the DBL report

Issue #79, May 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 March 20, 2014. The Committee reviewed Manufacturer submissions for thirty-five (35) 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 an additional thirty-five (35) Drug Products.

In addition, to those reviewed by the Expert Committee, twenty-nine (29) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 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 Line Extension Drug Products Added to the ADBL

The following Drug Product was added to the *ADBL*, effective May 1, 2014 after a Full Review by the Expert Committee:

- **RAN-ATENOLOL** (atenolol) (RAN) **25 mg tablet** was submitted and reviewed as a Line Extension to the currently listed 50 mg & 100 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic advantage.

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

In keeping with the recommendations from the CDR, the following Drug Products have been added to the *ADBL* (please refer to the current *ADBL* for a full listing of coverage criteria):

- **FYCOMPA*** (perampanel) (EIS) **2 mg, 4 mg, 6 mg, 8 mg, 10 mg & 12 mg tablets** via Special Authorization for the adjunctive therapy in patients with refractory partial-onset seizures.
- **LUCENTIS*** (ranibizumab) (NOV) **2.3 mg/vial injection** via Restricted Benefit for the new indication of macular edema secondary to retinal vein occlusion.

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 (05/2014)

Highlights of Products not Added

- **JAMP-QUININE** (quinine sulfate) (JPC) **200 mg & 300 mg capsules** were reviewed as Natural Health Products (NHPs). The Expert Committee indicated that these NHPs failed to demonstrate a therapeutic advantage. Accordingly, these products were not recommended for addition to the *ADBL*.
- **DOCUSATE SODIUM** (docusate sodium) (JPC) **100 mg capsule** was reviewed under the Non-Interchangeable Old Drug Products submission category. This Drug Product was not recommended for addition to the *Palliative Care Drug Benefit Supplement (PCDBS)* as it failed to demonstrate a therapeutic advantage.
- **THEO ER** (theophylline) (AAP) **400 mg & 600 mg sustained-release tablets** were reviewed as Resubmissions. The Expert Committee advised that no new information had been provided in support of interchangeability with the innovator that would warrant a change to their previous recommendation to not list these Drug Products. Accordingly, these products were not recommended for addition to the *ADBL* as they failed to offer a cost advantage.

Highlights of Non-Interchangeable Old Drug Products Added

The following Non-Interchangeable Old Drug Product has been added to the *PCDBS*:

- **JAMP-DOCUSATE CALCIUM** (docusate calcium) (JPC) **240 mg capsule**

Highlights of Entry Interchangeable (IC) Drug Products Added

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

- **FONDAPARINUX SODIUM** (fondaparinux sodium) (DRL) **2.5 mg/0.5 mL & 7.5 mg/0.6 mL injections**

Vimpat Special Authorization Criteria Changes

The criteria for coverage via Special Authorization have been revised for the following Drug Products to align with the Special Authorization criteria implemented for Fycompa (please refer to the current *ADBL* for a full listing of coverage criteria):

- **VIMPAT*** (lacosamide) (UCB) **50 mg, 100 mg, 150 mg & 200 mg tablets** for adjunctive therapy in patients with refractory partial-onset seizures.

Leflunomide Restricted Benefit Criteria Changes

The Restricted Benefit criteria have been revised for all brands of **Leflunomide** 10 mg & 20 mg tablet Drug Products:

Original Restricted Benefit criteria for leflunomide required all prescriptions to be written by a Specialist in Rheumatology or Internal Medicine, in order for coverage to be provided. The Expert Committee recommended that the Restricted Benefit criteria be modified to allow other prescribers to continue leflunomide for their patients after initial prescription by a Specialist in Rheumatology or Internal Medicine.

The new Restricted Benefit criteria, effective May 1, 2014, will read as follows:

This product is a benefit for the treatment of rheumatoid arthritis when the initial prescription is prescribed by a Specialist in Rheumatology or Internal Medicine.

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).*