

Trospium

Product:

TROSPIUM (Trosec®), 20 mg tablet

Class of drugs:

Antispasmodic

Indication:

Treatment of overactive bladder

Manufacturer:

Oryx Pharmaceuticals Inc.

CED Recommendation

The CED recommended that trospium (Trosec) not be listed on the Ontario Drug Benefit (ODB) Formulary, on the basis that there is no compelling evidence to indicate this medication offers meaningful benefits over an available Formulary alternative.

Executive Officer Decision

Based on the CED's recommendation, the Executive Officer decided not to list trospium (Trosec) on the ODB Formulary.

Status

No funding available through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Trospium (Trosec) is an antispasmodic drug used to treat overactive bladder.
- ◆ Treatments for overactive bladder that are currently available on the ODB Formulary include oxybutynin and tolterodine.
- ◆ Results from various clinical studies showed that trospium (Trosec), compared to placebo, improves urinary incontinence and frequency of urination.
- ◆ Side effects seen with trospium (Trosec) include dry mouth, constipation and vision problems.
- ◆ In one clinical study, trospium (Trosec) was compared with oxybutynin, a commonly prescribed drug for overactive bladder. The study reported that trospium (Trosec) and oxybutynin were equally efficacious. Although the incidence of side effects was slightly higher in patients who used oxybutynin, the number of patients who discontinued treatment was the same for both therapies. Therefore, the difference in incidence of side effects did not translate into an appreciable advantage for trospium (Trosec).
- ◆ The Committee indicated that drugs for overactive bladder may cause significant side effects (e.g. delirium) and should be used sparingly, especially in elderly patients, who are most at risk.
- ◆ At \$1.50 per day, trospium (Trosec) is significantly more expensive than oxybutynin, which costs \$0.50-\$0.75 per day.
- ◆ **Overall, the Committee concluded there is no compelling evidence that trospium (Trosec) offers meaningful clinical benefits over oxybutynin to justify its price premium.**

Background:

Overactive bladder refers to the involuntary spasm of the bladder muscle, or lack of control of bladder muscle contractions. The condition may result in a strong need to urinate right away, which may be accompanied by leaking or wetting accidents, and an increased need to urinate throughout the day and/or night.

The principles of treating overactive bladder involve increasing the total amount of urine released per bathroom visit, reducing the number of bathroom visits, reducing the number of incontinence episodes with lifestyle interventions, bladder training (such as pelvic exercises to strengthen bladder muscles), and only if these fail, drug therapy or surgery.

Standard drug treatments generally involve using antispasmodic drugs. Because all antispasmodic drugs work through blocking cholinergic activity, at doses typically needed to work on bladder muscles, side effects such as dry mouth, constipation, visual changes and delirium are also frequently encountered.

Trospium (Trosec) works by blocking involuntary contractions of the bladder muscle, allowing the bladder to relax and resulting in better bladder control.

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Detailed Discussion:

- ◆ The Committee reviewed trospium (Trosec) on two occasions, initially in October 2006 and again in June 2007.
- ◆ In clinical studies, trospium (Trosec) was demonstrated to be superior to placebo but equivalent to oxybutynin in terms of urinary incontinence episodes and number of voids per day.
- ◆ Results from clinical studies also showed the side effect profile of trospium (Trosec) is consistent with those for other anticholinergic drugs (e.g. dry mouth, constipation and visual disturbance). Although it has been suggested that trospium (Trosec) may produce less central nervous system side effects than oxybutynin, this advantage has not been demonstrated in clinical trials.
- ◆ The Committee reviewed one randomized controlled trial (*Halaska et al. World J Urology, 2003;20:392-399*) that compared trospium (Trosec) with oxybutynin. The study showed similar efficacy between the two drugs.
- ◆ The Halaska study reported that 64.8% of all trial patients who received trospium (Trosec) experienced adverse events. Although the incidence of adverse events was slightly higher in the oxybutynin group (77% versus 65%, mainly due to higher rates of dry mouth and gastrointestinal side effects), the drop-out rates between the treatment groups were virtually identical (25% versus 27%). Therefore, differences in adverse events did not translate into any clinically meaningful outcome.
- ◆ Given the significant risk of adverse events and the potential for inappropriate use (especially in the geriatric population), the Committee indicated that expanding the use of this class of drugs could negatively impact the health of Ontarians.
- ◆ Trospium costs \$1.50 per day. This is significantly more expensive than oxybutynin (\$0.50-\$0.75 per day) but slightly less expensive than tolterodine (\$1.75 per day).
- ◆ Overall, the Committee concluded there is no compelling data that trospium (Trosec) offers meaningful therapeutic advantages over oxybutynin to justify the significant price premium.

CEDAC Recommendation:

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

The Canadian Expert Drug Advisory Committee (CEDAC) recommended that trospium chloride (Trosec) be listed with conditions.



Ministry of
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