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An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:

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ALBERTA HEALTH LIAISON:

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ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Julia Chan, BSc (Pharm) Amanda Chung, BSc (Pharm) Sherry Dieleman, BSc (Pharm), MSc Connie Lussier, BSP, MA

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Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 22 and 23, 2018. The Committee reviewed Manufacturer submissions for thirty-four (34) 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-four (24) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, forty-four (44) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2018 and twelve (12) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2019.

The following are <u>highlights</u> 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* effective December 1, 2018:

- ACTIKERALL (5-fluorouracil/salicylic acid) (CIP) 0.5%/10% topical solution
- BRIVLERA* (brivaracetam) (UCB) 10 mg, 25 mg, 50 mg, 75 mg
 4 100 mg tablets via Special Authorization (SA)
- DYSPORT THERAPEUTIC (abobotulinumtoxinÁ) (ISP) 300
 IU/vial & 500 IU/vial injections
- ENSTILAR (calcipotriol monohydrate/betamethasone dipropionate) (LEO) 50 mcg/g/0.5 mg/g topical foam
- HEMANGIOL* (propranolol hydrochloride) (PIE) 3.75 mg/mL oral solution via SA
- LANCORA* (ivabradine hydrochloride) (SEV) 5 mg & 7.5 mg tablets via SA
- QUINSAIR* (levofloxacin) (RAP) 100 mg/mL inhalation solution via Step Therapy/SA
- SPINRAZA* (nusinersen sodium) (BIO) 2.4 mg/mL injection via SA
- TRESIBA FLEXTOUCH PEN (insulin degludec) (NNA) 100 unit/mL & 200 unit/mL injections

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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The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective January 1, 2019:

- OCALIVA* (obeticholic acid) (ICP) 5 mg & 10 mg tablets via SA
- RENFLEXIS* (infliximab) (SSB) 100 mg/vial injection via SA
- REVESTIVE* (teduglutide) (SHB) 5 mg/vial injection via SA
- SYNJARDY* (empagliflozin/metformin hydrochloride) (BOE) 5 mg/500 mg, 5 mg/850 mg, 5 mg/1000 mg, 12.5 mg/500 mg, 12.5 mg/850 mg & 12.5 mg/1000 mg tablets via Step Therapy/SA

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via SA effective February 1, 2019:

- MDK-NITISINONE* (nitisinone) (MEN) 2 mg, 5 mg & 10 mg capsules
- NITISINONE* (nitisinone) (CYC) 2 mg, 5 mg & 10 mg tablets
- ORFADIN* (nitisinone) (BVM) 2 mg, 5 mg, 10 mg & 20 mg capsules
- PRALUENT* (alirocumab) (SAV) 75 mg/mL & 150 mg/mL injection pens & syringes

Highlights of Drug Products Added

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2019:

- CAMPRAL* (acamprosate calcium)
 (MVP) 333 mg delayed-release tablet via SA
- MEZERA (mesalazine) (AVP) 1 g rectal suppository

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 New IC Groupings, effective December 1, 2018:

APO-HYDROMORPHONE CR
 (hydromorphone hydrochloride) (APX) 3 mg, 4.5 mg, 6 mg, 9 mg, 18 mg, 24 mg & 30 mg controlled release capsules

- LACOSAMIDE* (lacosamide) (various brands: AUR, PMS, SDZ, TEV) 50 mg, 100 mg, 150 mg & 200 mg tablets listed via SA
- MAR-METHIMAZOLE (thiamazole) (MAR) 5 mg 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, 2019:

 TARO-DIPYRIDAMOLE/ ASA (dipyridamole/acetylsalicylic acid) (TAR) 200 mg/25 mg capsule

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective February 1, 2019:

- APO-HYDROMORPHONE CR (hydromorphone hydrochloride) (APX) 12 mg controlled-release capsule
- APO-NALTREXONE (naltrexone hydrochloride) (APX) 50 mg tablet
- APO-PINAVERIUM (pinaverium bromide) (APX) 50 mg & 100 mg tablets
- BACKUP PLAN ONESTEP (levonorgestrel) (APX) 1.5 mg tablet
- NALTREXONE HYDROCHLORIDE TABLETS USP (naltrexone hydrochoride) (JPC) 50 mg tablet

Step Therapy/Special Authorization Criteria Changes

The Step Therapy/Special Authorization criteria for coverage for the following Drug Product has been revised effective December 1, 2018:

 CAYSTON* (aztreonam) (GIL) 75 mg/vial powder for inhalation solution

The Step Therapy/Special Authorization criteria for coverage for the following Drug Products have been revised effective January 1, 2019:

JARDIANCE* (empagliflozin) (BOE) 10 mg & 25 mg tablets