

SA2489 - Tocilizumab

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

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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)

or	☐ The patient has had an initial Special Authority approval for adalimumab and/or etanercept for adult-onset Still's disease (AOSD)
	☐ The patient has been started on tocilizumab for AOSD in a Health NZ Hospital
and	
or	☐ The patient has experienced intolerable side effects from adalimumab and/or etanercept
	☐ 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	
and	☐ Patient diagnosed with AOSD according to the Yamaguchi criteria (J Rheumatol 1992;19:424-430)
	☐ 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)

and	☐ The patient has had an initial Special Authority approval for both etanercept and adalimumab for polyarticular course juvenile idiopathic arthritis (JIA)
	☐ The patient has experienced intolerable side effects, or has received insufficient benefit from, both etanercept and adalimumab
or	
and	☐ Treatment with a tumour necrosis factor alpha inhibitor is contraindicated
	☐ 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	
or	☐ 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)
	☐ 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

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)

☐ and ☐

The individual has shown clinical improvement and ongoing treatment is required

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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