the ADBL report

Issue #83, February 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 November 25 & 26, 2014. The Committee reviewed Manufacturer submissions for twenty-nine (29) 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 (20) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, sixteen (16) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2014, and forty-seven (47) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 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 Product was reviewed by CDR and the Expert Committee and was added to the *ADBL* effective December 1, 2014 via Special Authorization:

- **AUBAGIO*** (teriflunomide) (GZM) **14 mg tablet**

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

- **GALEXOS*** (simeprevir sodium) (JAI) **150 mg capsule**

In keeping with the recommendation from the CDR and the Expert Committee the following Drug Products have been added effective December 1, 2014 via Step Therapy/Special Authorization:

- **JENTADUETO*** (linagliptin/ metformin hydrochloride) (BOE) **2.5 mg/500 mg, 2.5 mg/850 mg & 2.5 mg/1000 mg tablets**

The following Drug Product has been reviewed by CDR and the Expert Committee, and the listing of this Drug Product has been deferred at this time:

- **BREO ELLIPTA** (fluticasone furoate/ vilanterol trifenatate) (GSK) **100 mcg/25 mcg powder for inhalation**

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

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Highlights of Drug Products Added

- **PONSTAN** (mefenamic acid) (ERF) **250 mg capsule** was added effective February 1, 2015 as a single-source product. This Drug Product will not be designated as interchangeable with the currently listed Mefenamic Acid (AAP) 250 mg capsule.

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

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

- **TEVA-CITALOPRAM** (citalopram hydrobromide) (TEV) **10 mg tablet**

The following Drug Products were reviewed by the Expert Committee and have been deferred at this time:

- **LATUDA** (lurasidone hydrochloride) (SUN) **20 mg & 60 mg tablets**

The following Drug Products were NOT added to the *ADBL* after a Full Review by the Expert Committee:

- **COMBIVENT RESPIMAT** (ipratropium bromide/salbutamol) (BOE) **20 mcg/100 mcg inhalation solution** was reviewed as a Line Extension to Combivent nebules but was not added as this Drug Product fails to offer a therapeutic advantage.
- **LUXIQ** (betamethasone valerate) (GSK) **0.12% topical foam** was reviewed as a Line Extension to Prevex 0.1% topical occlusive cream and not added as it fails to offer a cost advantage.

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective February 1, 2015:

- **APO-CLARITHROMYCIN XL** (clarithromycin) (APX) **500 mg extended-release tablet**

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective February 1, 2015:

- **CELECOXIB*** (celecoxib) (APX, APH, GMD, JPC, MAR, MPI, MYP, PMS, RAN, SDZ, and TEV) **100 mg & 200 mg capsules**
- **AURO-CEFIXIME** (cefixime) (AUR) **400 mg tablet**

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:*

- **JAMP-METHOTREXATE (UNPRESERVED)** (methotrexate) (JPC) **25 mg/mL injection**
- **JAMP-VANCOMYCIN** (vancomycin hydrochloride) (JPC) **500 mg/vial, 1 gram/vial & 10 gram/vial injections**

Highlights of Non-Interchangeable Old Drug Products (NICOD) Not Added

The following Old Drug Product has not been added to the *Palliative Care DBS* as it fails to demonstrate a therapeutic advantage:

- **BISACODYL** (bisacodyl) (JPC) **10 mg rectal suppository**

Special Authorization Criteria Changes

The criteria for coverage via Special Authorization for the following Drug Products have been revised to better reflect current practice:

- **APO-VALGANCICLOVIR*** (valganciclovir hydrochloride) (APX) **450 mg tablet**
- **VALCYTE*** (valganciclovir hydrochloride) (HLR) **450 mg tablet**
- **VALCYTE*** (valganciclovir hydrochloride) (HLR) **50 mg/mL oral suspension**
- **RITUXAN*** (rituximab) (HLR) **10 mg/mL injection**

Changes in Benefit Status due to product discontinuation

Vertex Pharmaceuticals (Canada) Inc. has made the decision to discontinue the sale and distribution of this Drug Product as of January 1, 2015:

- **INCIVEK** (telaprevir) (VER) **375 mg tablet**

Special Authorization criteria will remain part of the *ADBL* to ensure that all patients who initiated therapy prior to January 1, 2015 can finish their course of treatment by March 31, 2015. No new patients will be approved to initiate Incivek therapy at this time.

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