the DBL report

Issue #64, November 2011

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 22, 2011. The Committee reviewed Manufacturer submissions for 21 Drug Products.

In addition to Drug Products reviewed by the Expert Committee, 13 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective October 1, 2011, and another 68 generic Drug Products underwent Expedited Review for listing effective November 1, 2011. The following are highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Product Originally Reviewed via the Common Drug Review (CDR)

CAYSTON (aztreonam) (GIL) **75 mg/vial lyophilized powder for inhalation solution**. The Expert Committee recommended that this Drug Product be listed via Step Therapy/Special Authorization for the treatment of chronic pulmonary *Pseudomonas aeruginosa* infections when used as cyclic treatment (28-day cycles) in patients 6 years of age and older with moderate to severe cystic fibrosis and deteriorating clinical condition despite treatment with inhaled tobramycin.

Highlights of New Interchangeable (IC) Groupings

Addition of the following Drug Product to the *AHWDBL* has resulted in the creation of a New IC Grouping, effective October 1, 2011:

- **APO-LATANOPROST** (latanoprost) (APX) **0.005% ophthalmic solution**

Addition of the following Drug Product to the *AHWDBL* has resulted in the creation of a New IC Grouping, effective November 1, 2011:

- **TARO-MOMETASONE** (mometasone furoate) (TAR) **0.1% topical cream**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

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Highlights of Products Not Added

The following Drug Products have not been recommended for addition to the *AHWDBL*:

- **ACTONEL DR** (risedronate sodium) (WCC) **35 mg tablet** was not recommended for addition to the *AHWDBL* as the Manufacturer failed to provide sufficient evidence of cost and/or therapeutic advantage.
- **APO-TIMOP GEL** (timolol maleate) (APX) **0.5% ophthalmic long acting gellan solution** was reviewed as a resubmission. **APO-TIMOP GEL 0.5%** was not recommended to be added as the Manufacturer failed to provide sufficient evidence of interchangeability with the innovator Drug Product.

Highlights of New Products Added

Submissions for the following Drug Products did not meet the requirements for the Interchangeable Expedited Review process. Accordingly, these Drug Products were forwarded to the Expert Committee for a Full Review, and have subsequently been recommended for addition to the *AHWDBL* in interchangeable groupings, effective November 1, 2011:

- **APO-DICLO SR** (diclofenac sodium) (APX) **75 mg & 100 mg sustained release tablets**
- **CARVEDILOL** (carvedilol) (SNS) **3.125 mg, 6.25 mg, 12.5 mg & 25 mg tablets**
- **TEVA-LACTULOSE** (lactulose) (TEV) **667 mg/mL oral syrup**

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