CONSULTATION

PHARMAC
Pharmaceutical Management Agency

11 April 2014

Proposal to widen access to tocilizumab (Actemra) for rheumatoid arthritis in patients who are unable to be treated with methotrexate

PHARMAC is seeking feedback on a proposal to widen access to tocilizumab (Actemra) in DHB hospitals from 1 July 2014 through a provisional agreement with Roche Products (NZ) Limited (Roche).

In summary, from 1 July 2014 this proposal would result in:

- tocilizumab continuing to be listed on the hospital medicines list (HML) for the treatment of systemic juvenile idiopathic arthritis (sJIA), subject to the existing HML restrictions; and

- HML restrictions for tocilizumab being widened to include the treatment of severe rheumatoid arthritis in patients who are unable to be treated with methotrexate and have not responded to cyclosporine or leflunomide.

Details of the proposal can be found on the following pages.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Wednesday, 30 April 2014** to:

Geraldine MacGibbon	Email: geraldine.macgibbon@pharmac.govt.nz
Therapeutic Group Manager	Fax: 04 460 4995
PHARMAC	Post: PO Box 10 254, Wellington 6143

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.

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Details of the proposal

- Tocilizumab (Actemra) would continue to be listed in Part II of Section H of the Pharmaceutical Schedule (the HML) from 1 July 2014 at the following prices (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price
Tocilizumab	Inj 20 mg per ml, 4 ml vial	Actemra	1	$220.00
Tocilizumab	Inj 20 mg per ml, 10 ml vial	Actemra	1	$550.00
Tocilizumab	Inj 20 mg per ml, 20 ml vial	Actemra	1	$1,100.00

- From 1 July 2014 Actemra would be subject to a confidential rebate, which would reduce the net cost of tocilizumab to DHB hospitals.

- Tocilizumab would be subject to the following restrictions in the HML from 1 July 2014 (note there are no proposed changes to the sJIA criteria):

Initiation —Rheumatoid Arthritis
Rheumatologist
Re-assessment required after 6 months
All of the following:
1 Patient has had severe and active erosive rheumatoid arthritis for six months duration or longer; and
2 Tocilizumab is to be used as monotherapy; and
3 Either:
  3.1 Treatment with methotrexate is contraindicated; or
  3.2 Patient has tried and did not tolerate oral and/or parenteral methotrexate; and
4 Either:
  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
  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
5 Either:
  5.1 Patient has persistent symptoms of poorly controlled and active disease in at least 20 active, swollen, tender joints; or
  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
6 Either:
  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
  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.

Initiation – systemic juvenile idiopathic arthritis
Paediatric rheumatologist
Re-assessment required after 6 months
Both:
1 Patient diagnosed with systemic juvenile idiopathic arthritis; and
2 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.

Continuation – systemic juvenile idiopathic arthritis
Paediatric rheumatologist
Re-assessment required after 6 months
Either:
1 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
2 On subsequent reapplications, the patient demonstrates at least a continuing ACR Pedi 30 response from baseline.

Background

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 and sJIA. It is administered by intravenous infusion.

The Pharmacology and Therapeutics Advisory Committee (PTAC) and the Rheumatology Subcommittee of PTAC reviewed an application to fund tocilizumab for rheumatoid arthritis as monotherapy in patients who are unable to be treated with methotrexate. PTAC recommended listing tocilizumab for use in this indication subject to access criteria essentially as proposed, with a low priority. Details of the reviews can be found on PHARMAC's website at www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId_898.

We note that PTAC and the Rheumatology Subcommittee also reviewed an application to fund tocilizumab for a wider group of patients with rheumatoid arthritis. PTAC recommended funding tocilizumab for rheumatoid arthritis subject to access criteria restricting its use to patients who have not responded to prior treatment with standard disease modifying antirheumatic drugs and at least one tumour necrosis factor (TNF) inhibitor, with a low priority. Relative to other applications, funding tocilizumab for this patient group remains a low priority at this time and it is not part of this proposal. Details of this and other funding applications for tocilizumab can be found on PHARMAC's website at www.pharmac.govt.nz/patients/ApplicationTracker?SearchTerm_tocilizumab.