

SA2100 - Tocilizumab

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

Reg No: First Names: First Names:

Name: Surname: Surname:

Address: DOB: Address:

..... Address:

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Fax Number: Fax Number:

Tocilizumab

Initial application — cytokine release syndrome

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

Prerequisites(tick boxes where appropriate)

- The patient is enrolled in the Children’s Oncology Group AALL1731 trial
- and**
- 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**
- Tocilizumab is to be administered at doses no greater than 8 mg/kg IV for a maximum of 3 doses (if less than 30kg, maximum of 12 mg/kg)

or

- The patient is enrolled in the Malaghan Institute of Medical Research Phase I ENABLE trial
- and**
- The patient has developed CRS or CAR T-Cell Related Encephalopathy Syndrome (CRES) associated with the administration of CAR T-cell therapy for the treatment of relapsed or refractory B-cell non-Hodgkin lymphoma
- and**
- Tocilizumab is to be administered according to the consensus guidelines for CRS and CRES for CAR T-cell therapy (Neelapu et al. Nat Rev Clin Oncol 2018;15:47-62) at doses no greater than 8 mg/kg IV for a maximum of 3 doses

Initial application — previous use

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

Prerequisites(tick boxes where appropriate)

- Patient was being treated with tocilizumab prior to 1 February 2019
- and**
- Rheumatoid arthritis
- or**
- Systemic juvenile idiopathic arthritis
- or**
- Adult-onset Still’s disease
- or**
- Polyarticular juvenile idiopathic arthritis
- or**
- Idiopathic multicentric Castleman’s disease

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

Signed: Date:

Post application to Ministry of Health, Private Bag 3015, Wanganui – email: customerservice@health.govt.nz

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Tocilizumab - *continued*

Initial application — Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis
and	
<input type="checkbox"/>	The patient has experienced intolerable side effects from adalimumab and/or etanercept
or	
<input type="checkbox"/>	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	
<input type="checkbox"/>	The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor
or	
<input type="checkbox"/>	The patient has been started on rituximab for rheumatoid arthritis in a DHB hospital in accordance with the Section H rules
and	
<input type="checkbox"/>	The patient has experienced intolerable side effects from rituximab
or	
<input type="checkbox"/>	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

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Tocilizumab - continued

Initial application — Rheumatoid Arthritis

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	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	
<input type="checkbox"/>	Tocilizumab is to be used as monotherapy
and	
<input type="checkbox"/>	Treatment with methotrexate is contraindicated
or	
<input type="checkbox"/>	Patient has tried and did not tolerate oral and/or parenteral methotrexate
and	
<input type="checkbox"/>	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	
<input type="checkbox"/>	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	
<input type="checkbox"/>	Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints
or	
<input type="checkbox"/>	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	
<input type="checkbox"/>	Patient has a C-reactive protein level greater than 15 mg/L measured no more than one month prior to the date of this application
or	
<input type="checkbox"/>	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

Initial application — systemic juvenile idiopathic arthritis

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/>	Patient diagnosed with systemic juvenile idiopathic arthritis
and	
<input type="checkbox"/>	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

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Tocilizumab - continued

Initial application — adult-onset Still's disease

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

- The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD)
or
 The patient has been started on tocilizumab for AOSD in a DHB hospital in accordance with the General Rules of the Pharmaceutical Schedule

and

- The patient has experienced intolerable side effects from adalimumab and/or etanercept
or
 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

- Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430)
and
 Patient has tried and not responded to at least 6 months of glucocorticosteroids at a dose of at least 0.5 mg/kg, non-steroidal antiinflammatory drugs (NSAIDs) and methotrexate
and
 Patient has persistent symptoms of disabling poorly controlled and active disease

Initial application — polyarticular juvenile idiopathic arthritis

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 4 months.

Prerequisites(tick boxes where appropriate)

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

or

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

- At least 5 active joints and at least 3 joints with limited range of motion, pain or tenderness after a 3-month trial of methotrexate (at the maximum tolerated dose)
or
 Moderate or high disease activity (cJADAS10 score of at least 2.5) after a 3-month trial of methotrexate (at the maximum tolerated dose)
or
 Low disease activity (cJADAS10 score between 1.1 and 2.5) after a 6-month trial of methotrexate

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Tocilizumab - continued

Initial application — idiopathic multicentric Castleman’s disease

Applications only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

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

Initial application — moderate to severe COVID-19*

Applications from any relevant practitioner. Approvals valid for 4 weeks.

Prerequisites(tick boxes where appropriate)

Patient has confirmed (or probable) COVID-19
and
 Oxygen saturation of < 92% on room air, or requiring supplemental oxygen
and
 Patient is receiving adjunct systemic corticosteroids, or systemic corticosteroids are contraindicated
and
 Tocilizumab is to be administered at doses no greater than 8mg/kg IV for a maximum of one dose
and
 Tocilizumab is not to be administered in combination with baricitinib

Note: Indications marked with * are unapproved indications.

Renewal — Rheumatoid Arthritis

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

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

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
 On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count from baseline and a clinically significant response to treatment in the opinion of the physician

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Tocilizumab - continued

Renewal — systemic juvenile idiopathic arthritis

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

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> 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 <input type="checkbox"/> On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline

Renewal — adult-onset Still's disease

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

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick box where appropriate)

The patient has a sustained improvement in inflammatory markers and functional status

Renewal — polyarticular juvenile idiopathic arthritis

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

Applications only from a rheumatologist or Practitioner on the recommendation of a rheumatologist. Approvals valid for 6 months.

Prerequisites(tick boxes where appropriate)

<input type="checkbox"/> Treatment is to be used as an adjunct to methotrexate therapy or monotherapy where use of methotrexate is limited by toxicity or intolerance and <input type="checkbox"/> 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 <input type="checkbox"/> On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline
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Renewal — idiopathic multicentric Castleman's disease

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

Applications only from a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist. Approvals valid for 12 months.

Prerequisites(tick box where appropriate)

The treatment remains appropriate and the patient has a sustained improvement in inflammatory markers and functional status

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