NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

14 May 2014

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

PHARMAC is pleased to announce the approval of an agreement with Roche Products (NZ) Limited to widen access to tocilizumab (Actemra) in DHB hospitals from 1 July 2014. This was the subject of a consultation letter dated 11 April 2014, available on PHARMAC's website at http://www.pharmac.health.nz/news/consultation-2014-04-11-tocilizumab.

In summary, the effect of the decision is that, from 1 July 2014:

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

Details of the decision

- Tocilizumab (Actemra) will 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 will be subject to a confidential rebate, which will reduce the net cost of tocilizumab to DHB hospitals.

- Tocilizumab will be subject to the following restrictions in the HML from 1 July 2014:

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:

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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.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 30 April 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
One responder requested various changes to the proposed restrictions, one to allow for leflunomide intolerance in criterion 4.2 and two relating to the severity requirements.	We consider that the change requested for the leflunomide criterion is not necessary, as the criterion specifies response to leflunomide at the maximum tolerated dose, which allows for intolerance (where the maximum tolerated dose could be very low). We consider that the requested changes to the severity criteria would essentially further widen access to tocilizumab which is not something PHARMAC intends to progress at this time. We note that the severity criteria are based on those for the other funded biologic treatments for rheumatoid arthritis.
Two responders asked about funding of tocilizumab for rheumatoid arthritis in patients who have not responded to prior treatment with standard disease modifying antirheumatic agents (DMARDs) and funded biologic treatment(s).	PHARMAC's Pharmacology and Therapeutics Advisory Committee (PTAC) has recommended funding tocilizumab for rheumatoid arthritis in patients who have not responded to prior treatment with standard DMARDs and at least one TNF inhibitor, with a low priority. However, relative to other funding options, the funding of tocilizumab for this patient group remains a low priority at this time and it is not part of this decision. We will ensure to take responders comments into account in any ongoing assessment of this funding application.

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.