NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

14 May 2014

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

PHARMAC is pleased to announce that febuxostat (Adenuric) will be funded for treatment-resistant gout from 1 June 2014, through an agreement with Te Arai BioFarma. Febuxostat funding will be subject to Special Authority criteria in the community and restrictions in DHB hospitals.

This proposal was the subject of a consultation letter dated 7 April 2014, available on PHARMAC's website at: www.pharmac.health.nz/news/consultation-2014-04-07-febuxostat/

The proposal was approved as consulted on.

Details of the decision

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

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.

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- Febuxostat tablets will 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.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 28 April 2014 were considered in their entirety in making a decision on the proposed changes. While most responses were supportive of the proposal to fund febuxostat for treatment-resistant gout, the following issues were raised in relation to specific aspects of the proposal:

Theme	Comment
Several responders raised concerns about the potential for adverse effects if febuxostat is not prescribed appropriately, and made the following requests in relation to the Special Authority criteria to address these concerns: • the criteria should be changed such that Special Authority applications can be made only by a rheumatologist or on the recommendation of a rheumatologist; and • the Special Authority should include a requirement for regular liver function tests. Responders also considered that the Special Authority should highlight the need for prophylaxis with colchicine during febuxostat initiation to prevent gout flares.	Prescribers and their relevant professional bodies are responsible for ensuring appropriate prescribing – including where necessary ensuring sufficient education on the management of treatment-resistant gout and the use of febuxostat. This would mean ensuring they are able to prescribe it appropriately, safely and effectively, including making sure the appropriate testing (e.g. liver function testing) is performed. However, PHARMAC takes the concerns raised seriously and we intend to work with rheumatologists to develop educational material for primary care, for publication in the Best Practice Journal.
Responders requested various other changes be made to the criteria for febuxostat.	We intend to take further advice on these other requests from the Rheumatology Subcommittee of PTAC next time it meets.

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.