the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

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Highlights of:

ABC 81171 (07/2007)

Highlights of New Products Added

■ **DIOVAN** (valsartan) (NOV) **320 mg tablet** is a line extension to the currently listed 80 mg & 160 mg tablets. According to the manufacturer, this new, higher strength has been introduced as an alternative to the addition of a thiazide diuretic in patients with essential hypertension who are currently on DIOVAN 160 mg but are not adequately controlled. In the product submission the manufacturer provided evidence to support additional blood pressure lowering effect from dose increases. The updated product monograph indicates that it is "not recommended to prescribe the maximum dose of **320 mg** without prior up-titration." The Committee noted that higher strengths of DIOVAN may confer additional clinical benefit in select patients, and acknowledged that the use of the **320 mg tablet** would provide a cost savings for those who require 2 x 160 mg daily. Accordingly, the Committee recommended that this product be listed.

■ **APO-DESMOPRESSIN** (desmopressin acetate) (APX) **0.1 mg & 0.2 mg tablets** are first-entry generic products that have been deemed interchangeable with DDAVP 0.1 mg & 0.2 mg tablets. These products offer 30% savings compared to DDAVP tablets, with anticipated savings of over $165,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Accordingly, the Committee recommended the addition of these products to the *AHWDBL*.

■ **APO-ONDANSETRON** (ondansetron hydrochloride dihydrate) (APX) **4 mg & 8 mg tablets** were reviewed by the Committee and found to be interchangeable with ZOFRAN 4 mg & 8 mg tablets. **APO-ONDANSETRON** tablets are subsequent-entry generic products that offer just over 40% savings over the innovator, ZOFRAN, as well as additional savings over the listed least-cost alternative (LCA) price. The addition of these products to the *AHWDBL* could offer potential savings of over $113,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Accordingly, they have been added to the *AHWDBL* in the respective interchangeable groupings.

■ **APO-PERINDOPRIL** (perindopril erbumine) (APX) **8 mg tablet** was found to be interchangeable with COVERSYL 8 mg. The addition of this first-entry generic product to the *AHWDBL*, has the potential to bring over $131,000 in savings to the government-sponsored drug programs. Accordingly, **APO-PERINDOPRIL 8 mg tablet** has been added to the *AHWDBL*.

Highlights of Special Authorization Products Added

■ **SANDOZ ALENDRONATE** (alendronate sodium) (SDZ) **10 mg & 70 mg tablets** were reviewed and found to be interchangeable with the respective strengths of the innovator, FOSAMAX tablets. As a result, these products will be added to the *AHWDBL* in the applicable interchangeable groupings, and will be subject to special authorization with criteria at parity with the currently listed alendronate sodium 10 mg & 70 mg products.

Highlights of Products Not Added

■ **HUMALOG MIX50** (insulin lispro/insulin lispro protamine) (LIL) **50%/50% injection cartridge** is a line extension to the currently listed HUMALOG products. Upon review of the product submission provided by the manufacturer, the Committee noted that the clinical data did not demonstrate a clear therapeutic advantage for this product over other currently listed alternatives. As a result, the Committee recommended that this product should not be added to the *AHWDBL*.

Highlights of Special Authorization Criteria Changes

■ **PEGASYS RBV** (peginterferon alfa-2a/ribavirin) (HLR) and **PEGETRON** (peginterferon alfa-2b/ribavirin) (SCH) combination products are currently covered on the *AHWDBL* via special authorization for the treatment of chronic hepatitis C. The published special authorization criteria provide consideration for reimbursement for treatment in patients that have previously received therapy, only in specified situations. The Committee clarified that requests for patients with advanced fibrosis or cirrhosis will be eligible for coverage of 48 weeks, without the requirement for further qualitative or quantitative testing for HCV RNA at 12 or 24 weeks. The special authorization criteria have been modified to reflect this clarification. Please refer to the current *AHWDBL* for a full listing of special authorization criteria.

■ **PLAVIX** (clopidogrel bisulfate) (BMS) **75 mg tablet** is available on the *AHWDBL* as both a *limited restricted benefit* (LRB) and via *special authorization* (SA) coverage, for a number of indications. As a result of their ongoing commitment to refining coverage criteria of this product through the *AHWDBL*, the Committee continues to review information regarding the use of **PLAVIX** in the prevention of thrombosis following intravascular stent placement.

Coverage following placement of an intravascular stent: PLAVIX is currently accessible through the LRB for one month of coverage following the first intravascular stent placement when prescribed by a designated specialist, through SA for one month of coverage following a subsequent intravascular stent placement, or following the first intravascular stent placement when prescribed by an individual other than a designated specialist (please refer to the LRB criteria for the definition of designated prescriber). In light of emerging information, the Committee has recommended that SA coverage be extended for up to a total of 12 months if the intravascular stent being placed is a **drug-eluting stent (DES)**.

*Please note: The LRB will remain available for the first month following the placement of an intravascular stent when prescribed by a designated specialist, regardless of the type of stent (i.e. bare metal stent or drug-eluting stent); however, if the patient has received a drug-eluting stent, an SA request will need to be submitted by the prescriber for additional coverage (up to 12 months). For a full listing of limited restricted benefit and special authorization criteria for **PLAVIX**, please refer to the current AHWDBL.*

Changes in Benefit Status

■ **VENTOLIN NEBULES P.F.** (salbutamol sulfate) (GSK) **2 mg/mL (base) inhalation unit dose solution**, as well as all other brands of this product currently listed in the interchangeable grouping published within the *AHWDBL*, have been recommended to be moved to an open listing. These products, previously available via special authorization for patients unable to use, or allergic to preservatives contained in, the multi-dose solution, will be available as unrestricted benefits. The additional affected brands include: APO, GEN, NU, PMS and RATIO.

■ **EUMOVATE** (clobetasone butyrate) (GKC) **0.05% topical cream** has been moved from prescription status to being available over-the-counter (OTC). As a result of this change in prescription status, the Committee conducted a review of this product and recommended that it be de-listed from the *AHWDBL*.