SA2489 - Tocilizumab

APPLICANT (stamp or sticker acceptable)	**PATIENT** NHI:	**REFERRER** Reg No: .....
Reg No:	First Names:	First Names: .....
Name:	Surname:	Surname: .....
Address:	DOB:	Address: .....
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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 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 ENABLE trial programme

and

- ☐ The patient has developed CRS or Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS) following 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 or ICANS for CAR T-cell therapy 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)

☐ The patient has had an initial Special Authority approval for adalimumab and/or etanercept for rheumatoid arthritis

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 rheumatoid arthritis

and

☐ The patient is seronegative for both anti-cyclic citrullinated peptide (CCP) antibodies and rheumatoid factor

or

☐ The patient has been started on rituximab for rheumatoid arthritis in a Health NZ Hospital

and

☐ The patient has experienced intolerable side effects from rituximab

or

☐ 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)

- ☐ 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

- ☐ Tocilizumab is to be used as monotherapy

and

- ☐ Treatment with methotrexate is contraindicated

or

- ☐ Patient has tried and did not tolerate oral and/or parenteral methotrexate

and

- ☐ 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

- ☐ 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

- ☐ Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints

or

- ☐ 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

- ☐ 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

- ☐ 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)

- ☐ Patient diagnosed with systemic juvenile idiopathic arthritis

and

- ☐ 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 Health NZ Hospital

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

and

- ☐ 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 barcitinib

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

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)

- ☐ 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

- ☐ On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline

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Tocilizumab *- continued*

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)

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

and

☐ Following 3 to 4 months' initial treatment, the patient has at least a 50% decrease in active joint count and an improvement in physician's global assessment from baseline

or

☐ On subsequent reapplications, the patient demonstrates at least a continuing 30% improvement in active joint count and continued improvement in physician's global assessment from baseline

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

Initial application — immune checkpoint inhibitor toxicity in malignancy*

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

Prerequisites(tick boxes where appropriate)

☐ The individual requires treatment for moderate to severe autoimmune toxicity following immune checkpoint inhibitor treatment for malignancy

and

☐ The individual has received insufficient benefit from use of corticosteroids

and

☐ Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly

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Tocilizumab *- continued*

Renewal — immune checkpoint inhibitor toxicity in malignancy*

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

Applications from any relevant practitioner. Approvals valid for 4 months.
Prerequisites(tick boxes where appropriate)

☐ The individual has shown clinical improvement and ongoing treatment is required

and

☐ Tocilizumab is to be administered at a maximum dose of 8 mg/kg fortnightly

Note: Indications marked with * are unapproved indications.

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