the ADBL report

Issue #76, November 2013

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 September 19, 2013. The Committee reviewed Manufacturer submissions for fifty-seven (57) 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 eight (8) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, eighteen (18) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2013, and sixty-seven (67) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 1, 2013.

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 Drug Products Added

- **MONUROL** (fosfomycin tromethamine) (TPI) **3 gram oral powder packet** is indicated in the treatment of acute uncomplicated lower urinary tract infections (acute cystitis) in women of 18 years of age and older caused by the following susceptible pathogens: *Escherichia coli*, *Enterococcus faecalis*. This Drug Product was added to the *ADBL* as evidence provided in the Manufacturer submission supported that it provides a therapeutic advantage.

Highlights of Line Extension Drug Products Added

The following Drug Product was added to the *ADBL*, effective November 1, 2013 after a Full Review by the Expert Committee:

- **CO AMLODIPINE** (amlodipine besylate) (COB) **2.5 mg tablet** was submitted and reviewed as a Line Extension to the currently listed 5 mg & 10 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.

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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Highlights of Natural Health Products Added

The following Natural Health Products (NHPs) have been added to the *ADBL* and the Maximum Allowable Cost (MAC) Price Policy applies to the MAC groupings:

- **EURO-K20** (potassium chloride) (EUP) **20 mEq sustained-release tablet**
- **EURO-K 600** (potassium chloride) (EUP) **8 mEq sustained-release tablet**

Highlights of Non-Interchangeable Old Drug Products Added

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

- **EURO FOLIC** (folic acid) (EUP) **5 mg tablet**

Highlights of Expedited Interchangeable Drug Products Added

Addition of the following IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective November 1, 2013:

- **ZAMINE 21** (drospirenone/ethinyl estradiol) (APX) **3 mg/0.03 mg tablets**
- **ZARAH 21 (drospirenone/ethinyl estradiol) (COB) 3 mg/0.03 mg tablets**

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

In keeping with the recommendations from the CDR, the following Drug Product has been added to the *ADBL* via Special Authorization:

- **ORENCIA** (abatacept) (BMS) **125 mg/mL injection syringe** for adults with rheumatoid arthritis. The addition of this new strength and formulation resulted in associated revisions to the existing Special Authorization criteria for coverage for the currently listed **250 mg/vial injection** formulation. Please refer to the current *ADBL* for a full listing of coverage criteria.

Also in keeping with the recommendations from the CDR, the following Drug Product has not been added to the *ADBL*:

- **BYSTOLIC** (nebivolol hydrochloride) (FLC) **2.5 mg, 5 mg, 10 mg & 20 mg tablets**

Finally, in keeping with CDR recommendations, the coverage status of the following Drug Products will be maintained (i.e., coverage will not be extended to the new indications):

- **REBIF** (interferon beta-1a) (SRO) **44 mcg/0.5 ml (12 million IU) injection syringe** for the indication of Clinically Isolated Syndrome in Multiple Sclerosis
- **SOLIRIS** (eculizumab) (API) **300 mg/vial injection** for the indication of Atypical Hemolytic Uremic Syndrome

Highlights of Interchangeable (IC) Drug Products Added

The following are Drug Products added to the *ADBL* effective November 1, 2013 in Established IC Groupings, after a Full Review by the Expert Committee:

- **MINT-RIVASTIGMINE** (rivastigmine hydrogen tartrate) (MPI) **1.5 mg, 3 mg, 4.5 mg & 6 mg capsules**
- **RAN-MONTELUKAST** (montelukast sodium) (RAN) **4 mg & 5 mg chewable tablets**

Highlights of Special Authorization (SA) Criteria Changes

PROLIA (denosumab) (AMG) **60 mg/mL injection syringe** was originally reviewed via the CDR and was listed on the *ADBL* via SA for postmenopausal osteoporosis, effective July 1, 2011. The Expert Committee considered requests from prescribers for clarification of the SA criteria, and have recommended that the criteria be revised; specifically defining oral bisphosphonate hypersensitivity and allowing coverage for patients with severe gastrointestinal intolerance. Please refer to the current *ADBL* for a full listing of coverage criteria.

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).****