the DBL report

Issue #82, November 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 September 25, 2014. The Committee reviewed Manufacturer submissions for twenty-five (25) 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 fifty (50) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, seventeen (17) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2014, and thirty (30) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 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 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 November 1, 2014:

- **Ezetimibe*** (ACT, MYLAN, RAN, SANDOZ and TEVA brands) **10 mg tablets**
- **Escitalopram** (APO, AURO, CO, Sanis, MYLAN, PMS, RAN and TEVA brands) **10 mg & 20 mg tablets**

The following Drug Products were also added to the *ADBL* effective November 1, 2014, in already Established IC groupings, after a Full Review by the Expert Committee:

- **PENICILLIN G SODIUM** (penicillin G sodium) (PPC) **1,000,000 unit/vial, 5,000,000 unit/vial & 10,000,000 unit/vial injections**

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

ABC 81171 (11/2014)

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

The following Drug Products were added to the *ADBL* effective October 1, 2014:

- **LATUDA** (lurasidone HCL) (SUN) **40 mg, 80 mg & 120 mg tablets**
- **LODALIS** (colesevelam HCL) (VCL) **625 mg tablet**

In keeping with CDR recommendations, the following Drug Product was added to the *ADBL* as of November 1, 2014:

- **TUDORZA GENUAIR** (aclidinium bromide) (ALM) **400 mcg /dose inhalation powder**.

The following Drug Products have been reviewed by CDR and the Expert Committee, and the listing of these drug products have been deferred pending a Product Listing Agreement (PLA) at this time:

- **AUBAGIO** (teriflunomide) (GZS) **14 mg tablet**
- **GALEXOS** (simeprevir sodium) (JAI) **150 mg capsule**
- **IBAVYR** (ribavirin) (PPH) **400 mg & 600 mg tablets**
- **KOMBOGLYZE** (saxagliptin HCL/ metformin HCL) (AZC) **2.5 mg/500 mg, 2.5 mg/850 mg & 2.5 mg/1000 mg tablets**
- **SIMPONI I.V.** (golimumab) (JAI) **50 mg/4 mL vial injection**
- **SOVALDI** (sofosbuvir) (GIL) **400 mg tablet**

Highlights of Changes to Currently Listed Products

Additional indications for Special Authorization were added for the following Drug Products effective October 1, 2014:

- **REMICADE*** (infliximab) (JAI) **100 mg/vial injection** for Ulcerative Colitis was reviewed by the Expert Committee, in consultation with Alberta gastroenterologists, and this indication is now eligible for coverage via Special Authorization.
- **HUMIRA*** (adalimumab) (ABV) **40 mg/syringe injection** for pediatric Juvenile Idiopathic Arthritis was reviewed by the Expert Committee and this indication is now eligible for coverage via Special Authorization.

Criteria for coverage via Special Authorization were revised for the following Drug Products effective October 1, 2014:

- **PROLIA*** (denosumab) (AMG) **60 mg/mL injection syringe**
- **Zoledronic Acid*** (NOVARTIS, DR. REDDY'S LABORATORIES, TARO and TEVA brands) **5 mg/100 mL injection**

A clinical review of the benefit status of rifabutin was undertaken in response to Specialist feedback. The Expert Committee gave due consideration to the information, and as a result, Special Authorization criteria for coverage have been revised for the following Drug Product effective November 1, 2014:

- **MYCOBUTIN*** (rifabutin) (PFI) **150 mg capsule**

After assessment by the Expert Committee and consultation with pediatric Specialists, the listing status of Chloral Hydrate is changed from an open benefit to a Restricted Benefit, effective November 1, 2014, for patients less than 18 years of age:

- **PMS-CHLORAL HYDRATE*** (chloral hydrate) (PMS) **100 MG/ML oral syrup**

Criteria for coverage via Special Authorization have also been revised for the following Drug Products effective November 1, 2014:

- **SOLIRIS*** (eculizumab) (API) **300 mg/vial injection**
- **GILENYA*** (fingolimod HCL) (NOV) **0.5 mg capsule**
- **TYSABRI*** (eculizimab) (BIO) **20 mg/mL injection**

Highlights of Interchangeable Drug Products Not Added

As there are currently no published criteria in the *ADBL* specific to use of Canadian Non-Innovator Reference Products (CNIRPs), the Expert Committee was unable to consider demonstration of bioequivalence with a CNIRP as evidence of interchangeability. Therefore, each of the following Drug Products will not be added to the *ADBL:*

- **CYANOCOBALAMIN** (cyanocobalamin) (MYP) **1000 mcg/mL injection**
- **MAR-AMITRIPTYLINE** (amitriptyline) (MAR) **10 mg, 25 mg, 50 mg & 75 mg tablets**
- **METHOTREXATE** (methotrexate sodium) (MYP) **25 mg/mL injection (unpreserved)**

The Expert Committee advised that insufficient information was provided to support bioequivalence of the following Products with the Canadian Reference Products. As a result, these Drug Products will not be added to the *ADBL:*

- **DOXYCIN** (doxycycline hyclate) (RIV) **100 mg capsule and tablet**

Highlights of Other Changes to the ADBL

The following Drug Products were added to the *ADBL* as Restricted Benefits effective October 1, 2014 for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) for patients 6 years of age and older:

- **BIPHENTIN*** (methylphenidate HCL) (PUR) **10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg & 80 mg controlled-release capsules**

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