NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

9 December 2014

Tocilizumab for rheumatoid arthritis – use in DHB hospitals

PHARMAC is pleased to announce a decision to widen access to tocilizumab in DHB hospitals from 1 January 2015 for use in patients with severe rheumatoid arthritis who have received inadequate benefit from both a tumour necrosis factor (TNF)-alpha inhibitor (adalimumab or etanercept) and rituximab.

This was the subject of a consultation letter dated 13 November 2014, which can be found online at www.pharmac.health.nz/assets/consultation-2014-11-13-tocilizumab.pdf

The proposal was approved as consulted on.

Details of the decision

- From 1 January 2015 the following restrictions will apply to tocilizumab inj 20 mg per ml, 4 ml, 10 ml and 20 ml vial (Actemra) for rheumatoid arthritis in Part II of Section H of the Pharmaceutical Schedule (the Hospital Medicines List, or HML)

Initiation —Rheumatoid Arthritis
Rheumatologist
Re-assessment required after 6 months
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 The patient has been started on rituximab for rheumatoid arthritis in a DHB hospital in accordance with the HML rules; and
  1.4 Either:
    1.4.1 The patient has experienced intolerable side effects from rituximab; or
    1.4.2 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 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 cyclosporine 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

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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.

Continuation – Rheumatoid Arthritis
Rheumatologist
Re-assessment required after 6 months
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.

- The price of tocilizumab, and the restrictions applying to tocilizumab for Adult-onset Still's disease and systemic juvenile idiopathic arthritis, will remain unchanged.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 27 November 2014 were considered in their entirety in making a decision on the proposed changes. Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Responders asked how patients can access tocilizumab under the new criteria if they have received one of the prerequisite prior treatments (i.e. a community TNF inhibitor or rituximab) in another setting (e.g. privately funded or overseas), or if one or both of these treatments are contraindicated.	In either of these scenarios a NPPA application would need to be made as it would need to be demonstrated that the patient met the severity criteria required under the TNF inhibitor Special Authority and the rituximab HML restrictions (as applicable). These severity criteria are not specified on the tocilizumab restrictions as they are assumed to have been met when patients access the prior treatment according to the funding rules.
One responder asked about the funding of tocilizumab in multicentric Castleman's disease.	PHARMAC is seeking advice from the Pharmacology and Therapeutics Advisory Committee (PTAC) in February 2015 in relation to an application for funding of tocilizumab in this setting.

More information

If you have any questions about this decision, you can email us at enquiry@pharmac.govt.nz or call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.