CONSULTATION

PHARMAC
Pharmaceutical Management Agency

13 November 2014

Proposal to widen access to tocilizumab for treatment of rheumatoid arthritis in DHB hospitals

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

Details of the proposed changes and background information can be found below and on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5 pm** on **Thursday, 27 November 2014** to:

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All feedback received before the closing date will be considered by PHARMAC's Board (or its delegate) prior to making a decision on this proposal.

Feedback we receive is subject to the Official Information Act 1982 (OIA) and we will consider any request to have information withheld in accordance with our obligations under the OIA. Anyone providing feedback, whether on their own account or on behalf of an organisation, and whether in a personal or professional capacity, should be aware that the content of their feedback and their identity may need to be disclosed in response to an OIA request.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do, and then only to the extent permissible under the OIA and other relevant laws and requirements. If you would like us to withhold any commercially sensitive, confidential proprietary, or personal information included in your submission, please clearly state this in your submission and identify the relevant sections of your submission that you would like it withheld. PHARMAC will give due consideration to any such request

Details of the proposal

- From 1 January 2015 the restrictions in Part II of Section H of the Pharmaceutical Schedule (the Hospital Medicines List, or HML) applying to tocilizumab inj 20 mg per ml, 4 ml, 10 ml and 20 ml vial (Actemra) for rheumatoid arthritis would be amended as follows (additions in bold, deletions in strikethrough, existing restrictions renumbered for clarity):

  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

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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

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

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.

- No other changes to the listing of tocilizumab on the HML are proposed (i.e. there would be no changes to the price or to the restrictions applying to tocilizumab for Adult-onset Still's disease or systemic juvenile idiopathic arthritis).

Further Information

Tocilizumab is a recombinant humanised monoclonal antibody that binds specifically to both soluble and membrane-bound interleukin (IL)-6 receptors, thereby inhibiting IL-6 receptor-mediated signaling. It is used to suppress the immune system in diseases including rheumatoid arthritis. It is administered by intravenous infusion.

Tocilizumab is currently listed on the HML for use in rheumatoid arthritis (as monotherapy in patients who are unable to be treated with methotrexate), adult-onset Still's disease and systemic juvenile idiopathic arthritis.

The Pharmacology and Therapeutics Advisory Committee (PTAC) and the Rheumatology Subcommittee have considered tocilizumab as a last-line treatment for rheumatoid arthritis. The proposed criteria are in line with the advice received, which can be found on PHARMAC's website at: www.pharmac.govt.nz/patients/ApplicationTracker?SearchTerm=tocilizumab

We anticipate that approximately 80 to 180 additional patients per year would have access to tocilizumab as a result of this proposal. Feedback on this assumption would be appreciated.