

11 August 2009

Proposal relating to Douglas Pharmaceutical's anastrozole approved

PHARMAC is pleased to announce the approval of a proposal to remove the endorsement from Douglas Pharmaceutical's brand of anastrozole.

Detail

From 1 September 2009 the 'subsidy by endorsement' restriction that currently applies to the prescribing and dispensing of Douglas Pharmaceuticals Limited's brand of anastrozole (DP-Anastrozole) tab 1 mg in the Oncology Agents and Immunosuppressants therapeutic group in Section B of the Pharmaceutical Schedule will be removed as follows:

ANASTROZOLE-DP – Subsidy by endorsement			
Subsidised only for patients with hormone receptor positive advanced breast cancer and the prescription is endorsed accordingly			
Tab 1 mg.....	29.50	30	√ DP-Anastrozole

The purpose of removing the endorsement is to remove the barrier to the use of DP-Anastrozole in patients with advanced breast cancer. PHARMAC considers that the endorsement created an unnecessary administrative burden on prescribers and removing it should increase the use of DP-Anastrozole in advanced breast cancer patients. This would result in savings to the community pharmaceuticals budget - savings which may be used to fund other pharmaceuticals.

Feedback Received

We appreciate all the feedback we received during consultation and acknowledge the time people took to respond. All consultation responses received were considered by the PHARMAC Board in their entirety prior to the Board making its decision on the proposal.

Consultation responses raised a variety of issues.

- Some expressed concerns that DP-Anastrozole was not indicated for early breast cancer and, therefore, in their view removing the endorsement would result in its use in these patients which is outside its Medsafe approved indication (i.e. off-label prescribing); and
- Some considered that the current endorsement assists prescribers and pharmacists by making them aware of the approved indication for DP-Anastrozole.

PHARMAC notes that the purpose of an endorsement, on a listing in the Pharmaceutical Schedule, is not to inform authorised prescribers and pharmacists of a medicine's approved indications; rather, endorsements, as with other restrictions on medicines listed in the Pharmaceutical Schedule, are used to manage expenditure.

As a result of PHARMAC's decision both DP-Anastrozole and Arimidex will be fully funded without restriction from 1 September 2009. As noted in some consultation responses, the two products are approved for different indications.

The Medsafe approved indication for Arimidex is:

1. Treatment of early breast cancer in hormone receptor positive post-menopausal women.
2. Adjuvant treatment of early breast cancer in hormone receptor positive postmenopausal women who have received 2 to 3 years of adjuvant tamoxifen.
3. Reduction in the incidence of contralateral breast cancers in post menopausal women receiving Arimidex as adjuvant treatment for early breast cancer.
4. Treatment of advanced breast cancer in post-menopausal women.

The Medsafe approved indication for DP-Anastrozole is:

1. Treatment of advanced breast cancer in post-menopausal women.

PHARMAC considers that the Medsafe approved medicine Datasheet, not the Pharmaceutical Schedule, is the most appropriate document to inform authorised prescribers of a medicine's approved indication(s). In the context of providing information regarding indications in the Pharmaceutical Schedule Notes are generally used only where Special Authorities target funding specifically at patients for "Unapproved Indications", that is not the case here.

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).