the DBL report

Issue #70, November 2012

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 September 20, 2012. The Committee reviewed Manufacturer submissions for 76 Drug Products for potential listing, or change in listing status, on the *ADBL*.

In addition to these Drug Products, 32 generic Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2012, and 16 generic Drug Products underwent Expedited Review for listing effective November 1, 2012.

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

Highlights of Products Added to the ADBL

- **OPTICHAMBER DIAMOND** (aerosol holding chamber) (RNA) **with small, medium & large masks and chamber only** were submitted as Line Extensions to the currently listed OPTICHAMBER ADVANTAGE II aerosol holding chamber and masks with the Manufacturer indicating their intention of phasing out the currently listed OPTICHAMBER devices in the future. The Expert Committee recommended **OPTICHAMBER DIAMOND** be listed on the *ADBL* via Restricted Benefits as each of these products offers a cost advantage. Please refer to the current *ADBL* for a full listing of coverage criteria.
- **LAX-A-DAY** (polyethylene glycol 3350) (PPH) **powder for solution**, a laxative, will be listed on the *Palliative Care Drug Benefit Supplement (PCDBS)* effective November 1, 2012. Alberta Health sponsors *Palliative Care Drug Coverage*, which is offered through Alberta Blue Cross to any Albertan who has been diagnosed as being palliative and whose physician or nurse practitioner has applied on their behalf.
- **ROVAMYCINE-250** (spiramycin) (ODN) **750,000 unit** & **ROVAMYCINE-500 1,500,000 unit capsules** are indicated for the treatment of infections of the respiratory tract, buccal cavity, skin and soft tissues due to susceptible organisms. The Expert Committee recommended these Drug Products for listing on the *ADBL*, following consultation with Alberta specialists in infectious diseases.
- **SANDOZ FLUOROMETHOLONE** (fluorometholone) (SDZ) **0.1% ophthalmic solution** is indicated for steroid responsive inflammation of palpebral and bulbar conjunctiva, cornea and anterior segment of globe. The Expert Committee recommended this Drug Product for listing on the *ADBL* as it offers a therapeutic advantage.

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).*

ABC 81171 (11/2012)

Highlights of Entry IC Products Added

The following are Entry IC Drug Products, added to the ADBL, effective November 1, 2012 after a Full Review by the Expert Committee:

- **CLOXACILLIN FOR INJECTION** (cloxacillin sodium) (STM) **0.5 g/vial, 1 g/vial & 2 g/vial powders for injection**
- **VANCOMYCIN HYDROCHLORIDE** (vancomycin hydrochloride) (PPC) **125 mg & 250 mg capsules**

Highlights of Expedited Entry IC Products Added

The following are Entry IC Drug Products, added to the ADBL, effective November 1, 2012:

- **CO CANDESARTAN/HCT** (candesartan cilexetil/ hydrochlorothiazide) (COB) **16 mg/12.5 mg tablet**
- **pms CANDESARTAN/HCTZ** (candesartan cilexetil/ hydrochlorothiazide) (PMS) **16 mg/12.5 mg tablet**
- **MYLAN-CANDESARTAN/HCTZ** (candesartan cilexetil/ hydrochlorothiazide) (MYP) **16 mg/12.5 mg tablet**
- **SANDOZ CANDESARTAN PLUS** (candesartan cilexetil/ hydrochlorothiazide) (SDZ) **16 mg/12.5 mg tablet**

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):

- **ACTEMRA** (tocilizumab) (HLR) **80 mg/4 mL, 200 mg/10 mL** & **400 mg/20 mL vial injections** was reviewed for the new indication of active systemic juvenile idiopathic arthritis (sJIA). The Expert Committee recommended each of these Drug Products for listing on the *ADBL*, via Special Authorization, as they offer a therapeutic advantage.
- **INCIVEK** (telepravir) (VER) **375 mg tablet** is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment naïve or who have previously been treated with interferon-based treatment, including prior null responders, partial responders, and relapsers. This Drug Product was recommended for listing on the *ADBL*, via Special Authorization, as it offers a therapeutic advantage.
- **RITUXAN** (rituximab) (HLR) **10 mg/mL injection** was reviewed for the new indications of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). The Expert Committee recommended this Drug Product for listing on the *ADBL*, via Special Authorization, as it offers a therapeutic advantage.
- **VISANNE** (dienogest) (BAI) **2 mg tablet** was reviewed for treatment of pelvic pain associated with endometriosis. The Expert Committee recommended this Drug Product for listing on the *ADBL*, via Special Authorization, as it offers cost and/or therapeutic advantage.

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

- **BYETTA** (exenatide) (LIL) **5 mcg/dose (1.2 mL) & 10 mcg/dose (2.4 mL) injection syringes**
- **RESOTRAN** (prucalopride succinate) (JAI) **1 mg & 2 mg film coated tablets**

Changes in SA Criteria for Clopidogrel

The Expert Committee completed a review of anti-platelet agents for secondary prevention of ischemic stroke. The Expert Committee agreed that the available evidence supported removing the requirement for a trial of dipyramidole plus ASA before patients could be provided coverage on the *ADBL* for **CLOPIDOGREL 75 mg tablet**. Accordingly, the Special Authorization criteria pertaining to this indication have been revised to:

"For the prevention of ischemic events (cerebrovascular (e.g. stroke, TIA) or noncerebrovascular) in patients who have experienced an ischemic event while on ASA, or who have a contraindication to ASA. Special authorization for this criterion may be granted for 6 months."

In addition, auto-renewal is available for patients approved for coverage under these criteria. Please refer to the *ADBL* for a complete listing of coverage criteria and **CLOPIDOGREL** Drug Products affected.

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).****