

Record of Recommendation

Re: Funding Degarelix (Firmagon[®]) in Advanced or Metastatic Hormone Dependent Prostate Cancer

January 2011

Discussion facilitated using the Decision Making Framework.

- All present will vote electronically when the vote is called by the Chair. The voting process will be completed by 5 pm on January 24, 2011. The decision will be made by a majority with dissenting voters given the opportunity to record their opinion. Dissenting opinions must be recorded within seven days of the result of the vote being announced.
- Core values and principles were reviewed and discussed along with competing obligations, constraints and relevant information.
- Options for a recommendation to the Deputy Minister were reviewed and each option was discussed. Two options were identified at this time:
 - 1) Approval of funding with restrictions
 - 2) Denial of funding
- An analysis of the projected benefits and burdens of each option was discussed.

Background:

- ✓ Androgen deprivation therapy is used in advanced and metastatic prostate cancer to reduce testosterone levels and slow tumour growth.
- ✓ Androgen deprivation can be achieved through surgical castration or treatment with GnRH/LHRH agonists which are currently on the market.
- ✓ Degarelix (Firmagon[®]) is a GnRH/LHRH antagonist. Degarelix binds to pituitary GnRH receptors which rapidly reduces the release of LH and FSH. Testosterone is reduced to castration levels within 3 days.

Projected Benefits:

- ✓ A phase III trial compared degarelix (initial dose of 240mg and maintenance dose of 160mg or 80mg) versus leuprolide 7.5mg i.m. monthly in men with confirmed adenocarcinoma of prostate (all stages) for whom endocrine treatment was indicated.
- ✓ Testosterone suppression between 28 and 364 days was similar for degarelix 240/160mg, degarelix 240/80mg and leuprolide (98.3%, 97.2% versus 96.4%). By day 3, 95.5 % and 96.1% of patients receiving degarelix had reached castration levels, with no flare or microsurgers, and very low testosterone levels maintained over 1 year.
- ✓ PSA levels were assessed as a surrogate marker for disease progression in an exploratory subgroup analysis. The one year incidence and probability of PSA recurrence, death, and probability of death was lower with degarelix.
- ✓ In a cost minimization analysis, which assumes the clinical equivalence of comparators, degarelix is a cost saving option.

Projected Burdens:

- ✓ The most frequently reported adverse events were of mild to moderate intensity. Degarelix injection was associated with a higher rate of injection site reactions than leuprolide; reactions were predominantly after the first injection.
 - ✓ Degarelix has not been compared with the gold standard of orchiectomy or versus other dosing schedules of leuprolide (with the standard practice of adding bicalutamide) or other agents. It requires monthly dosing whereas alternative products have longer-acting formulations available.
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Result of Vote:

The vote was conducted electronically. The question the Committee was asked to vote on was: “Should the Committee support a recommendation to the Deputy Minister of Health to fund degarelix as a therapeutic option for testosterone suppression in patients with advanced or metastatic hormone dependent prostate cancer”.

- The result of the vote was a majority recommending funding.
- This recommendation has been accepted by the Deputy Minister of Health and funding has been approved in the Nova Scotia Pharmacare Programs.