

CEDAC FINAL RECOMMENDATION on RECONSIDERATION and REASONS for RECOMMENDATION

SOLIFENACIN (Vesicare[®] – Astellas Pharma Canada Inc.)

Description:

Solifenacin is an anticholinergic agent that is approved for the treatment of overactive bladder in adults with symptoms of urge urinary incontinence, urinary urgency and urinary frequency.

Dosage Forms:

5 and 10 mg tablets. The recommended dose is 5 – 10 mg daily.

Recommendation:

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

Reasons for the Recommendation:

1. There is insufficient evidence that solifenacin provides clinically important differences in outcomes compared to less expensive alternatives.
2. Overactive bladder is most commonly observed in older populations, who are most susceptible to anticholinergic-induced adverse effects. The long serum half-life (~60 hours) and accumulation of solifenacin in patients with chronic kidney disease, increase the possibility of prolonged adverse drug events, especially in patients with impaired renal function.

Summary of Committee Considerations:

The Committee considered a systematic review of randomized controlled trials (RCTs) comparing solifenacin with other drug therapies in the treatment of adults with overactive bladder having symptoms of urge urinary incontinence, urgency and frequency. Three RCTs comparing solifenacin with tolterodine, between four and 12 weeks duration, met the inclusion criteria for the systematic review. Compared to tolterodine, one of the three RCTs reported that solifenacin resulted in fewer episodes of urge incontinence (mean reduction of 0.59 episodes per day), incontinence episodes (mean reduction of 0.49 episodes per day) and improvements in quality of life as measured by the Perception of Bladder Condition scale (mean difference of 0.18 on a total scale of 6 points). Two of the three RCTs reported a statistically significant difference in favour of solifenacin in the number of urgency episodes (mean reductions ranging from 0.43 to 1.02 episodes per day). The clinical significance of these differences is uncertain.

Solifenacin causes typical anticholinergic side effects. All three RCTs reported a higher incidence of constipation with solifenacin compared with tolterodine.

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Solifenacin costs \$1.64 per day which is more expensive than immediate-release oxybutynin (\$0.50 – 0.93 per day).

Of Note:

1. Both published and unpublished data were reviewed and taken into consideration in making this recommendation.
2. The Committee had concerns about the increase in the number of anticholinergic agents available to treat overactive bladder disorder, the increased use of these agents and the balance between benefits and risks, especially in older populations. The Committee recommends that drug plans consider a drug class review of the effectiveness, safety and cost-effectiveness of these agents.

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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