PHARMAC
Pharmaceutical Management Agency

24 May 2013

Approval of proposal involving pegfilgrastim and tocilizumab

PHARMAC is pleased to announce the approval of 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 an agreement with Roche Products (NZ) Limited.

This was the subject of a consultation letter dated 12 April 2013 which can be found on PHARMAC's website at: www.pharmac.health.nz/news#consultation

Details of the decision

Pegfilgrastim

- Pegfilgrastim (Neulastim) will 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 will apply to Neulastim, which will reduce its net price.

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

- Pegfilgrastim (Neulastim) will 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 where used 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.

- Pegfilgrastim will 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) will 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):

Level 9, 40 Mercer Street, PO Box 10-254, Wellington 6143, New Zealand
Phone: 64 4 460 4990 - Fax: 64 4 460 4995 - www.pharmac.govt.nz

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 will be subject to the following restrictions 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.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses 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 requested that the wording on the tocilizumab application be changed to "Paediatric Rheumatologist or a Paediatrician or Rheumatologist on the recommendation of a Paediatric Rheumatologist"	This change is not necessary as Section H rules (from 1 July) will allow prescribing on the recommendation of a paediatric rheumatologist or in accordance with hospital protocols.
One responder requested that tocilizumab also be available for use in adult-onset Still's disease (AOSD).	We have recently received an application for AOSD, which is being assessed. The application was reviewed by the Pharmacology and Therapeutics Advisory Committee (PTAC) at its meeting on 9 & 10 May 2013. The minutes of that meeting will be posted on our website once they are finalised.

Theme	Comment
One responder requested that tocilizumab also be available for use in rheumatoid arthritis.	We have previously received an application for tocilizumab in rheumatoid arthritis, which has been reviewed by both PTAC and the Rheumatology Subcommittee of PTAC. PTAC recommended listing 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 medicines that could be funded, tocilizumab for rheumatoid arthritis remains a low priority at this time.
One responder was concerned about the cost to pharmacies associated with the distribution of pegfilgrastim.	We have passed this feedback on to DHBs.

More information

If you have any questions about this decision, you can call our toll free number (9 am to 5 pm, Monday to Friday) on 0800 66 00 50.