

6 November 2008

## Funding of a new brand of anastrozole

We are pleased to advise that the PHARMAC Board has approved the proposal to fund Douglas Pharmaceuticals' brand of the aromatase inhibitor anastrozole and amend the Special Authority criteria applying to some other funded aromatase inhibitors. The effect of this decision is that:

- new patients with advanced breast cancer will not be eligible for the additional subsidy for letrozole (Femara) or the Arimidex brand of anastrozole;
- new patients with advanced breast cancer will be able to receive a full subsidy for DP-Anastrozole under endorsement;
- new patients with early breast cancer will continue to be eligible for the additional subsidy for letrozole and Arimidex; and
- patients with existing Special Authority approvals for letrozole or Arimidex will continue to receive a full subsidy for these products, regardless of whether they have early or advanced breast cancer.

Please note that access to exemestane, which is fully subsidised without restriction, is unaffected by these changes.

### Details of the decision

From 1 December 2008 Douglas Pharmaceuticals Limited's brand of anastrozole 1 mg tablet will be listed in the Section B, and in Part II of Section H, of the Pharmaceutical Schedule fully subsidised at a price and subsidy of \$29.50 per 30 tablets (ex-manufacturer, excluding GST).

The subsidy payable for Douglas Pharmaceuticals Limited's brand of anastrozole in Section B of the Pharmaceutical Schedule will be subject to the following endorsement:

Subsidy by endorsement – subsidised only for patients with hormone receptor positive advanced breast cancer and the prescription is endorsed accordingly.

From 1 December 2008 the Special Authority criteria for Alternate Subsidy applying to letrozole (Femara) and AstraZeneca's brand of anastrozole (Arimidex) in Section B of the Pharmaceutical Schedule will be amended as follows (changes marked in bold and strikethrough):

Special Authority for Alternate Subsidy

Initial application - **New Patients** - only from a relevant specialist. Approvals valid for 5 years for applications meeting the following criteria:

All of the following:

- 1 Patient is a postmenopausal woman; and
- 2 Patient has hormone receptor positive **early** breast cancer; and

- 3 Either:
- ~~3.1 The cancer is advanced (Stage IIIb, or metastatic Stage IV); or~~
  - 3.1 The patient has a very clear history of intolerance to tamoxifen; or
  - 3.2 The use of tamoxifen is contraindicated due to a history of thromboembolic disease.

**Initial application – Patient has had a Special Authority approval for anastrozole/letrozole prior to 1 December 2008 – only from a relevant specialist. Approval valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.**

Renewal - only from a relevant specialist. Approvals valid without further renewal unless notified where the treatment remains appropriate and the patient is benefiting from treatment.

**Note: If the patient had an approval for anastrozole/letrozole prior to 1 December 2008 the applicant is required to submit a fresh initial application in the first instance, not a renewal application. Please phone HealthPAC on 0800 243 666 for clarification if needed.**

Please note that letrozole and Arimidex will have separate Special Authority forms.

### Feedback received

This change was the subject of a consultation letter dated 30 July 2008. We appreciate all the feedback that we received and acknowledge the time that people took to respond. All responses received by 13 August 2008 were considered in their entirety prior to making a decision. Many responses were supportive of the proposal, but raised some issues in relation to specific aspects of the change:

Theme	Comment
Some consultation responders asked about bioequivalence of the new brand of anastrozole to the existing brand.	Douglas Pharmaceuticals' brand of anastrozole has been registered by Medsafe as being bioequivalent to Arimidex.
Some consultation responders expressed concern about the reduced subsidy for letrozole for patients with advanced breast cancer.	<p>Patients with a current Special Authority approval for letrozole will not be affected by this change. Similarly, new patients with early breast cancer will be unaffected.</p> <p>For new patients with advanced breast cancer, DP-Anastrozole would be available fully funded. We note that the Cancer Treatments Subcommittee of PTAC (CaTSoP) considers that all aromatase inhibitors have the same or similar therapeutic effect.</p>

### More information

If you have any queries about these changes please contact the PHARMAC helpline on 0800 66 00 50 (9 am to 5 pm weekdays).