

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

TRIPTORELIN PAMOATE (Trelstar® – Paladin Labs Inc.)

Description:

Triptorelin is a synthetic agonist analog of luteinizing hormone-releasing hormone (LHRH) that is approved for use in the palliative treatment of hormone dependent advanced carcinoma of the prostate gland (stage D2).

Dosage Forms:

3.75 mg vial (1 month slow release), 11.25 mg vial (3 month slow release) for intramuscular (IM) injection

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that triptorelin pamoate be listed in a similar manner as drug plans list other LHRH analogs for prostate cancer.

Reasons for the Recommendation:

1. The Committee reviewed one randomized controlled trial (RCT) which compared triptorelin pamoate 3.75 mg IM monthly with leuprolide 7.5 mg IM monthly in 277 men with stage C and D prostate cancer. Although significantly more men in the leuprolide group achieved castration levels of testosterone at day 29 of therapy, there was no difference between the groups in this outcome between two and nine months of therapy. There were no significant differences between the groups in bone pain scores, prostate specific antigen concentrations, measures of quality of life or adverse events.
2. In this RCT, there were no significant differences between triptorelin and leuprolide in all-cause mortality or disease-progression related deaths. The publication reports a Kaplan-Meier analysis that claims a statistically significant difference in mortality in favour of triptorelin. However, the Committee was not convinced that this difference was due to triptorelin since there were differences in the duration of disease at baseline between the two groups.
3. The most common adverse effects of triptorelin are related to decreases in testosterone levels – hot flushes, impotence and reduced libido. The rates of these adverse effects with triptorelin appear similar to other LHRH agonists.

4. Triptorelin 3.75 mg monthly costs approximately \$345 per month, which is similar to or slightly less expensive than other LHRH agonists.

Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.