CANADIAN COORDINATING OFFICE FOR HEALTH TECHNOLOGY ASSESSMENT

OFFICE CANADIEN DE COORDINATION DE L'ÉVALUATION DES TECHNOLOGIES DE LA SANTÉ

CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

QUINAGOLIDE
(Norprolac® – Ferring Pharmaceuticals Inc.)

Description:
Quinagolide is a selective dopamine-2 receptor agonist indicated for the treatment of hyperprolactinemia (idiopathic or originating from a prolactin-secreting pituitary microadenoma or macroadenoma).

Recommendation:
The Canadian Expert Drug Advisory Committee (CEDAC) recommends that quinagolide not be listed.

Dosage Forms:
0.075 and 0.15 mg tablets

Reasons for the recommendation:
1. In four randomized controlled trials (RCTs) quinagolide was similar in efficacy compared with bromocriptine with respect to lowering/normalizing serum prolactin, resolution of amenorrhea/oligomenorrhea and resolution of galactorrhea. Limited evidence from direct comparisons of quinagolide and cabergoline (2 small RCTs) suggest similar efficacy.

2. A meta-analysis of three RCTs comparing quinagolide with bromocriptine found fewer withdrawals due to adverse effects in quinagolide treated patients, although the interpretation of this information is difficult as many of the patients in these trials had been previously treated with bromocriptine.

3. Women wishing to conceive may be treated with quinagolide, but its risk to the fetus are not known because there are limited published data to support its safety in pregnancy. In one published summary of 169 pregnancies with exposure to quinagolide, there were two cases of aneuploidy (one case of trisomy 21 and one case of trisomy 13).

4. At average doses, quinagolide ($1.7l-3.06 per day) is more expensive than bromocriptine ($1.09-1.63 per day) and similar in cost to cabergoline ($0.90-3.38 per day).

Of Note:
1. There are no RCTs of newly diagnosed patients with hyperprolactinemia that compare quinagolide to bromocriptine or cabergoline.

2. Both published and unpublished data were used and taken into consideration in making this recommendation.