-80. Quality of life measured using an appropriate quality of life scale such as that published in Gilworth et al J Rheumatol. 2004;31:931-7.
- 2 Treatments appropriate for the particular symptoms are those that are considered standard conventional treatments for these symptoms, for example intravenous/oral steroids and other immunosuppressants for ocular symptoms; azathioprine, steroids, thalidomide, interferon alpha and ciclosporin for mucocutaneous symptoms; and colchicine, steroids and methotrexate for rheumatological symptoms.

**Renewal - (severe Behcet's disease)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient has had a good clinical response to initial treatment with measurably improved quality of life; and
- 2 Infliximab to be administered at doses no greater than 5 mg/kg every 8 weeks.

# Rituximab

Special Authority for Subsidy

**Initial application - (Antibody-mediated renal transplant rejection)** only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid without further renewal unless notified where patient has been diagnosed with antibody-mediated renal transplant rejection\*

Note

Indications marked with \* are unapproved indications.

**Initial application - (ABO-incompatible renal transplant)** only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid without further renewal unless notified where patient is to undergo an ABO-incompatible renal transplant\*

Note

Indications marked with \* are unapproved indications.

**Initial application – (previous use)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient was being treated with rituximab prior to 1 February 2019; and
- 2 Either:
  - 2.1 haemophilia with inhibitors; or
  - 2.2 rheumatoid arthritis; or
  - 2.3 severe cold haemagglutinin disease (CHAD); or
  - 2.4 warm autoimmune haemolytic anaemia (warm AIHA); or
  - 2.5 immune thrombocytopenic purpura (ITP); or
  - 2.6 thrombotic thrombocytopenic purpura (TTP); or
  - 2.7 pure red cell aplasia (PRCA); or
  - 2.8 ANCA associated vasculitis; or
  - 2.9 treatment refractory systemic lupus erythematosus (SLE); or
  - 2.10 steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS).

**Initial application - (haemophilia with inhibitors)** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:

Any of the following:

- 1 Patient has mild congenital haemophilia complicated by inhibitors; or
- 2 Patient has severe congenital haemophilia complicated by inhibitors and has failed immune tolerance therapy; or
- 3 Patient has acquired haemophilia.

**Renewal - (haemophilia with inhibitors)** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Patient was previously treated with rituximab for haemophilia with inhibitors; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment.

**Initial application - (post-transplant)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

Both:

- 1 The patient has B-cell post-transplant lymphoproliferative disorder\*; and
- 2 To be used for a maximum of 8 treatment cycles.

Note

Indications marked with \* are unapproved indications.

**Renewal - (post-transplant)** from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has B-cell post-transplant lymphoproliferative disorder\*; and
- 3 To be used for no more than 6 treatment cycles.

Note

Indications marked with \* are unapproved indications.

**Initial application - (indolent, low-grade lymphomas or hairy cell leukaemia\*)** from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

Either:

- 1 Both:
  - 1.1 The patient has indolent low grade NHL or hairy cell leukaemia\* with relapsed disease following prior chemotherapy; and
  - 1.2 To be used for a maximum of 6 treatment cycles; or
- 2 Both:
  - 2.1 The patient has indolent, low grade lymphoma or hairy cell leukaemia\* requiring first-line systemic chemotherapy; and
  - 2.2 To be used for a maximum of 6 treatment cycles.

Note

'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. \*Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

**Renewal - (indolent, low-grade lymphomas or hairy cell leukaemia\*)** from any relevant practitioner. Approvals valid for 9 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has indolent, low-grade NHL or hairy cell leukaemia\* with relapsed disease following prior chemotherapy; and
- 3 To be used for no more than 6 treatment cycles.

## Note

'Indolent, low-grade lymphomas' includes follicular, mantle, marginal zone and lymphoplasmacytic/Waldenstrom macroglobulinaemia. \*Unapproved indication. 'Hairy cell leukaemia' also includes hairy cell leukaemia variant.

**Initial application - (aggressive CD20 positive NHL)** from any relevant practitioner. Approvals valid for 12 months further renewal unless notified for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has treatment naive aggressive CD20 positive NHL; and
  - 1.2 To be used with a multi-agent chemotherapy regimen given with curative intent; and
  - 1.3 To be used for a maximum of 8 treatment cycles; or
- 2 Both:
  - 2.1 The patient has aggressive CD20 positive NHL with relapsed disease following prior chemotherapy; and
  - 2.2 To be used for a maximum of 6 treatment cycles.

## Note

'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

**Renewal - (aggressive CD20 positive NHL)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has had a rituximab treatment-free interval of 12 months or more; and
- 2 The patient has relapsed refractory/aggressive CD20 positive NHL; and
- 3 To be used with a multi-agent chemotherapy regimen given with curative intent; and
- 4 To be used for a maximum of 4 treatment cycles.

## Note

'Aggressive CD20 positive NHL' includes large B-cell lymphoma and Burkitt's lymphoma/leukaemia.

**Initial application - (Chronic lymphocytic leukaemia)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient has progressive Binet stage A, B or C chronic lymphocytic leukaemia (CLL) requiring treatment; and
- 2 The patient is rituximab treatment naive; and
- 3 Either:
  - 3.1 The patient is chemotherapy treatment naive; or
  - 3.2 Both:
    - 3.2.1 The patient's disease has relapsed following no more than three prior lines of chemotherapy treatment; and
    - 3.2.2 The patient has had a treatment-free interval of 12 months or more if previously treated with fludarabine and cyclophosphamide chemotherapy; and
- 4 The patient has good performance status; and
- 5 The patient does not have chromosome 17p deletion CLL; and
- 6 Rituximab to be administered in combination with fludarabine and cyclophosphamide or bendamustine for a maximum of 6 treatment cycles; and

- 7 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine.

Note

'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments. 'Good performance status' means ECOG score of 0-1, however, in patients temporarily debilitated by their CLL disease symptoms a higher ECOG (2 or 3) is acceptable where treatment with rituximab is expected to improve symptoms and improve ECOG score to <2.

**Renewal - (Chronic lymphocytic leukaemia)** from any relevant practitioner. Approvals valid for 12 months for applications meeting the following criteria:

All of the following:

- 1 The patient's disease has relapsed following no more than one prior line of treatment with rituximab for CLL; and
- 2 The patient has had an interval of 36 months or more since the commencement of initial rituximab treatment; and
- 3 The patient does not have chromosome 17p deletion CLL; and
- 4 It is planned that the patient receives full dose fludarabine and cyclophosphamide (orally or dose equivalent intravenous administration) or bendamustine; and
- 5 Rituximab to be administered in combination with fludarabine and cyclophosphamide or bendamustine for a maximum of 6 treatment cycles.

Note

'Chronic lymphocytic leukaemia (CLL)' includes small lymphocytic lymphoma. A line of chemotherapy treatment is considered to comprise a known standard therapeutic chemotherapy regimen and supportive treatments.

**Initial application - (rheumatoid arthritis - prior TNF inhibitor use)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Both:
  - 1.1 The patient has had an initial community Special Authority approval for at least one of etanercept and/or adalimumab for rheumatoid arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from a reasonable trial of adalimumab and/or etanercept; or
    - 1.2.2 Following at least a four month trial of adalimumab and/or etanercept, the patient did not meet the renewal criteria for adalimumab and/or etanercept for rheumatoid arthritis; and
- 2 Either:
  - 2.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  - 2.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 3 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

**Initial application - (rheumatoid arthritis - TNF inhibitors contraindicated)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Treatment with a Tumour Necrosis Factor alpha inhibitor is contraindicated; and
- 2 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
- 3 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
- 4 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
- 5 Any of the following:
  - 5.1 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
  - 5.2 Patient has tried and not responded to at least three months of oral or parenteral methotrexate in combination with intramuscular gold; or
  - 5.3 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
- 6 Either:
  - 6.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 swollen, tender joints; or
  - 6.2 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
- 7 Either:
  - 7.1 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
  - 7.2 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; and
- 8 Either:
  - 8.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  - 8.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 9 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

**Renewal - (rheumatoid arthritis - re-treatment in 'partial responders' to rituximab)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Any of the following:
  - 1.1 At 4 months following the initial course of rituximab infusions the patient had between a 30% and 50% decrease in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician; or
  - 1.2 At 4 months following the second course of rituximab infusions the patient had 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
  - 1.3 At 4 months following the third and subsequent courses of rituximab infusions, 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
- 2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
  - 3 Either:
    - 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
    - 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
  - 4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

**Renewal - (rheumatoid arthritis - re-treatment in 'responders' to rituximab)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months for applications meeting the following criteria:

All of the following:

- 1 Either:
  - 1.1 At 4 months following the initial course of rituximab infusions the patient had 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
  - 1.2 At 4 months following the second and subsequent courses of rituximab infusions, 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
- 2 Rituximab re-treatment not to be given within 6 months of the previous course of treatment; and
- 3 Either:
  - 3.1 Rituximab to be used as an adjunct to methotrexate or leflunomide therapy; or
  - 3.2 Patient is contraindicated to both methotrexate and leflunomide, requiring rituximab monotherapy to be used; and
- 4 Maximum of two 1,000 mg infusions of rituximab given two weeks apart.

**Initial application - (severe cold haemagglutinin disease (CHAD))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Patient has cold haemagglutinin disease\*; and
- 2 Patient has severe disease which is characterized by symptomatic anaemia, transfusion dependence or disabling circulatory symptoms.

Note

Indications marked with \* are unapproved indications.

**Renewal - (severe cold haemagglutinin disease (CHAD))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Either:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m<sup>2</sup> weekly for 4 weeks) is now planned; or

- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for severe cold haemagglutinin disease\*;  
and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note

Indications marked with \* are unapproved indications.

**Initial application - (warm autoimmune haemolytic anaemia (warm AIHA))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Patient has warm autoimmune haemolytic anaemia\*;  
and
- 2 One of the following treatments has been ineffective: steroids (including if patient requires ongoing steroids at doses equivalent to >5 mg prednisone daily), cytotoxic agents (e.g. cyclophosphamide monotherapy or in combination), intravenous immunoglobulin.

Note

Indications marked with \* are unapproved indications.

**Renewal - (warm autoimmune haemolytic anaemia (warm AIHA))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Either:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m<sup>2</sup> weekly for 4 weeks) is now planned;  
or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for warm autoimmune haemolytic anaemia\*;  
and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note

Indications marked with \* are unapproved indications.

**Initial application - (immune thrombocytopenic purpura (ITP))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Both:

- 1 Either:
  - 1.1 Patient has immune thrombocytopenic purpura\* with a platelet count of less than or equal to 20,000 platelets per microlitre; or
  - 1.2 Patient has immune thrombocytopenic purpura\* with a platelet count of 20,000 to 30,000 platelets per microlitre and significant mucocutaneous bleeding; and
- 2 Any of the following:
  - 2.1 Treatment with steroids and splenectomy have been ineffective; or
  - 2.2 Treatment with steroids has been ineffective and splenectomy is an absolute

- contraindication; or
- 2.3 Other treatments including steroids have been ineffective and patient is being prepared for elective surgery (e.g. splenectomy).

Note

Indications marked with \* are unapproved indications.

**Renewal - (immune thrombocytopenic purpura (ITP))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Either:

- 1 Previous treatment with lower doses of rituximab (100 mg weekly for 4 weeks) have proven ineffective and treatment with higher doses (375 mg/m<sup>2</sup> weekly for 4 weeks) is now planned; or
- 2 All of the following:
  - 2.1 Patient was previously treated with rituximab for immune thrombocytopenic purpura\*;
  - and
  - 2.2 An initial response lasting at least 12 months was demonstrated; and
  - 2.3 Patient now requires repeat treatment.

Note

Indications marked with \* are unapproved indications.

**Initial application - (thrombotic thrombocytopenic purpura (TTP))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

Either:

- 1 Patient has thrombotic thrombocytopenic purpura\* and has experienced progression of clinical symptoms or persistent thrombocytopenia despite plasma exchange; or
- 2 Patient has acute idiopathic thrombotic thrombocytopenic purpura\* with neurological or cardiovascular pathology.

Note

Indications marked with \* are unapproved indications.

**Renewal - (thrombotic thrombocytopenic purpura (TTP))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient was previously treated with rituximab for thrombotic thrombocytopenic purpura\*; and
- 2 An initial response lasting at least 12 months was demonstrated; and
- 3 Patient now requires repeat treatment.

Note

Indications marked with \* are unapproved indications.

**Initial application - (pure red cell aplasia (PRCA))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient has autoimmune pure red cell aplasia\* associated with a demonstrable B-cell lymphoproliferative disorder

Note

Indications marked with \* are unapproved indications.

**Renewal - (pure red cell aplasia (PRCA))** only from a haematologist or Practitioner on the recommendation of a haematologist. Approvals valid for 6 weeks where patient was previously treated with rituximab for pure red cell aplasia\* associated with a demonstrable B-cell lymphoproliferative disorder and demonstrated an initial response lasting at least 12 months

Note

Indications marked with \* are unapproved indications.

**Initial application - (ANCA associated vasculitis)** from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis\*; and
- 2 The total rituximab dose would not exceed the equivalent of 375 mg/m<sup>2</sup> of body-surface area per week for a total of 4 weeks; and
- 3 Any of the following:
  - 3.1 Induction therapy with daily oral or pulse intravenous cyclophosphamide has failed to achieve significant improvement of disease after at least 3 months; or
  - 3.2 Patient has previously had a cumulative dose of cyclophosphamide >15 g or a further repeat 3 month induction course of cyclophosphamide would result in a cumulative dose >15 g; or
  - 3.3 Cyclophosphamide and methotrexate are contraindicated; or
  - 3.4 Patient is a female of child-bearing potential; or
  - 3.5 Patient has a previous history of haemorrhagic cystitis, urological malignancy or haematological malignancy.

Note

Indications marked with \* are unapproved indications.

**Renewal - (ANCA associated vasculitis)** from any relevant practitioner. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient has been diagnosed with ANCA associated vasculitis\*; and
- 2 Patient has previously responded to treatment with rituximab but is now experiencing an acute flare of vasculitis; and
- 3 The total rituximab dose would not exceed the equivalent of 375 mg/m<sup>2</sup> of body-surface area per week for a total of 4 weeks.

Note

Indications marked with \* are unapproved indications.

**Initial application - (treatment refractory systemic lupus erythematosus (SLE))** only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 7 months for applications meeting the following criteria:

All of the following:

- 1 The patient has severe, immediately life- or organ-threatening SLE\*; and
- 2 The disease has proved refractory to treatment with steroids at a dose of at least 1 mg/kg; and
- 3 The disease has relapsed following prior treatment for at least 6 months with maximal tolerated doses of azathioprine, mycophenolate mofetil and high dose cyclophosphamide, or cyclophosphamide is contraindicated; and
- 4 Maximum of four 1000 mg infusions of rituximab.

Note

Indications marked with \* are unapproved indications.

**Renewal - (treatment refractory systemic lupus erythematosus (SLE))** only from a rheumatologist, nephrologist or Practitioner on the recommendation of a rheumatologist or nephrologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient's SLE\* achieved at least a partial response to the previous round of prior rituximab treatment; and
- 2 The disease has subsequently relapsed; and
- 3 Maximum of two 1000 mg infusions of rituximab.

Note

Indications marked with \* are unapproved indications.

**Initial application - (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS))** only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient is a child with SDNS\* or FRNS\*; and
- 2 Treatment with steroids for at least a period of 3 months has been ineffective or associated with evidence of steroid toxicity; and
- 3 Treatment with ciclosporin for at least a period of 3 months has been ineffective and/or discontinued due to unacceptable side effects; and
- 4 Treatment with mycophenolate for at least a period of 3 months with no reduction in disease relapses; and
- 5 The total rituximab dose used would not exceed the equivalent of 375 mg/m<sup>2</sup> of body surface area per week for a total of 4 weeks.

Note

Indications marked with a \* are unapproved indications.

**Renewal - (Steroid dependent nephrotic syndrome (SDNS) or frequently relapsing nephrotic syndrome (FRNS))** only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient who was previously treated with rituximab for nephrotic syndrome\*; and
- 2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m<sup>2</sup> of body surface area per week for a total of 4 weeks.

Note

Indications marked with a \* are unapproved indications.

**Initial application - (Steroid resistant nephrotic syndrome (SRNS))** only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient is a child with SRNS\* where treatment with steroids and ciclosporin for at least 3 months have been ineffective; and
- 2 Treatment with tacrolimus for at least 3 months has been ineffective; and
- 3 Genetic causes of nephrotic syndrome have been excluded; and
- 4 The total rituximab dose used would not exceed the equivalent of 375 mg/m<sup>2</sup> of body surface area per week for a total of 4 weeks.

Note

Indications marked with a \* are unapproved indications.

**Renewal - (Steroid resistant nephrotic syndrome (SRNS))** only from a nephrologist or Practitioner on the recommendation of a nephrologist. Approvals valid for 4 weeks for applications meeting the following criteria:

All of the following:

- 1 Patient who was previously treated with rituximab for nephrotic syndrome\*; and
- 2 Treatment with rituximab was previously successful and has demonstrated sustained response for greater than 6 months, but the condition has relapsed and the patient now requires repeat treatment; and
- 3 The total rituximab dose used would not exceed the equivalent of 375 mg/m<sup>2</sup> of body surface area per week for a total of 4 weeks.

Note

Indications marked with a \* are unapproved indications.

# Tocilizumab

Special Authority for Subsidy

**Initial application - (cytokine release syndrome)** only from a paediatric haematologist, paediatric oncologist or Practitioner on the recommendation of a paediatric haematologist or paediatric oncologist. Approvals valid without further renewal unless notified for applications meeting the following criteria:

All of the following:

- 1 The patient is enrolled in the Children's Oncology Group AALL1331 trial; and
- 2 The patient has developed grade 3 or 4 cytokine release syndrome associated with the administration of blinatumomab for the treatment of acute lymphoblastic leukaemia; and
- 3 Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses.

**Initial application – (previous use)** from any relevant practitioner. Approvals valid for 6 months for applications meeting the following criteria:

Both:

- 1 Patient was being treated with tocilizumab prior to 1 February 2019; and
- 2 Either:
  - 2.1 rheumatoid arthritis; or
  - 2.2 systemic juvenile idiopathic arthritis; or
  - 2.3 adult-onset Still's disease; or
  - 2.4 polyarticular juvenile idiopathic arthritis; or
  - 2.5 idiopathic multicentric Castleman's disease.

**Initial application - (Rheumatoid Arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 All of the following:
  - 1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
    - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for rheumatoid arthritis; and
  - 1.3 Either:
    - 1.3.1 The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor; or
    - 1.3.2 Both:
      - 1.3.2.1 The patient has been started on rituximab for rheumatoid arthritis in a DHB hospital in accordance with the Section H rules; and
      - 1.3.2.2 Either:
        - 1.3.2.2.1 The patient has experienced intolerable side effects from rituximab; or

1.3.2.2.2 At four months following the initial course of rituximab the patient has received insufficient benefit such that they do not meet the renewal criteria for rheumatoid arthritis; or

2 All of the following:

- 2.1 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
- 2.2 Tocilizumab is to be used as monotherapy; and
- 2.3 Either:
  - 2.3.1 Treatment with methotrexate is contraindicated; or
  - 2.3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
- 2.4 Either:
  - 2.4.1 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of ciclosporin alone or in combination with another agent; or
  - 2.4.2 Patient has tried and not responded to at least three months therapy at the maximum tolerated dose of leflunomide alone or in combination with another agent; and
- 2.5 Either:
  - 2.5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints; or
  - 2.5.2 Patient has persistent symptoms of poorly controlled and active disease in at least four active joints from the following: wrist, elbow, knee, ankle, and either shoulder or hip; and
- 2.6 Either:
  - 2.6.1 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
  - 2.6.2 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.

**Renewal - (Rheumatoid Arthritis)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Following 6 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
- 2 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.

**Initial application - (systemic 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 Patient diagnosed with systemic juvenile idiopathic arthritis; and
- 2 Patient has tried and not responded to a reasonable trial of all of the following, either alone or in combination: oral or parenteral methotrexate; non-steroidal anti-inflammatory drugs (NSAIDs); and systemic corticosteroids.

**Renewal - (systemic 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:

Either:

- 1 Following up to 6 months' initial treatment, the patient has achieved at least an American College of Rheumatology paediatric 30% improvement criteria (ACR Pedi 30) response from baseline; or
- 2 On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline.

**Initial application - (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

Either:

- 1 Both:
  - 1.1 Either:
    - 1.1.1 The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD); or
    - 1.1.2 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the General Rules of the Pharmaceutical Schedule; and
  - 1.2 Either:
    - 1.2.1 The patient has experienced intolerable side effects from adalimumab and/or etanercept; or
    - 1.2.2 The patient has received insufficient benefit from at least a three-month trial of adalimumab and/or etanercept such that they do not meet the renewal criteria for AOSD; or
- 2 All of the following:
  - 2.1 Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430); and
  - 2.2 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 antiinflammatory drugs (NSAIDs) and methotrexate; and
  - 2.3 Patient has persistent symptoms of disabling poorly controlled and active disease.

**Renewal - (adult-onset Still's disease)** only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months where the patient has a sustained improvement in inflammatory markers and functional status

**Initial application - (polyarticular juvenile idiopathic arthritis)** only from a rheumatologist or Practitioner on the recommendation of a 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 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 Patient has tried and not responded to at least three months of oral or parenteral methotrexate (at a dose of 10-20 mg/m<sup>2</sup> 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
  - 2.4 To be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance; 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.

**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.

**Initial application - (idiopathic multicentric Castleman's disease)** only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 6 months for applications meeting the following criteria:

All of the following:

- 1 Patient has severe HHV-8 negative idiopathic multicentric Castleman's disease; and
- 2 Treatment with an adequate trial of corticosteroids has proven ineffective; and
- 3 Tocilizumab to be administered at doses no greater than 8 mg/kg IV every 3-4 weeks.

**Renewal - (idiopathic multicentric Castleman's disease)** only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 12 months where the treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status