

30 March 2006

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To All Interested Parties

By facsimile (2 pages)

Proposal regarding widening access to goserelin acetate for locally advanced prostate cancer

PHARMAC and AstraZeneca have entered into a provisional agreement to amend the terms of listing of goserelin acetate (Zoladex).

PHARMAC proposes to widen the Special Authority access to provide a subsidy for patients with locally advanced prostate cancer.

If this proposal is approved by PHARMAC's Board (or Chief Executive acting under delegated authority), the change would occur from 1 June 2006. If you would like to make any comments on this proposal, please ensure that we receive them by **5pm, Thursday 13 April 2006**.

The key features of this proposal are as follows:

- The existing Special Authority criteria for access to a subsidy for goserelin acetate would be amended as follows (proposed changes in bold and strikethrough):

Initial application - (breast cancer) from any medical practitioner. Approvals valid for 1 year for applications meeting the following criteria:

Breast cancer in premenopausal women unwilling or unable to undergo surgical or radiation oophorectomy.

Initial application - (Prostate cancer) only from an oncologist, urologist or endocrinologist. Approvals valid for 1 year for applications meeting the following criteria:

Either:

1 Advanced prostatic cancer; ~~or when orchidectomy is contraindicated or where the patient strongly opposes orchidectomy.~~

2 Locally advanced prostatic cancer (only goserelin acetate indicated).

Note not to be prescribed with an anti-androgen except for a period of three weeks, if necessary, when GnRH analogue therapy is initiated.

Initial application - (endometriosis) only from a gynaecologist. Approvals valid for 3 months for applications meeting the following criteria:

Both:

3 endometriosis; and

4 either:

4.1 6 months treatment with medroxyprogesterone acetate, danazol or dimetrioise has proven ineffective; or

4.2 the patient has failed to tolerate the treatment with medroxyprogesterone acetate, danazol or dimetrioise for 6 months.

Note the maximum treatment period for a GnRH analogue is:

- 3 months to assess whether surgery is appropriate
- 3 months for infertile patients after surgery

- 6 months for patients with symptoms of endometriosis. After the first 3 months patients should be assessed to determine whether there has been a satisfactory response to the first 3 months treatment.

Initial application - (Precocious puberty) only from a paediatrician or endocrinologist. Approvals valid for 1 year for applications meeting the following criteria:

Patients affected by gonadotropin dependent precocious puberty.

Renewal - (breast or prostate cancer) from any medical practitioner. Approvals valid for 1 year for applications meeting the following criteria:

The treatment remains appropriate and the patient is benefiting from treatment.

Renewal - (endometriosis) from any medical practitioner. Approvals valid for 3 months for applications meeting the following criteria:

Either:

~~53~~ both:

~~53.1~~ there has been a satisfactory response to the first 3 months treatment;

and

~~53.2~~ Surgery is inappropriate; or

~~64~~ the first three months of therapy did not follow surgery for infertility.

Renewal - (Precocious puberty) only from a paediatrician or endocrinologist.

Approvals valid for 1 year for applications meeting the following criteria:

The treatment remains appropriate and the patient is benefiting from treatment.

Note: The approved indications for each of the presentations of GnRH analogues are different. Practitioners should be aware of the approved indications for each product and comply with their obligations under the Medicines Act 1981, the Medicines Regulations 1984 and the Health and Disability Commissioner's Code of Consumer Rights.

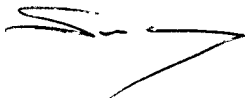
- Zoladex would be protected from price and subsidy changes (including reference pricing) and delisting until January 2011.
- The following restrictions applying to the use of goserelin acetate and leuprorelin would be deleted:

Goserelin acetate 10.8 mg ~~Subsidised only for the treatment of prostate cancer~~

Leuprorelin Inj 11.25 mg ~~Subsidised only for treatment of prostate cancer and breast cancer~~

PHARMAC's Board (or CEO under delegated authority) will consider this proposal in April 2006. If you have comments to make on this proposal and would like those comments to be considered by the PHARMAC Board then please send them to Steffan Crausaz at PHARMAC by **5pm, Thursday 13 April 2006**.

Yours sincerely



Steffan Crausaz
Acting Manager, Supply Side