the ADBL report

Issue #71, February 2013

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 November 27 & 28, 2012. The Committee reviewed Manufacturer submissions for 54 Drug Products for potential listing, or change in listing status, on the *ADBL*.

In addition to these Drug Products, 49 generic Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2012, and 28 generic Drug Products underwent Expedited Review for listing effective February 1, 2013.

The following are highlights of recent changes to the *ADBL*. A complete list of changes and the full *ADBL* can be found at

https://www.ab.bluecross.ca/dbl/publications.html

Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendations from the CDR, the following Drug Products have been added to the *ADBL* (please refer to the current *ADBL* for a full listing of coverage criteria):

- **TOVIAZ** (fesoterodine fumarate) (PFI) **4 mg & 8 mg extended-release tablets** are indicated for the treatment of patients with overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence, or any combination of these symptoms. The Expert Committee recommended these Drug Products for listing on the *ADBL*, via Step therapy/Special Authorization, as they offer a cost advantage.
- **ASMANEX TWISTHALER** (mometasone furoate) (MFC) **200 mcg/dose & 400 mcg/dose breath-acuated dry powder inhalers** was reviewed as a resubmission and is indicated for the prophylactic management of steroid-responsive bronchial asthma in patients 12 years of age and older. The Expert Committee recommended these Drug Products for listing on the *ADBL*, as they offer a cost and/or therapeutic advantage.
- **SAPRHIS** (asenapine maleate) (LBC) **5 mg & 10 mg sublingual tablets** was reviewed as a resubmission for the indication of Bipolar I Disorder. The Expert Committee recommended these Drug Products for listing on the *ADBL*, via Special Authorization, as they offer a therapeutic advantage.

In keeping with the recommendations from the CDR, the following Drug Product has not been added to the *ADBL*:

- **MOZOBIL** (plerixafor) (GZM) **20 mg/mL injection**

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).*

Highlights of Products Added to the ADBL

The Expert Committee recommended that the following Drug Products be added to the *ADBL*, effective February 1, 2013:

- **GD-AMLODIPINE** (amlodipine besylate) (GMD) **2.5 mg tablet**
- **JAMP-ATENOLOL** (atenolol) (JPC) **25 mg tablet**
- **JAMP-CITALOPRAM** (citalopram hydrobromide) (JPC) **10 mg tablet**

Highlights of Entry IC Products Added

The following are Entry IC Drug Products, added to the ADBL, effective February 1, 2013 after a Full Review by the Expert Committee:

- **ACCEL-CLARITHROMYCIN** (clarithromycin) (ACP) **25 mg/mL & 50 mg/mL oral suspensions**
- **APO-LAMIVUDINE HBV** (lamivudine) (APX) **100 mg tablet** as a restricted benefit

Highlights of Established IC Products Added

- **APO-RIZATRIPTAN** (rizatriptan benzoate) (APX) **10 mg tablet** as a restricted benefit
- **JAMPZINC-HC** (hydrocortisone acetate/zinc sulfate monohydrate) (JPC) **0.5%/0.5% rectal ointment**
- **MAR-GABAPENTIN** (gabapentin) (MAR) **100 mg, 300 mg & 400 mg capsules**

Highlights of Expedited Entry IC Products Added

The following are Entry IC Drug Products, added to the ADBL, effective February 1, 2013:

- **APO-CANDESARTAN/HCTZ** (candesartan cilexetil/ hydrochlorothiazide) (APX) **32 mg/12.5 mg & 32 mg/25 mg tablets**
- **APO-ENTECAVIR** (entecavir) (APX) **0.5 mg tablet** as a restricted benefit

Motherisk Guidance: Use of Pre-Requisite Medications Prior to Biologic Coverage

The Expert Committee reviewed the administration of coverage criteria for biologic agents when pregnancy or fertility issues are cited as reasons for not utilizing pre-requisite medications, particularly leflunomide and methotrexate. The Committee indicated that the fact that a patient may be of child bearing age or potential does not merit the practice of waiving the use of pre-requisite medications for biologics. Please see below for a response from The Motherisk Program:

“There is, to the best of our knowledge, no evidence that methotrexate or leflunomide should not be used in women of childbearing age, provided proper explanation of their teratogenic potential is given to the women and the importance of contraception is explained and emphasized by her treating physicians and proper contraception is practiced by her during the treatment period. It’s vital to emphasize the importance of pregnancy planning in this population in order to optimize pregnancy outcomes.”

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).****