the DBL report

Issue #95, February 2017

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 November 24 & 25, 2016. The Committee reviewed Manufacturer submissions for thirty-one (31) 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 one hundred and eleven (111) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, four (4) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2016, and eleven (11) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2017.

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 Product was reviewed by CDR and added to the *ADBL* via Special Authorization effective December 1, 2016:

- **INFLECTRA*** (infliximab) (CHH) **100 mg/vial injection** for the indications of Moderate to Severely Active Crohn's and Fistulizing Crohn's Disease and Ulcerative Colitis

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* as Regular Benefits, effective February 1, 2017:

- **ARNUITY ELLIPTA** (fluticasone furoate) (GSK) **100 mcg/dose & 200 mcg/dose powder for inhalation**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* via Step Therapy/Special Authorization effective February 1, 2017:

- **BREO ELLIPTA*** (fluticasone furoate/vilanterol trifenatate) (GSK) **200 mcg/25 mcg powder for inhalation**

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ABC 81171 (02/2017)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective December 1, 2016*:*

- **VISTITAN** (bimatoprost) (SDZ) **0.03% ophthalmic solution**

Vistitan is a pharmaceutical alternative which has been designated as interchangeable with Lumigan RC 0.01%. When Lumigan RC 0.01% was initially listed on the *ADBL*, based on evidence submitted by the Manufacturer, the Expert Committee on Drug Evaluation and Therapeutics considered it interchangeable with the original Lumigan 0.03% for purposes of the *ADBL*. Lumigan 0.03% was discontinued in 2013 and subsequently removed from the *ADBL.* Vistitan 0.03% has provided data demonstrating interchangeability with Lumigan 0.03%, thus is considered interchangeable with Lumigan RC 0.01% for purposes of the *ADBL*.

The following IC Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2017:

- **CEFAZOLIN** (cefazolin) (STM) **10 G/vial injection**
- **MYLAN-VERAPAMIL SR** (verapamil hydrochloride) (MYP) **240 mg sustained-release tablet**
- **SANDOZ PREDNISOLONE ACETATE** (prednisolone acetate) (SDZ) **1% ophthalmic suspension**

Highlights of Other Products Added

The following Non-Interchangeable Old Drug Product was added to the *ADBL* as a non-interchangeable Regular Benefit effective February 1, 2017:

- **JAMP-FOLIC ACID** (folic acid) (JPC) **5 mg tablet**

The following Natural Health Product was also reviewed by the Expert Committee and added to the *ADBL* as a non-interchangeable Regular Benefit effective February 1, 2017:

- **JAMP-K EFFERVESCENT** (potassium bicarbonate) (JPC) **975 mg (25 mEq) tablet**

Changes in Listing Status

The Expert Committee conducted a review of inhalers used in the treatment of Chronic Obstructive Pulmonary Disease (COPD) and asthma, in order to align their coverage status. As a result of the review, the Committee recommended changes to the listing status of all fixed-dose combination inhalers. Effective February 1, 2017, the listing status of the following products will be changed from Regular Benefit to Step Therapy/Special Authorization:

- **ADVAIR*** (salmeterol xinafoate/fluticasone propionate) (GSK) **125 mcg & 250 mcg metered dose aerosols and 100 mcg, 250 mcg & 500 mcg diskus powder for inhalation**
- **SYMBICORT TURBUHALER*** (budesonide/formoterol fumarate dihydrate) (AZC) **100 & 200 metered inhalation powder**

In addition, effective February 1, 2017, the listing status of the following products will be revised from Special Authorization to Step Therapy/Special Authorization:

- **ANORO ELLIPTA*** (umeclidinium bromide/ vilanterol trifenatate) (GSK) **62.5 mcg/25 mcg inhalation powder**
- **BREO ELLIPTA*** (fluticasone furoate/vilanterol trifenatate) (GSK) **100 mcg/25 mcg powder for inhalation**
- **DUAKLIR GENUAIR*** (aclidinium bromide/ formoterol fumarate dihydrate) (AZC) **400 mcg/12 mcg inhalation powder**
- **INSPIOLTO RESPIMAT*** (tiotropium bromide monohydrate/ olodaterol hydrochloride) (BOE) **2.5 mcg/actuation inhalation solution**
- **ULTIBRO BREEZHALER*** (indacaterol maleate/ glycopyrronium bromide) (NOV) **110 mcg/50 mcg inhalation capsule**

The listing status of select anti-infective medications was reviewed by the Expert Committee. As a result of their deliberations, certain anti-infectives will be made available to Specialists in Infectious Diseases as Restricted Benefits, and will continue to be available through the Special Authorization process for all other prescribers. The following products will be changed from Special Authorization to Restricted Benefit/Special Authorization effective February 1, 2017:

- **AMPICILLIN* 250 mg & 500 mg capsules** (all brands)
- **AZITHROMYCIN* 600 mg tablet** (all brands)
- **CANCIDAS*** (caspofungin) (MFC) **50 mg & 70 mg injection**
- **CEFADROXIL* 500 mg capsule** (all brands)
- **CEFOXITIN* 1 gram & 2 gram vials for injection** (all brands)
- **DIFLUCAN*** (fluconazole) (PFI) **10 mg/mL oral suspension**
- **INVANZ*** (ertapenem) (MFC) **1 gram vial injection**
- **LINEZOLID* 600 mg tablet** (all brands)
- **MEROPENEM* 500 mg & 1 gram vials for injection** (all brands)
- **MYCOBUTIN*** (rifabutin) (PFI) **150 mg capsule**
- **PIPERACILLIN/TAZOBACTAM* 2 gram/250 mg, 3 gram/375 mg & 4 gram/500 mg vials for injection** (all brands)
- **PRIMAXIN*** (imipenem/cilastatin) (MFC) **500 mg/500 mg vial for injection**
- **SPORANOX*** (itraconazole) (JAI) **10 mg/mL oral solution**
- **VANCOMYCIN* 125 mg & 250 mg capsules** (all brands)
- **VORICONAZOLE* 50 mg & 200 mg tablets, 40 mg/mL oral suspension & 200 mg/vial injection** (all brands)

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Changes in Listing Status, cont.

Effective February 1, 2017, the status of all brands of clopidogrel currently listed on the *ADBL* will change from a Limited Restricted Benefit/Special Authorization to a Regular Benefit.

Special Authorization Criteria Change

Due to the limited availability of the Insulin Tolerance Test (ITT) in some regions of Alberta, the Special Authorization Criteria of the following Drug Products have been revised to allow the use of an alternative, the glucagon stimulation test, effective February 1, 2017:

- **GENOTROPIN*** (somatropin) (PFI) **Miniquick 0.6 mg, 0.8 mg, 1 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg & 2 mg injection syringes, and Goquick 5.3 mg & 12 mg pen injection syringes**
- **HUMATROPE*** (somatropin) (LIL) **6 mg & 12 mg injections**
- **OMNITROPE*** (somatropin r-dna origin) (SDZ) **5 mg/1.5 mL & 10 mg/1.5 mL injection cartridges**
- **SAIZEN*** (somatropin r-dna origin) (SRO) **3.3 mg, 5 mg & 8.8 mg injections and 6 mg, 12 mg & 20 mg cartridges**

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