the DBL report

Issue #66, March 2012

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) 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 January 26, 2012. The Committee reviewed Manufacturer submissions for 43 Drug Products for potential listing or change in listing status on the *AHWDBL*.

In addition to these Drug Products, 82 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective February 1, 2012, and another 33 generic Drug Products underwent Expedited Review for listing effective March 1, 2012.

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

Highlights of New Products Added

- **OXYNEO** (oxycodone hydrochloride) (PUR) **10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg & 80 mg extended-release tablets** are a new formulation of sustained-release oxycodone, consisting of a matrix with hydrogelling properties (i.e., particles or whole tablets become highly viscous (gel-like) in water). The tablets have also been hardened, by a unique process, to reduce the risk of being broken, crushed or chewed. **OXYNEO** tablets were reviewed as line extensions to the currently listed OXYCONTIN Drug Products, which the Manufacturer intends to replace with **OXYNEO**. The Expert Committee recommended adding **OXYNEO** to the *AHWDBL*, as line extension Drug Products to, and in interchangeable groupings with, OXYCONTIN Drug Products. **OXYNEO** offers a therapeutic advantage in replacing a Drug Product that will be withdrawn from the market.
- **TWYNSTA** (telmisartan/amlodipine besylate) (BOE) **40 mg/5 mg, 40 mg/10 mg, 80 mg/5 mg & 80 mg/10 mg tablets** are new combination Drug Products indicated for the treatment of mild to moderate hypertension. **TWYNSTA** was originally reviewed via the Common Drug Review (CDR). The Expert Committee recommended that **TWYNSTA** be added to the *AHWDBL* as it offers a cost advantage over presently accepted therapies.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

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Highlights of New Interchangeable (IC) Groupings

The recent additions of the following Drug Products to the *AHWDBL* has resulted in the creation of New IC Groupings, effective March 1, 2012:

- **APO-CLOPIDOGREL** (clopidogrel bisulfate) (APX) **75 mg tablet**
- **CO CANDESARTAN** (candesartan cilexetil) (COB) **32 mg tablet**
- **CO CLOPIDOGREL** (clopidogrel bisulfate) (COB) **75 mg tablet**
- **MYLAN-CLOPIDOGREL** (clopidogrel bisulfate) (MYP) **75 mg tablet**
- **PMS-CLOPIDOGREL** (clopidogrel bisulfate) (PMS) **75 mg tablet**
- **PMS-RISPERIDONE ODT** (risperidone) (PMS) **3 mg & 4 mg orally disintegrating tablets**
- **SANDOZ CLOPIDOGREL** (clopidogrel bisulfate) (SDZ) **75 mg tablet**
- **TEVA-CLOPIDOGREL** (clopidogrel bisulfate) (TEV) **75 mg tablet**

Highlights of Benefit Coverage and Criteria Changes

- **CHAMPIX** (varenicline tartrate) (PFI) **0.5 mg & 1 mg tablets** and **0.5 mg/1 mg tablet starter pack** were reviewed, following receipt of a resubmission from the Manufacturer requesting consideration be given to revising the benefit status. **CHAMPIX** was initially listed on the *AHWDBL*, as a Restricted Benefit (RB), effective June 15, 2011. The original RB criteria required that a patient provide proof of enrolment in an eligible tobacco-cessation program in order to receive coverage of **CHAMPIX**. The Expert Committee recommended changes to the RB criteria to further facilitate access to this smoking cessation therapy. The revised RB criteria allow for initial coverage up to a total of 12 weeks, without requiring proof of enrolment in a tobacco-cessation program. In addition, the Expert Committee recommended **CHAMPIX** be made available via Special Authorization to provide supplementary coverage beyond the initial RB allowance, to a maximum of 24 weeks per year. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

Additional Products Originally Reviewed via the Common Drug Review (CDR)

- **XGEVA** (denosumab) (AMG) **120 mg/vial injection** received a CDR recommendation for listing for a specific indication, in jurisdictions where zoledronic acid is listed for the same indication. Zoledronic acid is not currently listed on the *AHWDBL* for the reviewed indication. Therefore, in keeping with the CDR recommendation, **XGEVA** has not been recommended for addition to the *AHWDBL*.

Also in keeping with the recommendations from the CDR, the following Drug Products have not been added to the *AHWDBL*:

- **ABSTRAL** (fentanyl) (PAL) **100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg & 800 mcg sublingual tablets**
- **REVOLADE** (eltrombopag olamine) (GSK) **25 mg & 50 mg tablets**

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