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

PREGABALIN
(Lyrica - Pfizer Canada Inc.)

Description:
Pregabalin is approved for the management of neuropathic pain associated with diabetic peripheral neuropathy (DPN) and postherpetic neuralgia (PHN).

Dosage Forms:
25 mg, 50 mg, 75 mg, 150 mg and 300 mg capsules

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

Reasons for the Recommendation:

1. The Committee considered the results of 12 randomized controlled trials (RCTs), 6 in painful DPN, 5 in PHN and 1 in a mixed painful DPN and PHN population. With the exception of 1 RCT in painful DPN that included amitriptyline as a comparator, all trials were placebo controlled and of relatively short duration (≤13 weeks). The lack of RCTs comparing pregabalin to other therapies makes it very difficult to determine the relative efficacy and safety of pregabalin.

2. Compared to placebo, pregabalin produced statistically significant improvements in numerical pain rating scales and patient global impression of change in patients with PHN and painful DPN. Higher doses were more likely to produce greater improvements in the pain rating scales. However, higher doses were also more likely to be associated with more frequent adverse effects.

3. In the studies reviewed, the withdrawal rate was between 5-38% in pregabalin treatment arms and 8-46% in the placebo arms. High withdrawal rates decrease confidence in the study results.

4. The rate of discontinuation due to adverse effects was 11.4% for pregabalin and 5.1% for placebo. Adverse effects that most frequently led to discontinuation of pregabalin include dizziness, somnolence, confusion, peripheral edema, ataxia and asthenia.

5. There are other treatment options for patients with painful DPN and PHN, including narcotic and non-narcotic agents. In the one RCT in painful DPN that compared placebo, pregabalin 600 mg daily and amitriptyline 75 mg daily, amitriptyline caused statistically significant improvement in pain control compared to placebo whereas pregabalin did not. In this trial there was no statistically significant difference in pain control between pregabalin and amitriptyline.

6. Pregabalin costs are higher than tricyclic antidepressants. Interpretation of the pharmacoeconomic model submitted by the manufacturer, which compared pregabalin with gabapentin, was limited by the difficulty in determining dose equivalency between these two agents.

Of Note:

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