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)

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ABC 81171 (10/2004)

Highlights of New Products Added

■ **ATROVENT HFA** (ipratropium bromide) (BOE) 20 mcg/dose metered dose inhaler (MDI) has been added due to the impending removal of the current chlorofluorocarbon (CFC)-containing ATROVENT 20 mcg/dose MDI from the Canadian market. The transition from the CFC-containing ATROVENT to **ATROVENT HFA** is in keeping with the Environment Canada national transition strategy (as per the Montreal Protocol) to phase-out the use of ozone-depleting substances such as CFCs in MDIs.

In making their recommendation to add **ATROVENT HFA**, the Committee considered pharmacodynamic and clinical studies that demonstrated a 40 mcg dose (2 puffs of 20 mcg) delivered via the HFA MDI was therapeutically equivalent to a 40 mcg dose of the CFC MDI. Interestingly, pharmacokinetic studies included in the submission showed that the systemic bioavailability of ipratropium was significantly higher with the HFA MDI than with the CFC MDI ($p<0.05$); however, evidence of therapeutic equivalence of the above doses was provided in the clinical studies. It should be noted that **ATROVENT HFA** has not been designated as interchangeable with ATROVENT (CFC-containing) as no information was provided upon which the bioequivalence of the two formulations could be assessed.

■ **LESCOL XL** (fluvastatin sodium) (NOV) 80 mg extended release tablet is a line extension to the currently listed LESCOL product line, consisting of the 20 mg & 40 mg capsules. **LESCOL XL** 80 mg is dosed once daily, and is therefore an alternative for patients currently prescribed a dose of 40 mg twice daily. In addition, it was noted that this product provides a cost advantage, as the cost of one 80 mg XL tablet is less expensive than the cost of 2 x 40 mg capsules. Accordingly, the Committee recommended the addition of **LESCOL XL** 80 mg as it offers a therapeutic and/or cost advantage.

■ **APO-ALENDRONATE** (alendronate sodium) (APX) 10 mg tablet is a subsequent-entry generic product that has been deemed interchangeable with the innovator, FOSAMAX 10 mg tablet. This product was recommended for addition to the *AHWDBL* at parity with FOSAMAX and NOVO-ALENDRONATE 10 mg tablets, the current least cost alternative (LCA) product. **APO-ALENDRONATE** is priced equivalent to NOVO-ALENDRONATE, both offering a 30% savings over FOSAMAX. All three products are subject to coverage via special authorization. Please refer to the current *AHWDBL* for a full listing of special authorization criteria for these products.

Pegetron Special Authorization Criteria Change

■ **PEGETRON** (peginterferon alfa-2b/ ribavirin) (SCH) is currently available via special authorization on the *AHWDBL*. Following the Expert Committee's review of the new Canadian consensus guidelines on the management of viral Hepatitis, they recommended a change to the special authorization criteria for **PEGETRON**. Specifically, patients who are infected with genotype 1, and achieve a 2-log drop but who do not clear HCV RNA from serum at week 12, will be required to undergo repeat testing at 24 weeks to determine if they have cleared the virus. Please refer to the current *AHWDBL* for a full listing of special authorization criteria for **PEGETRON**.

Highlights of Products Not Added

■ **ALDARA** (imiquimod) (MMH) 5% topical cream was originally reviewed for potential addition to the *AHWDBL* in 1999. At that time, the Expert Committee gave due consideration to the information provided; however, it was concluded that there was insufficient evidence to support that **ALDARA** offered a significant therapeutic or cost advantage vis-à-vis other available therapies listed on the *AHWDBL*. Furthermore, it was noted that there appeared to be no head-to-head comparisons with other active therapies. The Committee recently reviewed a resubmission for this product for the indication of in the treatment of external genital warts, but noted that no new information was presented that would merit reconsideration of their previous decision. Accordingly, the Committee recommended that **ALDARA** not be added to the *AHWDBL*.

■ **NASONEX** (mometasone furoate) (SCH) 50 mcg/dose nasal metered dose spray is currently listed on the *AHWDBL* as a restricted benefit *for patients 3 to 12 years of age inclusive for the treatment of seasonal allergic rhinitis or perennial allergic rhinitis*. The Expert Committee considered a resubmission from the manufacturer requesting that the **NASONEX** be listed via special authorization for the treatment of acute sinusitis as adjunctive treatment to antibiotics. The Committee had reviewed a similar request in 2001; however, it was noted that the clinical data provided at that time did not appear to support a significant therapeutic advantage that would warrant a change in benefit status. The Committee gave due consideration to the information provided with the resubmission, but noted that no new information was provided that had not been previously reviewed. Accordingly, the Committee recommended that **NASONEX** maintain its current listing as a restricted benefit.

Products Removed from the AHWDBL

■ **642** (propoxyphene hydrochloride) (LIO) 65 mg tablet and **DARVON-N** (propoxyphene napsylate) (PAL) 100 mg capsule – A comprehensive review of the medical literature pertaining to propoxyphene containing products was conducted as a component of the Review of Benefit Status (ROBS) process. The Expert Committee gave due consideration to the information available and concluded that these products no longer possess a demonstrated therapeutic advantage compared to other presently accepted therapies or treatments of the disease entity for which they are indicated. In addition, the Committee noted ongoing concerns regarding the safety of this product. Accordingly, these products were recommended for removal from the *AHWDBL*, **effective October 1, 2004**. A 60-day transition period will apply to both products, and therefore claims will be honored for processing until December 1, 2004. More detailed information on the ROBS process, including ROBS criteria, can be found in the currently published *AHWDBL*.