the DBL report

Issue #89, February 1, 2016

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***
- ***Highlights of:***
  - ***Products Originally Reviewed via the CDR***
  - ***Line Extension Drug Products***
  - ***Other Drug Products Reviewed but Not Added***
  - ***Interchangeable Drug Products Reviewed***
- ***Special Authorization Criteria Changes***
- ***ROBS Review of Growth Hormone Products***

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 26, 2015. The Committee reviewed Manufacturer submissions for nineteen (19) 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, twenty-seven (27) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2015, and twenty-seven (27) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2016.

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 added to the *ADBL* effective December 1, 2015:

- **SIMBRINZA** (brinzolamide/brimonidine tartrate) (ALC) **1%/0.2% ophthalmic suspension**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* as a Restricted Benefit effective January 1, 2016:

- **FIBRISTAL*** (ulipristal acetate) (ASC) **5 mg tablet**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization effective January 1, 2016:

- **FIRAZYR*** (icatibant acetate) (SOT) **10 mg/mL (3 mL) injection syringe**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective February 1, 2016:

- **INCRUSE ELLIPTA** (umeclidinium bromide) (GSK) **62.5 mcg inhalation powder**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization effective February 1, 2016:

- **DUAKLIR GENUAIR*** (aclidinium bromide/formoterol dihydrate) (AZC) **400 mcg/12 mcg inhalation powder**

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 Line Extension Drug Products Reviewed for the ADBL

The following Drug Product was added as a Regular Benefit to the *ADBL* effective December 1, 2015:

- **LODALIS** (colesevelam hydrochloride) (VCL) **3.75 gram/dose oral powder packet**

The following Drug Product was added to the *ADBL* via Special Authorization effective December 1, 2015:

- **IBAVYR*** (ribavirin) (PPH) **200 mg tablet**

The following Drug Product was added to the *ADBL* as a Regular Benefit effective February 1, 2016:

- **HUMALOG** (insulin lispro) (LIL) **200 unit/mL injection Kwikpen**

Highlights of Other Products Reviewed but Not Added

The following Drug Products were reviewed by the Expert Committee and have not been added to the *ADBL* because they do not offer a therapeutic advantage:

- **BUTRANS 5, BUTRANS 10 & BUTRANS 20** (buprenorphine) (PUR) **5 mcg/hr, 10 mcg/hr & 20 mcg/hr transdermal patches**.

In keeping with recommendations from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **CONSTELLA** (linaclotide) (FLC) **145 mcg & 290 mcg capsules**

Highlights of Interchangeable Drug Products Reviewed

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2016*:*

- **CO VALACYCLOVIR** (valacyclovir) (APH) **500 mg tablet (caplet)**
- **PMS-VALACYCLOVIR** (valacyclovir) (PMS) **1000 mg caplet**

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* via Step Therapy/Special Authorization effective February 1, 2016*:*

- **SANDOZ SOLIFENACIN*** (solifenacin succinate) (SDZ) **5 mg & 10 mg tablets**

Special Authorization Criteria Changes

Due to the addition of Aptiom, a new antiepileptic drug, the Special Authorization criteria for coverage for the following Drug Products have been revised effective December 1, 2015:

- **FYCOMPA*** (perampanel) (EIS) **2 mg, 4 mg, 6 mg, 8 mg, 10 mg & 12 mg tablets**
- **VIMPAT*** (lacosamide) (UCB) **50 mg, 100 mg, 150 mg & 200 mg tablets**

The Special Authorization criteria for coverage for the following Drug Products have been revised effective January 1, 2016:

- **XARELTO*** (rivaroxaban) (BAI) **15 mg & 20 mg tablets**

The Special Authorization criteria for coverage for the following Drug Product have been revised for a number of reasons effective February 1, 2016:

- **PROLIA*** (denosumab) (AMG) **60 mg/mL injection syringe**

The SA criteria have been updated to include the indication of Osteoporosis in Men. The SA criteria were also modified to provide greater clarity with regard to esophageal abnormalities, and to allow for denosumab to be used for patients in whom bisphosphonates are contraindicated due to severe renal impairment.

The Special Authorization criteria for coverage for the following Drug Products have also been revised to clarify esophageal abnormalities, effective February 1, 2016:

- **ACLASTA*** (zoledronic acid) (NOV) **5 mg/100 mL injection**
- **TARO-ZOLEDRONIC ACID*** (zoledronic acid) (TAR) **5 mg/100 mL injection**
- **ZOLEDRONIC ACID*** (zoledronic acid) (TEV) **5 mg/100 mL injection**
- **ZOLEDRONIC ACID*** (zoledronic acid) (DRL) **5 mg/100 mL injection**

ROBS Review of Growth Hormone Products

As part of the Review of Benefit Status (ROBS) process, comprehensive clinical reviews of growth hormone products were undertaken. Following discussion and consultation with stakeholders, and examination of all information available, the Expert Committee recommended that the Special Authorization criteria for somatropin Drug Products should not be changed, and should remain as currently listed.

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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