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 Products Added via Special Authorization

■ **EZETROL** (ezetimibe) (MFC) is a new class of lipid lowering compounds that selectively inhibit the intestinal absorption of cholesterol and related plant sterols. The Committee indicated that the clinical evidence reviewed supports that **EZETROL** may be of benefit to reduce cholesterol in select groups of high-risk patients. Accordingly, the Committee recommended that **EZETROL** be added to the *AHWDBL*, via the following special authorization criteria:

"For the treatment of hypercholesterolemia in patients who are intolerant to statins or in whom a statin is contraindicated and who are at high cardiovascular risk as defined by possessing one of the following: 1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or 2) Diabetes, or 3) Familial hypercholesterolemia, or 4) Three or more of the following risk factors: Family history of premature cardiovascular disease, Smoking, Hypertension, Obesity, Glucose Intolerance, Renal disease. Special authorization for these criteria may be granted for 24 months."

"For the treatment of hypercholesterolemia when used in combination with a statin in patients failing to achieve target LDL (<2.5mmol/L) with a statin at maximum tolerable dose or maximum recommended dose as per respective product monograph and who are at high cardiovascular risk as defined by possessing one of the following: 1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or 2) Diabetes, or 3) Familial hypercholesterolemia, or 4) Three or more of the following risk factors: Family history of premature cardiovascular disease, Smoking, Hypertension, Obesity, Glucose Intolerance, Renal disease. Special authorization for these criteria may be granted for 24 months."

■ **SPIRIVA** (tiotropium bromide monohydrate) (BOE) is a long-acting, broncho-selective anticholinergic agent indicated for the long term, once daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. The Committee noted that **SPIRIVA** reduces the number of severe COPD exacerbations, and indicated that it may reduce hospitalizations. Hence, the Committee recommended that **SPIRIVA** be added via special authorization with the following criteria for coverage: "For the treatment of patients with moderate to severe chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in one second (FEV_1) less than or equal to 65% of the normal predicted value and with a forced expiratory volume in one second to forced vital capacity ratio (FEV_1/FVC) of less than or equal to 70% and for whom breathlessness persists despite an adequate trial of a short-acting beta-2 agonist and inhaled ipratropium. Special authorization for these criteria may be granted for 24 months."

Novo-Alendronate 10 mg tablets

■ **NOVO-ALENDRONATE** (alendronate sodium) (NOP) 10 mg tablet is a first-entry generic product deemed interchangeable with the innovator, FOSAMAX 10 mg. The Committee recommended this product be listed in the *AHWDBL*, subject to the same special authorization criteria applied to FOSAMAX 10 mg. **NOVO-ALENDRONATE** was added to the *AHWDBL* effective November 1, 2003. This product offers a 30% savings over the innovator, and with the application of the least cost alternative (LCA) pricing policy beginning January 1, 2004, could result in anticipated savings of over $1,000,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

Changes to Special Authorization Criteria for Actos

■ **ACTOS** (pioglitazone hydrochloride) (LIL) – Effective October 1, 2003, the special authorization criteria for **ACTOS** 15 mg, 30 mg and 45 mg tablets were revised to read: "For the treatment of Type 2 diabetes mellitus in patients who are not adequately controlled by optimum doses or who are intolerant to metformin or sulfonylureas, or for whom these products are contraindicated. Special authorization may be granted for 24 months." Information is required regarding previous medications utilized and the patient's response to therapy. Information is also required regarding the requested Actos dose and dosing frequency. Coverage may be considered for once-daily dosing only.

Highlights of Products Added

■ **APO-CARVEDILOL** (carvedilol) (APO) and **PMS-CARVEDILOL** (carvedilol) (PMS) 3.125 mg, 6.25 mg, 12.5 mg & 25 mg tablets were deemed interchangeable with the respective strengths of COREG. The Committee recommended that these products be added to the *AHWDBL* as they offer 33% savings over the innovator product and anticipated savings of approximately $522,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. These products were listed effective November 1, 2003, as they met criteria for FAST-TRACK addition to the *AHWDBL*.

■ **CO-SIMVASTATIN** (simvastatin) (COB) 5 mg, 10 mg, 20 mg, 40 mg & 80 mg tablets are subsequent-entry interchangeable products. **CO-SIMVASTATIN** was added to the *AHWDBL* in an interchangeable grouping with APO-SIMVASTATIN, GEN-SIMVASTATIN and ZOCOR, effective November 1, 2003, as it met the criteria for FAST-TRACK addition by offering greater than $500,000 per year in additional savings to government-sponsored programs over the currently listed least cost alternative (LCA) price.

■ **METADOL** (methadone hydrochloride) (PMS) 1 mg, 5 mg, 10 mg and 25 mg tablets are line extensions of the Pharmascience methadone product line. The Committee noted that methadone capsules are currently compounded by pharmacists, and that commercially available methadone tablets might offer a therapeutic alternative for management of severe pain. Furthermore, the Committee commented that cost of **METADOL** tablets is less expensive to within the price range of other presently accepted therapies available for the treatment of pain. Accordingly, the Committee recommended this product be added to the *AHWDBL* as it offers a cost and/or therapeutic advantage.

Highlights of Products Not Added

■ **CONCERTA** (methylphenidate hydrochloride) (JOI) 18 mg, 36 mg & 54 mg tablets are extended-release formulations of methylphenidate hydrochloride, indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The Committee noted that the clinical evidence reviewed appeared to support that **CONCERTA** provides similar therapeutic benefit to methylphenidate IR tablets. However, given both the clinical and economic information provided, the Committee questioned whether the addition of this agent would merit the incremental costs that would be incurred. Accordingly, the Committee recommended that this product not be listed in the *AHWDBL* as it fails to offer a therapeutic and/or cost advantage over presently accepted therapies.

■ **PENNSAID** (diclofenac sodium) (DHC) is a 1.5% w/w topical solution of diclofenac sodium in 45.5% dimethylsulfoxide (DMSO). **PENNSAID** is indicated for treatment of the symptoms associated with osteoarthritis of the knee(s) only, for a treatment regimen of not more than three months duration, whether continuous or intermittent. The Committee noted that the financial impact of listing appears to be sensitive to the dose of medication used. Given the squeeze bottle format and the potential for the use of this product on greater than one knee or other areas of the body, the Committee indicated that the addition of this product would likely be cost additive. Accordingly, the Committee recommended that this product not be added as it fails to offer a therapeutic and/or cost advantage over other products currently listed on the *AHWDBL*.