CONSULTATION

PHARMAC
Pharmaceutical Management Agency

12 April 2013

Proposal involving pegfilgrastim and tocilizumab

PHARMAC is seeking feedback on a proposal to list pegfilgrastim (Neulastim) for prevention of neutropenia in patients undergoing cancer chemotherapy and tocilizumab (Actemra) for systemic juvenile idiopathic arthritis, from 1 July 2013, through a provisional agreement with Roche Products (NZ) Limited.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **5:00 pm on Monday 29 April 2013** to:

Geraldine MacGibbon	Email: geraldine.macgibbon@pharmac.govt.nz
Senior 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 Chief Executive acting under delegated authority) prior to making a decision on this proposal.

We are not able to treat any part of your feedback as confidential unless you specifically request that we do. 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 withheld.

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.

Details of the proposal

Pegfilgrastim

- Pegfilgrastim (Neulastim) would be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013 at a price and subsidy of $1,080 per prefilled syringe (6 mg per 0.6 ml) (ex-manufacturer, excluding GST).

- A confidential rebate would apply to Neulastim, which would reduce its net price to DHBs and the Funder.

- Neulastim would have protection from delisting and subsidy reduction until 31 December 2015.

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- Pegfilgrastim (Neulastim) would be subject to the following Special Authority restriction in Section B of the Pharmaceutical Schedule from 1 July 2013:

  Initial application only from a relevant specialist, vocationally registered general practitioner or medical practitioner on the recommendation of a relevant specialist. Approvals valid without further renewal unless notified for applications meeting the following criterion:
  1 Prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk ≥ 20%*).
  *Febrile neutropenia risk ≥ 20% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

- Pegfilgrastim would be subject to the following restriction in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013:

  For prevention of neutropenia in patients undergoing high risk chemotherapy for cancer (febrile neutropenia risk ≥ 20%*).
  *Febrile neutropenia risk ≥ 20% after taking into account other risk factors as defined by the European Organisation for Research and Treatment of Cancer (EORTC) guidelines.

Tocilizumab

- Tocilizumab (Actemra) would be listed in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013 at the following prices and subsidies (ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Price and subsidy
Tocilizumab	Inj 20 mg per ml, 4 ml vial	Actemra	1	$220
Tocilizumab	Inj 20 mg per ml, 10 ml vial	Actemra	1	$550
Tocilizumab	Inj 20 mg per ml, 20 ml vial	Actemra	1	$1,100

- Tocilizumab would be subject to the following restriction in Part II of Section H of the Pharmaceutical Schedule from 1 July 2013:

  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

Pegfilgrastim

Pegfilgrastim is a long-acting form of recombinant human granulocyte colony stimulating factor (G-CSF). G-CSF assists in the production of neutrophils, which are a type of white blood cell which have an important role in defending the body against infections.

Currently in New Zealand, access to pegfilgrastim is limited to DHB hospitals mainly for use in patients receiving chemotherapy for cancer. Only the short-acting form of G-CSF, filgrastim, is currently funded for use in the community in this patient group. One injection of pegfilgrastim is equivalent to about 10 injections of filgrastim.

When reviewing pegfilgrastim for listing in Part II of Section H from 1 July 2013, PTAC recommended that pegfilgrastim should be listed in Section H only if it is cost-neutral to filgrastim, taking into account current and future pricing of the two pharmaceuticals.

This proposal would enable patients to continue to access pegfilgrastim in hospitals beyond 1 July 2013 and would also enable patients to access funded pegfilgrastim in the community.

Tocilizumab

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 signalling. IL-6 has been implicated in the pathogenesis of diseases including rheumatoid arthritis and systemic juvenile idiopathic arthritis (sJIA). It is administered by intravenous infusion in hospital.

The Rheumatology Subcommittee of PTAC reviewed an application to list tocilizumab for sJIA at its meeting in October 2011. The application and the draft minutes from the Subcommittee meeting were subsequently reviewed by PTAC in November 2011. PTAC recommended listing tocilizumab for the treatment of sJIA subject to access criteria (with clear stopping criteria) restricting its use to patients who have not responded to prior treatment with non-steroidal anti-inflammatory drugs, methotrexate and systemic corticosteroids, with a high priority. Minutes of the PTAC and Subcommittee meetings can be found on PHARMAC's website at www.pharmac.health.nz/about/committees/ptac.

We note that at the same meetings, the Rheumatology Subcommittee and PTAC also reviewed an application to list tocilizumab for 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, tocilizumab for rheumatoid arthritis remains a low priority for listing at this time and we are not currently proposing to list tocilizumab for rheumatoid arthritis.