the DBL report

Issue #87, September 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 July 9, 2015. The Committee reviewed Manufacturer submissions for fifty (50) 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-nine (29) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, seventeen (17) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2015 and twenty-seven (27) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 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 Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization (SA) effective September 1, 2015:

- **ABILIFY MAINTENA*** (aripiprazole) (OTS) **300 mg/vial & 400 mg/vial injections**
- **BANZEL*** (rufinamide) (EIS) **100 mg, 200 mg & 400 mg tablets**
- **INSPRA*** (eplerenone) (PFI) **25 mg & 50 mg tablets**
- **ULTIBRO BREEZHALER*** (indacaterol maleate/ glycopyrronium bromide) (NOV) **110 mcg/50 mcg inhalation capsule**

The following Drug Product was reviewed by CDR and was added to the *ADBL* via SA effective September 1, 2015:

- **HOLKIRA PAK*** (ombitasvir/ paritaprevir/ ritonavir/ dasabuvir sodium monohydrate) (ABV) **12.5 mg/75 mg/50 mg/250 mg tablets**

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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 Products were reviewed by CDR and the Expert Committee and were added to the *ADBL* via Step Therapy / Special Authorization effective September 1, 2015:

- **MYRBETRIQ*** (mirabegron) (ASP) **25 mg & 50 mg extended-release tablets**

Highlights of Other Products Reviewed but Not Added

- **COMBIVENT RESPIMAT** (ipratropium bromide/salbutamol) (BOE) **20 mcg/100 mcg inhalation solution** re-submission was reviewed as a Line Extension to Combivent nebules but was not added as this Drug Product fails to offer a therapeutic advantage.

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

- **AFINITOR** (everolimus) (NOV) **2.5 mg, 5 mg & 10 mg tablets**
- **JUXTAPID** (lomitapide mesylate) (AEP) **5 mg, 10 mg & 20 mg capsules**

Highlights of Interchangeable Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective September 1, 2015*:*

- **TEVA-PROGESTERONE with peanut oil**** (progesterone) (TEV) **100 mg capsule**

****Note:** Due to the high prevalence of peanut allergies within the population, Alberta Health has chosen to highlight the fact that Teva-Progesterone 100mg Capsule (DIN 02439913) contains peanut oil while the brand name drug product, Prometrium 100 mg Capsule (DIN 02166704) does not. Please note that the Expert Committee does not regularly review possible allergens within drug products listed on the *ADBL* and it remains the responsibility of the prescribing physician and dispensing pharmacist to review all patient allergies.

The following Drug Product was reviewed by the Expert Committee and added to the *Palliative Coverage Drug Benefit Supplement* effective September 1, 2015*:*

- **RELAXA** (PEG 3350) (RED) **oral powder**

Special Authorization Criteria Changes

The criteria for coverage via Special Authorization for the following Drug Products have been revised effective September 1, 2015:

- **GILENYA*** (fingolimod HCL) (NOV) **0.5 mg capsule**
- **IBAVYR*** (ribavirin) (PPH) **400 mg & 600 mg tablets**
- **TYSABRI*** (natalizumab) (BIO) **20 mg/mL (15 mL) injection**

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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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