

Rivastigmine Patch

Product:

RIVASTIGMINE (Exelon®) transdermal patch; 5cm² (4.6mg/24 hours), 10cm² (9.5mg/24 hours)

Class of drugs:

Reversible cholinesterase inhibitor

Indication:

Treatment of Alzheimer's disease

Manufacturer:

Novartis Pharmaceuticals Canada Inc.

CED Recommendation

The CED recommended that rivastigmine (Exelon) transdermal patch not be funded through the Ontario Public Drug Programs. The CED noted that rivastigmine (Exelon) transdermal patch has not been shown to provide any meaningful clinical benefits over available alternatives on the Formulary.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to fund rivastigmine (Exelon) transdermal patch.

Status

Funding not available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Rivastigmine (Exelon) is indicated for the treatment of mild to moderate Alzheimer's disease.
- ◆ Rivastigmine (Exelon) is already available as an oral capsule, which is listed on the Ontario Drug Benefit Formulary as a Limited Use benefit. Rivastigmine (Exelon) patch is a new dosage format.
- ◆ When compared with placebo, rivastigmine (Exelon) 10cm² patch has been shown to provide small improvements in measures of cognition and daily function. The patch has not shown to provide any efficacy advantage over rivastigmine oral capsule.
- ◆ In terms of side effects, rivastigmine (Exelon) patch was shown to cause less stomach disturbance (e.g. nausea and vomiting) than rivastigmine oral capsule. It is unclear whether this difference in side effects is due to the fact that the patch delivers less medication to the body than the oral capsule.
- ◆ Rivastigmine (Exelon) patch has not been studied against alternative treatments for Alzheimer's disease. There is no evidence that rivastigmine (Exelon) patch provides added efficacy or side effect advantages over other drugs in the same class.
- ◆ Rivastigmine (Exelon) patch costs \$4.29 per day, which is slightly less expensive than the oral rivastigmine capsule and other drugs in the same class. However, generic versions of rivastigmine capsule are anticipated in the near future and they will be available at a lower price.
- ◆ **Overall, the Committee indicated that that rivastigmine (Exelon) transdermal patch has not been shown to provide any meaningful clinical benefits over available alternatives on the Formulary.**

Background:

Alzheimer's disease is a progressive, degenerative brain disorder that affects reason, judgment and memory. Changes in behavior and personality are also common. Over time, people with the disease lose their ability to think and reason clearly, judge situations, solve problems, concentrate, remember useful information, take care of themselves, and even speak. People with mild Alzheimer's disease usually require close supervision and help with everyday tasks; and those with severe disease can do little on their own and require complete full-time care. Alzheimer's disease severely impacts the quality of life of the patient, their family and caregivers.

There is currently no cure for Alzheimer's disease. However, some drugs may help keep symptoms from getting worse for a limited time. Drug treatments include donepezil (Aricept), rivastigmine (Exelon), and galantamine (Reminyl). These drugs affect the level of a neurotransmitter in the brain called acetylcholine.

continued...

Detailed Discussion:

- ◆ The Committee reviewed a single randomized controlled study of 24-week duration in 1,195 patients with mild to moderate Alzheimer's disease. The study compared rivastigmine (Exelon) 10cm² patch to oral rivastigmine 6mg capsule given twice daily and to placebo.
- ◆ Compared with patients on placebo, those treated with rivastigmine (Exelon) 10cm² patch experienced clinically small improvements on measures of cognition and daily function. There were no improvements on measures of behaviour.
- ◆ Patients treated with rivastigmine (Exelon) patch and those treated with the capsule achieved similar results on rating scale measurements for cognition, daily function and behaviour.
- ◆ The study reported no difference in serious adverse events between patients treated with the patch, the capsule or placebo. Although less nausea and vomiting were observed with the patch than the oral capsule, it is uncertain whether this difference was a result of lower drug concentrations being delivered by the patch.
- ◆ Caregivers in the study showed a preference for the use of the patch over the oral capsule. This preference may be due to fact that the patch is applied once daily, whereas the oral capsule is taken twice per day. The Committee noted that other once-daily treatment options, such as donepezil, are available on the Formulary.
- ◆ Quality of life was not assessed in the study. Rivastigmine (Exelon) patch has not been shown to improve important clinical outcomes, such as quality of life, mortality, caregiver burden and institutionalization.
- ◆ There are no direct comparison studies between rivastigmine (Exelon) patch and other cholinesterase inhibitors and no evidence that rivastigmine (Exelon) patch provides added therapeutic benefits compared with alternative treatments.
- ◆ The Committee recognized that there are patients who cannot swallow oral dosage forms. However, rivastigmine (Exelon) oral liquid is available through the Exceptional Access Program for these patients.
- ◆ Rivastigmine (Exelon) is only approved for patients with mild to moderate Alzheimer's disease. The Committee was concerned that the patch could be used inappropriately in patients with severe disease, given that patients with severe disease are the ones who have the most difficulty swallowing.
- ◆ Rivastigmine (Exelon) patch costs \$4.29 per day, which is slightly less expensive than the oral rivastigmine capsule and other cholinesterase inhibitors. However, generic versions of rivastigmine capsule are anticipated in the near future and they will be available at a lower price.
- ◆ Overall, the Committee indicated that that rivastigmine (Exelon) transdermal patch has not been shown to provide any meaningful clinical benefits over available alternatives on the Formulary.

CEDAC Recommendation:

(<http://www.cadth.ca/index.php/en/cdr/recommendations>)

The Canadian Expert Advisory Committee recommended rivastigmine (Exelon) patch not be listed.



Ministry of
Health and Long-Term Care
Ontario Public Drug Programs

For more information, please contact:

Ministry of Health and Long-Term Care

Ontario Public Drug Programs

Hepburn Block, 9th Floor

80 Grosvenor Street, Queen's Park

Toronto, Ontario M7A 1R3

or click: http://www.health.gov.on.ca/english/providers/program/drugs/ced_rec_table.html