the DBL report

Issue #57, September 2010

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 Thursday, July 29, 2010. At the meeting the Committee considered information regarding 84 Drug Products. This included review of manufacturer submissions as well as various supplementary assessments following examination of correspondence and issues raised by a range of stakeholders. An additional 51 Drug Products underwent expedited review for listing on the *AHWDBL* effective September 1, 2010. The recommendations of the Expert Committee and the listing decisions taken by Alberta Health and Wellness will result in the addition of 110 Drug Products, increasing available therapies for plan members, and providing potential cost savings of $1.8 million over the next year.

The following articles provide highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of Products Added

■ **UROMAX** (oxybutynin chloride) (PUR) **10 mg & 15 mg extended-release tablets** have been added to the *AHWDBL* via Step Therapy/Special Authorization. **UROMAX** may provide a therapeutic advantage over immediate release oxybutynin in reduction of nocturnal incontinence. It is less expensive than other currently listed alternatives to immediate release oxybutynin.

■ **VAGIFEM LD** (estradiol-17B) (NNA) **10 mcg vaginal tablet** has been added to the *AHWDBL* as an unrestricted benefit. It offers similar therapeutic benefits to currently listed Drug Products with a potential advantage of a lower dose of estrogen.

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Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

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Special Authorization Criteria Changes

■ **EXJADE** (deferasirox) (NOV) **125 mg, 250 mg & 500 mg tablets** – Revisions to the Special Authorization (SA) criteria have been accepted following a recent review of coverage. The revisions clarify one of the contraindications to use of Desferal (deferoxamine) that will qualify patients for coverage with Exjade, and add an educational note.

■ **TYSABRI** (natalizumab) (BIO) **20 mg/mL injection** - Following a year of experience with administration of Tysabri coverage via the *AHWDBL*, and in light of feedback and suggestions from a number of Alberta Neurologists, the criteria for coverage of Tysabri have been revised and clarified. These changes are intended to simplify the criteria and enhance patient care.

Changes in Benefit Status

■ **XEOMIN** (clostridium botulinum neurotoxin type A (150kD), free from complexing proteins) (MPC) **100 unit/vial injection** has been moved from Special Authorization to Regular Benefit status, **effective September 1, 2010**.

■ **FLUCONAZOLE** (fluconazole) (various manufacturers) **150 mg capsules** have changed from prescription to non-prescription status. Accordingly, **effective October 31, 2010**, these Drug Products will no longer be benefits on the *AHWDBL* and will not be considered for coverage by Special Authorization.

New IC Groupings

■ **MYLAN-CLARITHROMYCIN** (clarithromycin) (MYP) **250 mg tablet** has been added to the *AHWDBL*, creating a New Interchangeable (IC) Grouping with BIAXIN BID (ABB) 250 mg.

■ **MYLAN-NIFEDIPINE** (nifedipine) (MYP) **30 mg extended-release tablet** has been added to the *AHWDBL*, creating a New IC Grouping with ADALAT XL (BAI) 30 mg.

Products Originally Reviewed via the Common Drug Review (CDR)

■ **ORENCIA** (abatacept) (BMS) **250 mg/vial injection** was reviewed via the CDR process. In keeping with the recommendation from the Canadian Expert Drug Advisory Committee (CEDAC), the SA criteria of this product have been revised to indicate patients are eligible for coverage of ORENCIA without having failed treatment with one or more anti-tumor necrosis factor (anti-TNF) therapies.

■ The following products, reviewed via the CDR process, received recommendations not to list from CEDAC. Accordingly, these products will not be listed on the *AHWDBL*:

- **CIMZIA** (certolizumab pegol) (UCB) **200 mg/mL subcutaneous solution**
- **JURNISTA** (hydromorphone hydrochloride) (JOI) **4 mg, 8 mg, 16 mg & 32 mg extended release tablets**
- **LOTEMAX** (loteprednol etabonate) (BSH) **0.5% ophthalmic suspension**
- **MULTAQ** (dronedarone hydrochloride) (SAV) **400 mg tablet**
- **NPLATE** (romiplostim) (AMG) **250 mcg/0.5 mL & 500 mcg/1 mL vial injection**
- **ONGLYZA** (saxagliptin hydrochloride) (BMS) **5 mg tablet**

Product Not Added

■ **NIASPAN FCT** (niacin) (SPC) **500 mg, 750 mg & 1000 mg extended-release tablets** were not recommended for addition to the *AHWDBL*. The Expert Committee noted that there is no available outcomes data for this Drug Product. The Expert Committee also indicated that the Drug Product submission provided little evidence to support an advantage versus over-the-counter (OTC) niacin products regarding flushing, a common side effect with niacin preparations. Accordingly, the Expert Committee determined that there is no demonstrated therapeutic advantage of this Drug Product over currently listed Drug Products. Further, other niacin products are available OTC and are not listed on the *AHWDBL*. There is no cost advantage to listing this Drug Product.

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