

CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

RASAGILINE MESYLATE (Azilect™ – Teva Neuroscience)

Description:

Rasagiline is an irreversible, monoamine oxidase inhibitor (MAO) type B which is approved for the treatment of the signs and symptoms of idiopathic Parkinson's disease as initial monotherapy and as adjunct therapy to levodopa.

Dosage Forms:

0.5 and 1 mg tablets. The recommended dose is 1 mg once daily.

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that rasagiline not be listed.

Reasons for the Recommendation:

1. There have been no randomized controlled trials (RCTs) comparing rasagiline with selegiline, a MAO inhibitor in the same class as rasagiline. Therefore, it is unknown if rasagiline offers any clinically important advantages over selegiline.
2. At usual doses, rasagiline costs \$7 per day (dose of 1 mg daily), which is more expensive than selegiline (\$2.78 for 10 mg per day).

Summary of Committee Considerations:

The Committee considered a systematic review of randomized controlled trials (RCTs) of rasagiline in patients with idiopathic Parkinson's disease. Five RCTs met the inclusion criteria for the review, though the Committee focused its review on the results of three placebo controlled RCTs of 18 – 26 weeks duration, one of which was in patients with early Parkinson's disease who had never been treated with levodopa and two in patients who were already receiving levodopa therapy but still had significant daily "off" time (periods of the day with poor or absent motor function). One of the latter RCTs also included a treatment arm with entacapone, a drug which decreases the degradation of levodopa.

In comparison to placebo in patients with early Parkinson's disease who had never been treated with levodopa, rasagiline use was associated with statistically significant improvements in quality of life and the total score of the Unified Parkinson's Disease Rating Scale (UPDRS).

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In comparison to placebo in patients who were already receiving levodopa therapy, rasagiline use was associated with statistically significant improvements in motor fluctuations and the number of subjects with dyskinesia but no statistically significant difference in quality of life. There were no statistically significant differences between rasagiline and entacapone in any of the outcomes in the RCT that compared these agents.

Rasagiline use has been associated with weight loss, nausea, vomiting, anorexia and postural hypotension. There is also a potential for serious drug interactions with a number of other agents.

Of Note:

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

Background:

CEDAC provides formulary listing recommendations to publicly funded drug plans. Recommendations are based on an evidence-based review of the medication's effectiveness and safety and an assessment of its cost-effectiveness in comparison to other available treatment options. For example, if a new medication is more expensive than other treatments, the Committee considers whether any advantages of the new medication justify the higher price. If the recommendation is not to list a drug, the Committee has concerns regarding the balance between benefit and harm for the medication, and/or concerns about whether the medication provides good value for public drug plans.

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