the ADBL report

Issue #73, June 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 Alberta Health Expert Committee on Drug Evaluation and Therapeutics met on March 13, 2013. The Committee reviewed Manufacturer submissions for 50 Drug Products for potential listing, or change in listing status, on the *ADBL*. The Committee also considered information for a number of supplementary assessments of coverage status of 21 Drug Products.

In addition, thirty-five (35) generic Drug Products underwent Expedited Review for listing on the *ADBL*.

The following are highlights of recent changes to the *ADBL* effective June 1, 2013. A complete list of changes and the full *ADBL* can be found at https://www.ab.bluecross.ca/dbl/publications.html

Highlights of New Products Added

- **ALLERJECT** (epinephrine) (SAV) **0.3 mg/0.3 mL & 0.15 mg/0.15 mL solutions for injection,** for the emergency treatment of anaphylactic reactions, were added to the *ADBL* as they provide a therapeutic advantage.
- **DIVIGEL** (estradiol-17B) (FEI) **0.1% transdermal gel,** indicated in the treatment of moderate to severe vasomotor symptoms associated with menopause, was recommended to be added to the *ADBL* as it provides a slight cost advantage over currently listed Drug Products.
- **METHADOSE** and **METHADOSE SUGAR FREE** (methadone hydrochloride) (MAL) **10 mg/mL oral liquids** were added as they fulfill an unmet need and appear to be associated with improved safety and quality control as compared with compounded methadone preparations.

Highlights of Products Originally Reviewed via the Common Drug Review (CDR)

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

- **LATUDA** (lurasidone hydrochloride) (SUN) **40 mg, 80 mg & 120 mg tablets**
- **SAMSCA** (tolvaptan) (OTS) **15 mg & 30 mg tablets**

Highlights of Established IC Drug Products Added

- **TEVA-RAMIPRIL/HCTZ** (ramipril/hydrochlorothiazide) (TEV) **2.5 mg/12.5 mg, 5 mg/12.5 mg, 10 mg/12.5 mg, 5 mg/25 mg & 10 mg/25 mg tablets**

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 Natural Health Products Added

The Expert Committee reviews Natural Health Product (NHP) submissions based on the submission requirements including evidence that the active moiety or moieties or Natural Health Product was previously or is currently listed on the *ADBL* and evidence from the Manufacturer to demonstrate that there is an unmet need for the submitted product.

The following NHPs have been added to the *ADBL*:

- **JAMP-K 8** (potassium chloride) (JPC) **600 mg tablet**
- **JAMP-K 20** (potassium chloride) (JPC) **1500 mg tablet**
- **JAMP MAGNESIUM GLUCONATE** (magnesium gluconate) (JPC) **500 mg tablet**
- **JAMP POTASSIUM CHLORIDE LIQUID** (potassium chloride) (JPC) **1.33 mEq/mL oral liquid**

The following NHPs have been added to the *Palliative Care Drug Benefit Supplement* (*PCDBS*)*:*

- **JAMP-SENNA** (sennosides) (JPC) **8.6 mg tablet**
- **JAMP SENNAQUIL** (sennosides) (JPC) **1.7 mg/mL liquid**
- **SENNOSIDES** (sennosides) (JPC) **8.6 mg & 12 mg tablets**

Highlights of Entry 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 June 1, 2013:

- **PMS-TETRABENAZINE** (tetrabenazine) (PMS) **25 mg tablet**
- **SANDOZ LATANOPROST/TIMOLOL** (latanoprost/timolol maleate) (SDZ) **0.005%/0.5% ophthalmic solution**

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

- **ONDISSOLVE ODF** (ondansetron) (TAK) **4 mg & 8 mg orally disintegrating films**

Highlights of Criteria Changes

The criteria for coverage via Special Authorization have been revised for the following Drug Products:

- **ACTEMRA** (tocilizumab) (HLR) **80 mg/4 mL, 200 mg/10 mL & 400 mg/20 mL vial injections** (Indication - Rheumatoid Arthritis)
- **ARANESP** (darbepoetin) (AMG) **10 mcg/0.4 mL & 20 mcg/0.5 mL injection syringes, 100 mcg/mL, 200 mcg/mL & 500 mcg/mL injections** (Indication – Anemia of Chronic Renal Failure)
- **EPREX** (epoetin alfa) (JAI) **1,000 unit/0.5 mL injection, 10,000 unit/mL, 2,000 unit/0.5 mL, 20,000 unit/0.5 mL, 3,000 unit/0.3 mL, 4,000/0.4 mL, 5,000 unit/0.5 mL, 6,000 unit/0.6 mL & 8,000 unit/0.8 mL injection syringes** (Indication – Anemia of Chronic Renal Failure)

The Restricted Benefit criteria have been revised for the following Drug Products:

- **ABILIFY** (aripiprazole) (BMS) **2 mg & 5 mg tablets**

Follow-up: Pre-Requisite Medications for Biologic Coverage

Special Authorization (SA) coverage criteria for biologic agents were recently reviewed for when pregnancy or fertility issues are cited as reasons for not utilizing pre-requisite medications (e.g., leflunomide, methotrexate). Please note: The requirement for a trial of pre-requisite medications will not be waived due to a patient being of child bearing age or potential.

The following statement is from Motherisk, which provides evidence-based information and guidance about the safety or risk to the developing fetus or infant, of maternal exposure to drugs, chemicals, diseases, radiation and environmental agents (www.motherisk.org):

“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.”

The following, provided for interested clinicians, is for information only and is not intended to constitute medical advice.

Leflunomide and pregnancy:
Leflunomide is recommended to be discontinued and a wash out procedure performed prior to conception. One procedure involves administering cholestyramine 8 g, three times daily, for a period of 11 days, followed by two separate levels of the active metabolite, taken at least 14 days apart (*Drugs. 2011;71(15):1973-87*). Another regimen involves activated charcoal administration. The plasma levels of the active metabolite must be < 0.02 mg/L for the teratogenic risk to be considered low (sanofi-aventis Canada Inc., Arava product monograph, December 6, 2012).

Methotrexate and pregnancy:
Methotrexate is recommended to be discontinued three months prior to conception (*Drugs. 2011;71(15):1973-87*). High dose folic acid supplementation is recommended preconception and during the first trimester of pregnancy at least.

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