

30 July 2008

Proposal to list DP-Anastrozole and amend the Special Authority criteria applying to Aromatase Inhibitors for hormone receptor positive breast cancer

Proposal summary

PHARMAC and Douglas Pharmaceuticals Ltd have reached a provisional agreement for funding of Douglas' brand of the aromatase inhibitor anastrozole (DP-Anastrozole) from 1 December 2008.

DP-Anastrozole would be fully subsidised for patients with hormone receptor positive advanced breast cancer without the requirement for Special Authority, however the prescriber would need to endorse the prescription to confirm that the patient has advanced breast cancer.

The current subsidy payable for the AstraZeneca brands of anastrozole (Arimidex) and letrozole (Femara) for all patients (including early breast cancer) would remain at \$146.46 per pack. However, the Special Authority criteria for a higher Alternate Subsidy would be amended from 1 December 2008 such that the higher Alternative Subsidy would not be available for patients with advanced breast cancer.

Breast cancer patients with existing Special Authority approvals for anastrozole or letrozole would continue to receive full funding for Arimidex or Femara as appropriate. Other advanced breast cancer patients would not receive full subsidy for Arimidex or Femara, instead these patients would have fully funded access to DP-Anastrozole so long as their prescriptions are endorsed by the prescriber.

Further details of the proposal can be found on the following pages.

Feedback sought

We welcome your feedback on this proposal. To provide feedback please submit an email, fax or letter by **4 pm, Wednesday 13 August 2008** to:

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Email: jackie.evans@pharmac.govt.nz
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All feedback received before the closing date will be considered by PHARMAC's Board (or Chief Executive acting under delegated authority) prior to making a decision on this proposal.

The details of the proposal

Anastrozole (DP-Anastrozole)

We have entered into a provisional agreement with Douglas Pharmaceuticals Ltd to list its brand of anastrozole (DP-Anastrozole) in the Oncology and Immunosuppressants, Endocrine Therapy section of Section B, and in Part II of Section H, of the Pharmaceutical Schedule from 1 December 2008, at the following price and subsidy (ex-manufacturer, excluding GST):

| Pharmaceutical | Brand Name | Form and Strength | Pack Size | Proposed Price and Subsidy |
|-----------------------|-------------------|--------------------------|------------------|-----------------------------------|
| Anastrozole | DP-Anastrozole | 1 mg tablet | 30 | \$29.50 |

DP-Anastrozole would be listed subject to a requirement for the following prescription endorsement for subsidy:

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

DP-Anastrozole would have protection from delisting and subsidy reduction until 1 July 2011.

DP-Anastrozole is an interim brand name; the final brand name of Douglas Pharmaceuticals' anastrozole listed in the Pharmaceutical Schedule may differ.

Anastrozole (Arimidex)

The Special Authority criteria for the higher Alternate Subsidy of \$240.00 per pack applying to AstraZeneca's brand of anastrozole (Arimidex) in Section B of the Pharmaceutical Schedule would be amended from 1 December 2008 as follows (changes marked in bold and strikethrough):

SA0810 Special Authority for Alternate Subsidy

Initial application 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 Any of the following:
 - ~~3.1~~ ~~The cancer is advanced (Stage IIIb, or metastatic Stage IV); or~~
 - 3.1² The patient has a very clear history of intolerance to tamoxifen; or
 - 3.2³ The use of tamoxifen is contraindicated due to a history of thromboembolic disease.

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.

Letrozole (Femara)

The Special Authority criteria for Alternate Subsidy of \$200.00 per pack applying to letrozole (Femara) in Section B of the Pharmaceutical Schedule would be amended from 1 December 2008 as follows (changes marked in bold and strikethrough):

SA0810 Special Authority for Alternate Subsidy

Initial application 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 Any of the following:
 - ~~3.1 The cancer is advanced (Stage IIIb, or metastatic Stage IV); or~~
 - 3.12 The patient has a very clear history of intolerance to tamoxifen; or
 - 3.23 The use of tamoxifen is contraindicated due to a history of thromboembolic disease.

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.

Background to the proposal

Tamoxifen is the standard endocrine treatment for patients with hormone receptor positive breast cancer. Selective aromatase inhibitors offer an alternative management option.

There are currently three aromatase inhibitors listed in the Pharmaceutical Schedule – anastrozole (Arimidex), letrozole (Femara) and exemestane (Aromasin). Anastrozole and letrozole are reversible (Type II) non-steroidal aromatase inhibitors. Exemestane is a steroidal aromatase inhibitor. The Cancer Treatments Subcommittee of PTAC considers that all the aromatase inhibitors demonstrate the same or similar therapeutic effect.

PHARMAC understands that, currently, the suppliers of both Arimidex (AstraZeneca) and Femara (Novartis) are bonusing stock to pharmacists, which enables patients who do not meet the current Special Authority criteria for alternate subsidy (for example, patients with early breast cancer who have not previously taken tamoxifen) to obtain these products without having to pay the manufacturers' surcharge. This proposal would not prevent suppliers from continuing to bonus stock.

The price and subsidy payable for exemestane (Aromasin) 25 mg would remain unchanged. Subsidised access to Aromasin is not subject to any restriction.

PHARMAC had previously indicated to some parties that we may run a Request For Proposals (RFP) for the supply of Aromatase Inhibitors. If this proposal is approved by PHARMAC's Board (or Chief Executive acting under delegated authority) it does not preclude PHARMAC from running an RFP or Tender in the future, however, any such RFP or Tender (if run) would not allow for subsidy reduction or delisting of DP-Anastrozole prior to 1 July 2011.

Where can I find more information?

You can seek further information by contacting Jackie Evans on +64 (0) 4 916 7557 or by e-mail jackie.evans@pharmac.govt.nz.