CONSULTATION

PHARMAC
Pharmaceutical Management Agency

7 April 2014

Proposal to fund febuxostat (Adenuric) for treatment-resistant gout

PHARMAC is seeking feedback on a proposal to fund febuxostat (Adenuric) for treatment-resistant gout from 1 June 2014, subject to Special Authority criteria in the community and restrictions in DHB hospitals, through a provisional agreement with Te Arai BioFarma. Details of the proposal are shown below and on the following page.

Feedback sought

PHARMAC welcomes feedback on this proposal. To provide feedback, please submit it in writing by **Monday 28 April 2014** to:

Geraldine MacGibbon
Therapeutic Group Manager
PHARMAC

Email: geraldine.macgibbon@pharmac.govt.nz
Fax: 04 460 4995
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.

Details of the proposal

- Febuxostat tablets (Adenuric) would be listed in Section B and in Part II of Section H (the Hospital Medicines List; HML) of the Pharmaceutical Schedule from 1 June 2014 as follows (prices and subsidies ex-manufacturer, excluding GST):

Chemical	Presentation	Brand	Pack size	Proposed price and subsidy
Febuxostat	Tab 80 mg	Adenuric	28	$39.50
Febuxostat	Tab 120 mg	Adenuric	28	$39.50

- Febuxostat tablets would be listed in Section B of the Pharmaceutical Schedule subject to the following Special Authority criteria from 1 June 2014:

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

Special Authority for Subsidy
Initial application from any relevant practitioner. Applications valid for 6 months for applications meeting the following criteria:
Any of the following:
1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and appropriate doses of probenecid; or
2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite appropriate doses of probenecid; or
3 Both:
  3.1 The patient has renal impairment and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note); and
  3.2 The patient has a rate of creatinine clearance greater than or equal to 30 ml/min.

Renewal from any relevant practitioner. Approvals valid for 2 years for applications where the treatment remains appropriate and the patient is benefitting from treatment.

Note: Optimal treatment with allopurinol in patients with renal impairment is defined as treatment to the creatinine clearance-adjusted dose of allopurinol then, if serum urate remains greater than 0.36 mmol/l, a gradual increase of the dose of allopurinol to 600 mg or the maximum tolerated dose.

- Febuxostat tablets would be listed on the HML subject to the following restrictions from 1 June 2014:

Restricted
Any of the following:
1 The patient has a serum urate level greater than 0.36 mmol/l despite treatment with allopurinol at doses of at least 600 mg/day and appropriate doses of probenecid; or
2 The patient has experienced intolerable side effects from allopurinol such that treatment discontinuation is required and serum urate remains greater than 0.36 mmol/l despite appropriate doses of probenecid; or
3 Both:
  3.1 The patient has renal impairment and serum urate remains greater than 0.36 mmol/l despite optimal treatment with allopurinol (see Note); and
  3.2 The patient has a rate of creatinine clearance greater than or equal to 30 ml/min.

Note: Optimal treatment with allopurinol in patients with renal impairment is defined as treatment to the creatinine clearance-adjusted dose of allopurinol then, if serum urate remains greater than 0.36 mmol/l, a gradual increase of the dose of allopurinol to 600 mg or the maximum tolerated dose.

Background

Febuxostat is a non-purine, selective xanthine oxidase inhibitor which inhibits uric acid production by preventing the normal oxidation of purines to uric acid. It is indicated for the treatment of chronic hyperuricaemia in adults with gout.

PHARMAC's Pharmacology and Therapeutics Advisory Committee (PTAC) has reviewed a funding application for febuxostat. The Committee recommended that it be funded, with a medium priority, for patients with treatment-resistant gout subject to criteria similar to the first two criteria in this proposal (i.e. criteria 1 and 2 in the proposed Special Authority and HML restrictions). Further details can be found on PHARMAC's Application Tracker at:
http://www.pharmac.govt.nz/patients/ApplicationTracker?ProposalId=_83

Note that PTAC reviewed febuxostat again in February 2014. The minutes of that meeting have not yet been confirmed by PTAC. The Application Tracker will be updated as soon as the minutes are publicly available.