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

ATOMOXETINE (StratteraTM – Eli Lilly Canada Inc)

Description:

Atomoxetine (StratteraTM) is an inhibitor of norepinephrine re-uptake approved by Health Canada for the treatment of attention deficit hyperactivity disorder (ADHD) in children 6 years of age and over, adolescents and adults. It is indicated as part of a program that includes psychological, educational and social measures.

Dosage Forms:

10, 18, 25, 40 and 60 mg capsules

Recommendation:

The Canadian Expert Drug Advisory Committee recommends that atomoxetine not be listed.

Reasons for the Recommendation:

- 1. In randomized controlled trials (RCTs), atomoxetine has been shown to be more effective than placebo for ADHD symptoms. However, atomoxetine has not been proven superior to methylphenidate products. There are no published studies that assess the efficacy of atomoxetine in patients who have not responded to methylphenidate or dexamphetamine.
- 2. Atomoxetine is the only agent approved in Canada for ADHD in adults. However, there is clinical evidence and experience with the use of less expensive alternatives in adults with ADHD.
- 3. Atomoxetine is not contraindicated in patients with ADHD who also have motor tics or Tourette's syndrome. Although methylphenidate product monographs list patients with motor tics or with a family history or diagnosis of Tourette's syndrome under "Contraindications", there are studies that show that methylphenidate can be used to treat ADHD in patients with co-morbid tics or Tourette's syndrome.
- 4. The cost of atomoxetine is higher than the cost of methylphenidate products or dexampletamine, particularly if taken more than once per day.
- 5. Although there are no RCTs in patients who are intolerant to methylphenidate or dexamphetamine, atomoxetine may be considered an alternative in patients who have not been able to tolerate an appropriate trial of methylphenidate and dexamphetamine.

Common Drug Review

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Of Note:

- 1. The adverse effects of atomoxetine are qualitatively similar to methylphenidate and dexamphetamine, and include increases in blood pressure, heart rate, mydriasis, insomnia, urinary disorders and reduced weight gain.
- 2. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.

Common Drug Review