

Darifenacin

Product:

DARIFENACIN (Enablex®)

Class of drugs:

Antispasmodic

Indication:

Treatment of overactive bladder

Manufacturer:

Novartis Pharmaceuticals Canada Inc.

CED Recommendation

The CED recommended that darifenacin (Enablex) not be listed on the Ontario Drug Benefit (ODB) Formulary, on the basis that it is not more effective than available alternatives, and is more expensive.

Executive Officer Decision

Based on the CED recommendation, the Executive Officer has decided not to list darifenacin (Enablex).

Status

No funding through the Ontario Public Drug Programs.

Highlights of Recommendation:

- ◆ Darifenacin (Enablex) is used to treat overactive bladder, which may cause urinary incontinence, increased frequency of urination, or an increased urge to urinate.
- ◆ Studies suggest that darifenacin (Enablex) works as well as alternatives available on the Ontario Drug Benefit Formulary (e.g. oxybutynin, tolterodine) in patients with overactive bladder. Oxybutynin is available as a general benefit on the Formulary. Tolterodine is another alternative listed on the Formulary as a Limited Use benefit.
- ◆ At \$1.58 per day, darifenacin (Enablex) is significantly more expensive than regular oxybutynin (\$0.50 - \$0.75 per day) but slightly less expensive than tolterodine.
- ◆ The Committee felt that the class of drugs used to treat overactive bladder may be overused, especially in the elderly. These agents may cause significant side effects that can occur more frequently in the elderly, including dry mouth, constipation, dizziness, vision problems and delirium.
- ◆ **Overall, the Committee noted that darifenacin (Enablex) has not been proven to work better than standard options available for overactive bladder, and darifenacin (Enablex) is more expensive. The Committee also noted that this class of drugs is overused and strategies need to be put in place to reduce inappropriate use.** The Committee recommended that darifenacin (Enablex) not be listed on the ODB Formulary.

Background:

Overactive bladder refers to the involuntary spasm of the bladder muscle or a patient's inability to control bladder muscle contractions. The condition may result in a strong need to urinate right away, with or without leakage or wetting accidents caused by a sudden, unstoppable urge to urinate, and an increased need to urinate throughout the day and/or night (frequent bathroom visits).

Darifenacin (Enablex) is an antispasmodic agent used to treat overactive bladder. The medication works by blocking involuntary contractions of the bladder muscle that allow muscles to relax, resulting in better control of the bladder.

The principles of treating overactive bladder are to increase the total amount of urine expressed per bathroom visit, reduce the number of bathroom visits, and to reduce the number of incontinence episodes through lifestyle interventions, bladder training (such as pelvic exercises to strengthen the muscles of the bladder), drug therapy or surgery. First-line drug treatments generally involve the use of antispasmodic drugs.

Oxybutynin and tolterodine are alternatives to darifenacin (Enablex) and are available on the ODB Formulary.

Detailed Discussion:

- ◆ The manufacturer, Novartis Pharmaceuticals Canada Inc., asked the Ministry of Health and Long-Term Care to consider listing darifenacin (Enablex) on the ODB Formulary.
- ◆ The Committee considered eight randomized controlled trials that evaluated the efficacy of darifenacin (Enablex). For five of the eight trials that were placebo-controlled, patients on active treatment with darifenacin (Enablex) experienced improved efficacy but more side effects.

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- ◆ One study compared darifenacin (Enablex) to tolterodine. It showed comparable efficacy and tolerability between the two treatments.
- ◆ Two studies evaluated darifenacin (Enablex) versus oxybutynin. No differences in efficacy or side-effect profile were demonstrated between the two agents.
- ◆ At \$1.58 per day, darifenacin (Enablex) is significantly more expensive than immediate release oxybutynin (\$0.50 - \$0.75 per day) but slightly less expensive than tolterodine.
- ◆ Given the prevalence of the inappropriate use of drugs to treat overactive bladder and the significant risk of clinically important side effects, especially in the geriatric population, the Committee indicated expanding the use of this class of drugs could negatively effect the overall health of the Ontario population.
- ◆ The Committee also indicated that the Formulary should not consider reimbursing darifenacin (Enablex) unless it offers a therapeutic and/or a cost advantage compared with formulary alternatives, and unless programs to reduce inappropriate use are put in place.

CEDAC Recommendation:

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

The Canadian Expert Drug Advisory Committee recommended that darifenacin (Enablex) not be listed.



Ministry of
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