the DBL report

Issue #102, May 2018

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 20, 2018. The Committee reviewed Manufacturer submissions for twenty-three (23) 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 eleven (11) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty (30) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 1, 2018.

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 Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization (SA) effective April 1, 2018:

- **HUMIRA*** (adalimumab) (ABV) **40 mg/0.8 mL injection syringe** for the indication of Hidradenitis Suppurativa (HS)
- **XOLAIR*** (omalizumab) (NOV) **150 mg vial injection** for the indication of chronic idiopathic urticaria (CIU)

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via SA effective May 1, 2018:

- **NUCALA*** (mepolizumab) (GSK) **100 mg/mL vial injection**
- **PHEBURANE*** (sodium phenylbutyrate) (MDK) **483 mg/g granules**
- **RAVICTI*** (glycerol phenylbutyrate) (HZN) **1.1 g/mL liquid**

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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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The following Drug Product was reviewed by CDR and added to the *ADBL* via SA effective May 1, 2018:

- **VOSEVI*** (sofosbuvir /velpatasvir /voxilaprevir) (GIL) **400 mg/100 mg/100 mg tablet**

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 April 1, 2018:

- **ACT DEXTROAMPHETAMINE SR** (dextroamphetamine sulfate) (APH) **15 mg sustained-release capsule**

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective May 1, 2018:

- **TEVA-BUDESONIDE** (budesonide) (TEV) **0.125 mg/mL & 0.5 mg/mL inhalation suspensions**

Highlights of Drug Products Added

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective April 1, 2018:

- **METOJECT SUBCUTANEOUS** (methotrexate sodium) (MDX) **17.5 mg/0.35 mL, 20 mg/0.4 mL, 22.5 mg/0.45 mL & 25 mg/0.5 mL injection syringes**

The following Line Extension Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective May 1, 2018:

- **ESBRIET*** (pirfenidone) (HLR) **267 mg & 801 mg tablets** listed via SA

Highlights of Expedited Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective May 1, 2018:

- **MINT-ACITRETIN** (acitretin) (MPI) **10 mg & 25 mg capsules**
- **TARO-ACITRETIN** (acitretin) (TAR) **10 mg capsule**
- **PERINDOPRIL** (perindopril erbumine) (APX, AUR, PMS, SDZ and TEV) **2 mg, 4 mg & 8 mg tablets**
- **PERINDOPRIL/INDAPAMIDE** (perindopril erbumine/indapamide hemihydrate) (SDZ and TEV) **4 mg/1.25 mg & 8 mg/2.5 mg tablets**

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective April 1, 2018:

- **DAKLINZA*** (daclatasvir dihydrochloride) **30 mg & 60 mg tablets**
- **EPCLUSA*** (sofosbuvir/velpatasvir) **400 mg/100 mg tablet**
- **HARVONI*** (sofosbuvir/ledipasvir) **400 mg/90 mg tablet**
- **SOVALDI*** (sofosbuvir) **400 mg tablet**
- **ZEPATIER*** (elbasvir/grazoprevir) **50 mg/100 mg tablet**

The Special Authorization criteria for coverage for the following Drug Products have been revised effective May 1, 2018:

- **DIFLUCAN*** (fluconazole) (PFI) **10 mg/mL oral suspension**
- **Zoledronic Acid*** (ACLASTA, Dr. Reddys & Taro brands) **0.05 mg/mL injections**

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