

CEDAC FINAL RECOMMENDATION and REASONS for RECOMMENDATION

TROSPIUM CHLORIDE (TrosecTM – Oryx Pharmaceuticals Inc.)

Description:

Trospium is an anticholinergic agent that is approved for use in the treatment of overactive bladder with symptoms of urge or mixed urinary incontinence, urgency and urinary frequency.

Dosage Forms:

20 mg tablet

Recommendation:

The Canadian Expert Drug Advisory Committee (CEDAC) recommends that trospium be listed for patients who cannot tolerate immediate-release oxybutynin and in a similar manner as drug plans list tolterodine.

Reasons for the Recommendation:

1. The Committee reviewed 12 randomized controlled trials (RCTs) of trospium in the treatment of overactive bladder. Nine of these RCTs were of short duration (2-4 weeks) and seven used urodynamic outcome measures. Therefore, the Committee focused its review on two 12-week, placebo controlled RCTs and one 52 week RCT comparing trospium with oxybutynin, all of which used clinical outcome measures. Trospium was found to be superior to placebo and equivalent to oxybutynin as assessed by the number of episodes of urge incontinence and number of voids per day. In the two placebo-controlled RCTs, the number of voids per day was reduced, from a baseline of approximately 13, by a mean of 2.4 to 3 with trospium compared with 0.6 to 1.8 for placebo.
2. Trospium causes typical anticholinergic side effects such as dry mouth, constipation and visual disturbances. Trospium offers the potential of a reduction in central nervous system side effects compared with oxybutynin (due to reduced penetration of the blood-brain barrier), but this purported advantage has not yet been proven in clinical trials in elderly patients in whom this adverse effect is most important.
3. Trospium costs \$1.50 per day which is more expensive than immediate-release oxybutynin (\$0.50 – 0.75 per day) but less expensive than extended-release oxybutynin and tolterodine (\$1.75 per day).

Of Note:

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 Both published and unpublished data were reviewed and taken into consideration in making this recommendation.

Common Drug Review

2. The Committee had concerns about the increase in number of anticholinergic agents available to treat overactive bladder disorder, the increased use of these agents and their risk to benefit ratio, especially in elderly patients. The Committee recommends that drug plans consider a drug class review of the effectiveness, safety and cost-effectiveness of these agents.