

23 September 2008

Bicalutamide to be funded for advanced prostate cancer

We are pleased to advise that the PHARMAC Board has accepted the tender from Douglas Pharmaceuticals Limited for its brand of bicalutamide tab 50 mg, Bicalox, to be the sole subsidised brand of this pharmaceutical in Section B and the hospital supply status brand in Part II of Section H of the Pharmaceutical Schedule until 30 June 2011.

This means that bicalutamide will be fully subsidised under Special Authority for patients with advanced prostate cancer from 1 November 2008.

The listing of bicalutamide will provide a new funded treatment option for patients with advanced prostate cancer. Bicalutamide is at least as efficacious as flutamide, another funded medicine, in the advanced prostate cancer setting for prolonging survival and preventing or delaying disease progression, but it has fewer side effects and has more convenient dosing (50 mg tablet once daily) compared with flutamide (3 x 250 mg tablets daily).

Details of the decision

Bicalutamide tab 50 mg (Bicalox) will be listed in Section B and in Part II of Section H of the Pharmaceutical Schedule from 1 November 2008 at a price and subsidy of \$27.10 per 30 tablets, and will be subject to the following Special Authority restriction in Section B of the Pharmaceutical Schedule:

Special Authority for Subsidy

Initial application from any medical practitioner, approvals valid without further renewal, unless notified, for patients with advanced prostate cancer.

Other changes relating to the listing of Bicalox in Part II of Section H of the Pharmaceutical Schedule will be notified elsewhere.

What feedback was received?

This change was the subject of a consultation letter dated 27 June 2008, in which we proposed that access would be restricted to treatment only in combination with other medicines known as GnRH analogues.

We appreciate all the feedback we received and acknowledge the time people took to respond. All consultation responses received by 18 July 2008 were considered in their entirety in making a decision on the proposed changes. Clinicians that responded were generally supportive of the proposal whereas pharmaceutical companies were not.

Theme	Response
<p>Arguments were put forward in favour of monotherapy.</p>	<p>Having considered the issues raised we decided to make access available for monotherapy.</p>
<p>Suppliers were concerned about the extent of consultation and the opportunity to provide feedback, and asked that the tender be declined and an alternate process conducted.</p>	<p>Bicalutamide was not included in the draft tender list in 2007. Feedback from suppliers resulted in bicalutamide being added. This has been the established practice for many years.</p> <p>Bicalutamide was included in the tender document in December 2007, and widely circulated. Additionally, we issued a consultation on 27 June 2008, primarily seeking feedback on the proposed access criteria.</p> <p>Having evaluated the issues raised we considered that the extent of consultation and opportunity to provide feedback was appropriate, and no further action was needed.</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).