the DBL report

Issue #56, July 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:

Highlights of recent changes to the AHWDBL and other topics of general interest

Highlights of Products Added

■ **ARIXTRA** (fondaparinux sodium) (GSK) **7.5 mg/0.6 mL injection syringe**, a synthetic antithrombotic agent, is a line extension to the currently listed 2.5 mg/0.5 mL injection syringe. This product was added to the *AHWDBL* as it provides a therapeutic advantage and a potential cost advantage.

■ **EDECRIN** (ethacrynic acid) (ATP) **25 mg tablet** will be added to the *AHWDBL* as an unrestricted benefit. The product monograph indicates it is especially useful in patients unresponsive to the commonly used diuretics.

■ **EMEND** (aprepitant) (MFC) **80 mg capsule** will be added as a Restricted Benefit to be prescribed by Directors of Alberta Health Services – Cancer Care "Cancer Centres" (or their designates). Previously, only the **EMEND TRI-PACK**, which contained one 125 mg capsule and two 80 mg capsules, was listed.

■ **LUMIGAN RC** (bimatoprost) (ALL) **0.01% ophthalmic solution** will be listed as interchangeable with the original LUMIGAN 0.03%, as these products were shown to be therapeutically equivalent and can be considered pharmaceutical alternatives within the context of interchangeability.

■ **PMS-HYDROCHLOROTHIAZIDE** (hydrochlorothiazide) (PMS) **12.5 mg tablet** is being added to the *AHWDBL* in order to provide access, to avoid tablet splitting, to enhance patient safety and to reduce potential product wastage.

■ **STALEVO** (levodopa/carbidopa/entacapone) (NOV) **75 mg/18.75 mg/200 mg & 125 mg/31.25 mg/200 mg tablets** are intermediate strengths to currently listed STALEVO products, and will provide a therapeutic advantage by allowing more flexibility in dosing.

■ The following aerosol holding chambers for use with metered dose aerosol inhalers will also be added to the *AHWDBL* as Restricted Benefits:

- **AEROCHAMBER PLUS FLOW-VU** (aerosol holding chamber) (TMI) **with mouthpiece, with small mask, with medium mask and with large mask**
- **OPTICHAMBER ADVANTAGE II** (aerosol holding chamber) (ACM) **chamber only, with small mask, with medium mask and with large mask**

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).*

ABC 81171 (7/2010)

Highlights of New IC Groupings

■ As part of the Expedited Review process for interchangeable (IC) products, updates to the *AHWDBL* are now posted on a monthly basis (when applicable). Of note, the following products will be listed in a New IC Grouping with LIPITOR (atorvastatin calcium) (PFI) 10 mg, 20 mg, 40 mg & 80 mg tablets, **effective July 1, 2010**:

- **APO-ATORVASTATIN** (APX)
- **ATORVASTATIN** (RPH)
- **ATORVASTATIN** (SNS)
- **CO ATORVASTATIN** (COB)
- **NOVO-ATORVASTATIN** (TEV)
- **PMS-ATORVASTATIN** (PMS)
- **RAN-ATORVASTATIN** (RAN)
- **RATIO-ATORVASTATIN** (RPH)
- **SANDOZ ATORVASTATIN** (SDZ)

■ The following products were deemed interchangeable with respective strengths of the innovator, AMERGE (naratriptan hydrochloride) (GSK), and will be listed in a New IC Grouping as Restricted Benefits/ Special Authorization benefits:

- **NOVO-NARATRIPTAN** (naratriptan hydrochloride) (TEV) **1 mg & 2.5 mg tablets**
- **SANDOZ NARATRIPTAN** (naratriptan hydrochloride) (SDZ) **2.5 mg tablet**

Products Originally Reviewed via the Common Drug Review (CDR)

■ **AZARGA** (brinzolamide/timolol maleate) (ALC) **1%/0.5% ophthalmic suspension** was reviewed via the CDR process. In keeping with the recommendation from the Canadian Expert Drug Advisory Committee (CEDAC), this product will be listed in a similar manner as other carbonic anhydrase inhibitor/beta blocker combination products. Accordingly, this product will be granted an unrestricted listing on the *AHWDBL*.

■ **SIMPONI** (golimumab) (SCH) **50 mg/0.5 mL injection syringe & autoinjector** received positive recommendations for listing for the indications of ankylosing spondylitis (AS), psoriatic arthritis (PsA) and rheumatoid arthritis (RA). Accordingly, this product will be listed via Special Authorization. *In keeping with the CEDAC recommendation, this product will be limited to 12 doses per 12 month period.*

■ **XEOMIN** (botulinum neurotoxin type A, free from complexing proteins) (MPC) **100 U/vial injection** received positive recommendations for listing for the indications of blepharospasm and cervical dystonia (spasmodic torticollis). Accordingly, this product will be listed via Special Authorization.

■ 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*:

- **ABILIFY** (aripiprazole) (BMS) **2 mg, 5 mg, 10 mg, 15 mg, 20 mg & 30 mg tablets**
- **FORTEO** (teriparatide) (LIL) **250 mcg/mL injection**
- **SOLIRIS** (eculizumab) (API) **10 mg/mL vial for intravenous infusion**
- **VYVANSE** (lisdexamfetamine dimesylate) (SHB) **30 mg & 50 mg capsules**

Highlights of Products Not Added

■ The following products will not be added as data has not been provided to demonstrate interchangeability with the *Canadian innovator product*:

- **MYLAN-CARVEDILOL** (carvedilol) (MYP) **3.125 mg, 6.25 mg, 12.5 mg & 25 mg tablets**
- **NOVO-SALBUTAMOL HFA** (salbutamol) (TEV) **100 mcg/dose metered dose aerosol inhaler**

According to current published criteria for interchangeability, multisource drug products seeking a listing designation as interchangeable may be eligible for listing if "the drug product has been granted a Notice of Compliance by Health Canada that includes a declaration of bioequivalence with a Canadian brand/innovator reference product that is listed (or at the sole discretion of Alberta Health and Wellness and/or the Minister, has been previously listed) on the *Alberta Health and Wellness Drug Benefit List*."

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