NOTIFICATION

PHARMAC
Pharmaceutical Management Agency

17 December 2012

Decision to list posaconazole

PHARMAC is pleased to announce the approval of an agreement with Merck Sharp & Dohme (New Zealand) Limited to list posaconazole (Noxafil) oral suspension. This was the subject of a consultation letter dated 2 November 2012. In summary, the effect of the decision is that:

- Posaconazole oral suspension 40mg/mL (Noxafil) will be listed in the Pharmaceutical Schedule from 1 January 2013;
- Posaconazole will be fully funded under Special Authority for prophylaxis of invasive fungal infections in immunocompromised patients.

A copy of the consultation letter can be found at the following link: http://pharmac.govt.nz/2012/11/02?q=posaconazole

Details of the decision

- Posaconazole oral suspension will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 January 2013. The following price and subsidy will apply (all prices are ex-manufacturer and exclude GST):

Pharmaceutical	Brand	Pack size	Price and subsidy
Posaconazole oral suspension, 40 mg per ml	Noxafil	105 ml OP	$761.13

- A confidential rebate will apply, reducing the net price of Noxafil to the Funder.
- The following Special Authority criteria will apply to the listing of posaconazole:

Initial application only from a haematologist or infectious disease specialist. Approvals valid for 6 weeks for patients meeting the following criteria:
Either:
1. Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation chemotherapy; or
2. Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppressive therapy*.

Renewal only from a haematologist or infectious disease specialist. Approvals valid for 6 weeks for patients meeting the following criteria:
Either:
1. Patient has acute myeloid leukaemia and is to be treated with high dose remission induction, re-induction or consolidation therapy; or
2. Patient has received a stem cell transplant and has graft versus host disease and is on significant immunosuppression* and requires on going posaconazole treatment.

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

* Graft versus host disease (GVHD) on significant immunosuppression is defined as acute GVHD, grade II to IV, or extensive chronic GVHD, or if they were being treated with intensive immunosuppressive therapy consisting of either high-dose corticosteroids (≥1 mg per kilogram of body weight per day for patients with acute GVHD or ≥0.8 mg per kilogram every other day for patients with chronic GVHD), antithymocyte globulin, or a combination of two or more immunosuppressive agents or types of treatment.

Please note that, following consideration of the feedback received, the wording of the Special Authority criteria has been changed from that consulted upon.

Feedback received

We appreciate all of the feedback that we received and acknowledge the time people took to respond. All consultation responses received by 16 November 2012 were considered in their entirety in making a decision on the proposal.

Most responses were supportive of the proposal, and the following issues were raised in relation to specific aspects of the proposal:

Theme	PHARMAC Comment
Taken at face value, funding would apply only to the first cycle of chemotherapy for most patients with acute myeloid leukaemia (AML) as they mostly achieve remission after that first cycle. Fungal infections are not limited to the first cycle of chemotherapy. Posaconazole prophylaxis should be available for use during "Intensive chemotherapy of AML".	PHARMAC agree and has amended the Special Authority criteria accordingly.
Patients don't have consolidation therapy after a stem cell transplant. The renewal should be for the same criteria as the initial application.	PHARMAC agree and has amended the Special Authority accordingly.

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.