RS2125 - Tocilizumab

Use this checklist to determine if a patient meets the restrictions for funding in the **hospital setting**. For more details, refer to Section H of the Pharmaceutical Schedule. For community funding, see the Special Authority Criteria.

PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab

INITIATION – cytokine release syndrome
Re-assessment required after 3 doses
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

INITIATION – previous use
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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 that the above details are correct:

Signed: ..... Date: .....

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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

INITIATION – Rheumatoid Arthritis (patients previously treated with adalimumab or etanercept)
Re-assessment required after 6 months

Prerequisites (tick boxes where appropriate)

- ❍ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ❍ 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

INITIATION – Rheumatoid Arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

INITIATION – systemic juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

INITIATION – adult-onset Still's disease
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

INITIATION – polyarticular juvenile idiopathic arthritis
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

INITIATION – idiopathic multicentric Castleman's disease
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

INITIATION – moderate to severe COVID-19
Re-assessment required after 1 dose
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

CONTINUATION – Rheumatoid Arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION – systemic juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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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Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

CONTINUATION – adult-onset Still's disease
Re-assessment required after 6 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

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

CONTINUATION – polyarticular juvenile idiopathic arthritis
Re-assessment required after 6 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by a rheumatologist or Practitioner on the recommendation of a rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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

CONTINUATION – idiopathic multicentric Castleman's disease
Re-assessment required after 12 months
Prerequisites (tick box where appropriate)

- ○ Prescribed by, or recommended by a haematologist, rheumatologist or Practitioner on the recommendation of a haematologist or rheumatologist, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

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

INITIATION – immune checkpoint inhibitor toxicity in malignancy*
Re-assessment required after 4 months
Prerequisites (tick boxes where appropriate)

- ○ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

- ○ 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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PRESCRIBER

Name: .....

Ward: .....

PATIENT:

Name: .....

NHI: .....

Tocilizumab *- continued*

CONTINUATION – immune checkpoint inhibitor toxicity in malignancy*
Re-assessment required after 4 months

Prerequisites (tick boxes where appropriate)

❍ Prescribed by, or recommended by any relevant practitioner, or in accordance with a protocol or guideline that has been endorsed by the Health NZ Hospital.

and

❍ 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.

I confirm that the above details are correct:

Signed: ..... Date: .....