the DBL report

Issue #86, July 2015

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 May 12 & 13, 2015. The Committee reviewed Manufacturer submissions for seventy-three (73) 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 twenty-six (26) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, eight (8) Drug Products underwent Expedited Review for listing on the *ADBL* effective June 1, 2015 and seven (7) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 1, 2015.

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)

The following Drug Products were reviewed by CDR and the Expert Committee and were added to the *ADBL* via Special Authorization (SA) effective June 1, 2015:

- **ANORO ELLIPTA*** (umeclidinium bromide/vilanterol trifenatate) (GSK) **62.5 mcg/25 mcg metered inhalation powder**
- **BREO ELLIPTA*** (fluticasone furoate/vilanterol trifenatate) (GSK) **100 mcg/25 mcg metered inhalation powder**

The following Drug Product was reviewed by CDR and the Expert Committee and was added to the *ADBL* via SA effective July 1, 2015:

- **CUBICIN*** (daptomycin) (CUB) **500 mg/vial injection**

The following Drug Products were reviewed by the CDR and the Expert Committee and were not added to the *ADBL*:

- **REVOLADE** (eltrombopag olamine) (GSK) **25 mg & 50 mg tablets**

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).*

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

- **SIGNIFOR** (pasireotide diaspartate) (NOV) **0.3 mg/mL, 0.6 mg/mL & 0.9 mg/mL injections**
- **VIMIZIM** (elosulfase alfa) (BMI) **5 mg/5 mL (single-use) vial injection**

Highlights of Products Not Added

- **COLCHICINE** (colchicine) (EUP) **0.6 mg tablet** was reviewed as a Resubmission. This Drug Product was not recommended for addition to the *ADBL* as there was insufficient information upon which to base an interchangeability designation.
- **TIMOLOL MALEATE-EX** (timolol maleate) (ALC) **0.25% & 0.5% ophthalmic solutions** were reviewed under the Interchangeable Drug Products submission category. As no new information was provided in the current submission to warrant a change to their previous recommendation, the Expert Committee upheld their prior recommendation to not add these Drug Products to the *ADBL*.
- **VIDEXTRA** (vitamin D3) (ORI) **10,000 unit tablet** was reviewed under the Non-Interchangeable Old Drug Products submission category. The Expert Committee advised that this Drug Product does not offer a therapeutic advantage over the alternative over-the-counter vitamin D3 Drug Products. Accordingly, this Drug Product was not recommended for addition to the *ADBL*.

Highlights of Non-Interchangeable Old Drug Products Added

The following Non-Interchangeable Old Drug Product has been added to the *ADBL* effective July 1, 2015:

- **METADOL-D** (methadone hydrochloride) (PAL) **1 mg/mL oral solution**

Highlights of Line Extension Drug Products Reviewed for Addition to the ADBL

The following Drug Product was added to the *ADBL* effective July 1, 2015 after a Full review by the Expert Committee:

- **METADOL-D CONCENTRATE** (methadone hydrochloride) (PAL) **10 mg/mL oral liquid**

Highlights of Interchangeable Drug Products Added

Due to recent changes to the front section of the *ADBL*, there are now published criteria specific to the use of Canadian Non-Innovator Reference Products (CNIRPs). As of April 1, 2015, the Expert Committee is able to consider demonstration of bioequivalence with a CNIRP as evidence of interchangeability. Each of the following Drug Products were reviewed as Resubmissions by the Expert Committee and were added to the *ADBL* effective July 1, 2015*:*

- **MAR-DOMPERIDONE** (domperidone maleate) (MAR) **10 mg tablet**
- **MYLAN-BISOPROLOL** (bisoprolol fumarate) (MYP) **5 mg & 10 mg tablets**

Highlights of Drug Products De-Listed from the ADBL

The following Drug Product was de-listed and removed from the *ADBL* effective July 1, 2015:

- **Synacthen Depot** (cosyntropin zinc hydroxide complex) (QST) **1 mg/mL injection**

Special Authorization Criteria Changes

The criteria for coverage via Special Authorization for the following Drug Product have been revised effective June 1, 2015 to enable improved patient access:

- **XOLAIR*** (omalizumab) (NOV) **150 mg/vial injection**

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).*

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