the DBL report

Issue #104, September 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)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 24, 2018. The Committee reviewed Manufacturer submissions for twenty-two (22) 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 seven (7) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirteen (13) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2018, and seventy (70) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 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* effective September 1, 2018:

- **PROCYSBI*** (cysteamine bitartrate) (RAP) **25 mg & 75 mg delayed-release capsules** via Special Authorization (SA)

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *Palliative Coverage Drug Benefit Supplement* effective September 1, 2018:

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

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 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 September 1, 2018:

- **APO-VARENICLINE STARTER PACK*** (varenicline tartrate/varenicline tartrate) (APX) **0.5 mg/1 mg tablets** listed via Restricted Benefit/SA
- Pregabalin (APX, PMS, RAN, SNS, SIV & SDZ) **25 mg, 50 mg, 75 mg, 150 mg & 300 mg capsules**
- Pregabalin (MPI) **25 mg, 50 mg, 75 mg, 150 mg capsules**
- Trandolapril (PMS & SDZ) **0.5 mg, 1 mg, 2 mg, & 4 mg capsules**

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 September 1, 2018:

- **PMS-NITROFURANTOIN** (nitrofurantoin) (PMS) **100 mg capsule**
- **RAN-RAMIPRIL HCTZ** (ramipril/ hydrochlorothiazide) (RAN) **2.5 mg/12.5 mg & 5 mg/25 mg tablets**

Special Authorization Criteria Changes

SA criteria have been revised for the following Drug Products effective August 1, 2018:

- **LEMTRADA*** (alemtuzumab) (GZM) **12 mg/vial injection**
- **TYSABRI*** (natalizumab) (BIO) **20 mg/mL injection**

SA criteria have been revised for the following Drug Product effective September 1, 2018:

- **DIFICID*** (fidaxomicin) (MFC) **200 mg film-coated tablet**

Non-Innovator Policy Review

The Non-Innovator Policy of the *ADBL* provides a mechanism by which Multisource Drug Products may seek a listing designation as interchangeable with a Canadian Innovator Reference Product (CIRP) that is not currently listed on the *ADBL* when that CIRP has been identified by the Minister. The Minister may identify a CIRP that has been considered but never listed on the *ADBL* and where the availability of a Multisource Drug Product(s) may now alter the cost effectiveness of the molecule. Through this process, a comprehensive clinical review of the following Drug Products was undertaken by the Expert Committee and this category will be added in the Non-Innovator Policy effective September 1, 2018. Once published, Submissions for Multisource Drug Products for the following non-listed CIRP will be accepted and considered for addition to the *ADBL* as per current Submission and Price Policy Guidelines:

- **REVIA (NALTREXONE HYDROCHLORIDE) 50 mg tablet**

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