the ADBL report

Issue #81, September 2014

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) 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 July 24, 2014. The Committee reviewed Manufacturer submissions for thirty (30) Drug Products for potential listing, or change in listing, on the *ADBL*. The Committee also considered information for a number of supplementary assessments of the coverage status of thirteen (13) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-four (34) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2014, and twelve (12) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 1, 2014.

The following are highlights of recent changes to the *ADBL* and other topics of general interest. A complete list of changes, as well as the full *ADBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html

Highlights of Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendation from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **INSPRA** (eplerenone) (PFI) **25 mg and 50 mg tablets** for NYHA class II systolic chronic heart failure. Although this Drug Product demonstrated benefit for the population studied, the Expert Committee agreed with the CDR recommendation of not listing at the submitted price.
- **NEUPRO** (rotigotine) (UCB) **2 mg/24 hour, 4 mg/24 hour, 6 mg/24 hour and 8 mg/24 hour transdermal patches.** CDR recommended that rotigotine not be listed for the treatment of idiopathic Parkinson disease (PD).

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (09/2014)

Highlights of Entry Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective September 1, 2014:

- **ACT DUTASTERIDE*** (dutasteride) (APH) **0.5 mg capsule**
- **APO-DUTASTERIDE*** (dutasteride) (APX) **0.5 mg capsule**
- **PMS-DUTASTERIDE*** (dutasteride) (PMS) **0.5 mg capsule**
- **SANDOZ DUTASTERIDE*** (dutasteride) (SDZ) **0.5 mg capsule**
- **TEVA-DUTASTERIDE*** (dutasteride) (TEV) **0.5 mg capsule**
- **VPI-BACLOFEN INTRATHECAL** (baclofen) (VPI) **0.05 mg/mL, 0.5 mg/mL and 2 mg/mL injections**

Highlights of Non-Interchangeable Old Drug Products Not Added

The Following Old Drug Products have not been added to the *ADBL*:

- **CELESTODERM-V** (betamethasone valerate) (VLP) **0.05% and 0.1% topical creams, and 0.05% and 0.1% topical ointments.** The Expert Committee reviewed a re-submission for Celestoderm-V but noted that no new information had been provided in support of the Manufacturer's wish to resubmit as a Multisource Drug Product. Therefore, the Expert Committee recommended that Celestoderm-V not be added to the *ADBL* as these Drug Products fail to offer a therapeutic advantage.

Highlights of Line Extension Drug Products Reviewed by the Expert Committee

The following Drug Products were added to the *ADBL*, effective September 1, 2014 after a Full Review by the Expert Committee:

- **ACUVAIL** (ketorolac tromethamine) (ALL) **0.45% ophthalmic solution** was submitted and reviewed as a Line Extension to the currently listed Acular 0.5% ophthalmic solution. The Expert Committee recommended this Drug Product be listed on the *ADBL* as it offers a therapeutic advantage.
- **VALCYTE*** (valganciclovir) (HLR) **50 mg/mL oral suspension** was submitted and reviewed as a Line Extension to the currently listed 450 mg tablet. The Expert Committee recommended this Drug Product be listed on the *ADBL* via Special Authorization with the same criteria as the valganciclovir tablets as it offers a therapeutic advantage.

The following Drug Product was NOT added to the *ADBL* after a Full Review by the Expert Committee:

- **TECFIDERA** (dimethyl fumarate) (BIO) **240 mg delayed-release capsule** was submitted and reviewed as a Line Extension to the Tecfidera 120 mg* delayed-release capsule which is currently listed via Special Authorization. The Expert Committee recommended that Tecfidera 240 mg capsule not be listed as this Drug Product fails to offer a cost or therapeutic advantage.

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Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*