the AHWDBL 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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Highlights of New Products Added

■ **CRESTOR** (rosuvastatin) (AZC) **5 mg tablet** is a line extension to the currently listed 10 mg, 20 mg and 40 mg tablets. The Expert Committee noted that the **CRESTOR** product monograph indicates 5 mg is the recommended starting dose for Asian patients, as well as patients with severe renal impairment. Also, initiation of therapy with 5 mg may be considered for patients requiring less aggressive LDL-C reductions or who have predisposing factors for myopathy. It was further noted that the 10 mg tablet is not scored. Accordingly, this product was recommended for addition to the *AHWDBL* as it offers the therapeutic advantage of being able to initiate therapy at a lower dose in select patients.

■ **EPREX** (epoetin alfa) (JOI) **5,000 IU pre-filled syringe** is a line extension to the currently listed pre-filled syringes, available in differing sizes ranging from 1,000 IU to 10,000 IU per syringe. The Expert Committee recognized that this additional size will provide increased dosing flexibility. In addition, the Committee noted that the cost per unit of the new syringe size is at parity with that of the other listed **EPREX** syringes. Accordingly, the Committee recommended that the **5000 IU/mL pre-filled syringe** be added as it offers a therapeutic advantage and is cost neutral. This product will be added via special authorization with the same criteria for coverage as the currently listed **EPREX** pre-filled syringes. Please refer to the current *AHWDBL* for a full listing of available formulations and special authorization criteria.

■ **OXYCONTIN** (oxycodone HCl) (PUR) **5 mg sustained-release tablet** is a line extension to the currently listed 10 mg, 20 mg, 40 mg and 80 mg strengths. The Committee acknowledged that there is a therapeutic advantage in being able to initiate patients at a lower dose and titrate more carefully and specifically to the lowest effective dose for pain management. In addition, it was acknowledged that a lower dose may also reduce opioid related side effects in opioid naïve patients. Accordingly, the Committee recommended that this product be added to the *AHWDBL* as it offers a therapeutic advantage.

■ **REMINYL ER** (galantamine hydrobromide) (JOI) **8 mg, 16 mg and 24 mg extended release capsules** are line extensions to the currently listed 4 mg, 8 mg and 12 mg immediate release (IR) tablets, which are currently available on the *AHWDBL* via special authorization for the treatment of Alzheimer's Disease. The Expert Committee considered the manufacturer's submission and justification for the new formulation, which is that the once daily administration schedule should improve adherence to therapy. In addition, the Committee recognized that the daily cost of therapy with the ER formulation is less than for the IR tablets. As a result, due to the potential therapeutic advantage of once daily dosing and the cost advantage over the IR product, the Committee recommended that **REMINYL ER** be added via special authorization at parity with the currently listed Reminyl tablets. Please refer to the current *AHWDBL* for a full listing of special authorization criteria.

Neulasta Addition

■ **NEULASTA** (pegfilgrastim) (AMG) 6 mg/0.6 mL syringe was reviewed through the Common Drug Review process. The Canadian Expert Drug Advisory Committee (CEDAC) recommended that **NEULASTA** be listed for patients with non-myeloid cancer receiving regimens with curative intent who are at high risk of developing prolonged neutropenia. However, CEDAC also expressed concerns about the cost effectiveness of **NEULASTA** and recommended that the cost effectiveness of granulocyte colony stimulating factors should be reviewed as a "class". In addition, they recommended that funding jurisdictions evaluate their current utilization of NEUPOGEN (filgrastim) (AMG), because both drugs are similar in efficacy and the relative cost of the two depend on the dose and length of use of NEUPOGEN. The Expert Committee reviewed current utilization and based on this, advised that **NEULASTA** should be covered for adult patients (18 years of age and older) subject to the following special authorization criteria for this population, effective October 1, 2005:

"To decrease the incidence of infection, as manifested by febrile neutropenia, in patients 18 years of age and older with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs with curative intent. This drug product must be prescribed by the Directors of Alberta Cancer Board Centres (or their designates)." Coverage cannot be considered for palliative patients.

Neupogen Criteria Change

Please note, the first special authorization criterion for **NEUPOGEN** have been revised to the following:

"To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs with curative intent. This drug product must be prescribed by the Directors of Alberta Cancer Board Centres (or their designates)." Coverage cannot be considered for palliative patients.

Highlights of Interchangeable Products Added

■ **APO-ALENDRONATE** (alendronate sodium) (APX) **70 mg tablet** is a first-entry generic product that was deemed interchangeable with the innovator, FOSAMAX 70 mg. At a savings of 33% over the innovator, the addition of this product to the *AHWDBL* could offer potential savings of over $2,000,000 to the government-sponsored drug programs in the first year of listing, thereby meeting criteria for FAST-TRACK addition. Accordingly, it has been added to the *AHWDBL*, **effective August 1, 2005**, subject to the same special authorization criteria as the currently listed alendronate 70 mg tablet.

■ **APO-LITHIUM CARBONATE SR** (lithium carbonate) (APX) **300 mg sustained-release tablet** was deemed interchangeable, as a first-entry generic product, with the innovator, DURALITH 300 mg. The Committee recommended that this first-entry generic product be added to the *AHWDBL* as it offers just over 40% savings compared to DURALITH with anticipated savings of approximately $17,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

Highlights of Special Authorization Criteria Changes

■ **PEGASYS RBV** (peginterferon alfa-2a/ribavirin) (HLR) and **PEGETRON** (peginterferon alfa-2b/ribavirin) (SCH) have had further refinements made to their special authorization criteria. Due to recent numerous revisions to these criteria they have been redrafted to simplify and better clarify the requirements for specific Hepatitis C genotypes and patient populations. Please refer to the current *AHWDBL* for a full listing of available formulations and current special authorization criteria.

■ **SPORANOX** (itraconazole) (JOI) **10 mg/mL oral solution** special authorization criteria have been revised as follows:

"For the treatment of oral and/or esophageal candidiasis in immunocompromised patients who are intolerant to fluconazole, or who have failed fluconazole as evidenced by significant clinical deterioration due to the fungal infection during a course of therapy or no resolution after a full course of therapy."

■ **VFEND** (voriconazole) (PFI) 200 mg/vial injection and 50 mg & 200 mg tablets are antifungal products indicated in the treatment of invasive aspergillosis. **VFEND** was added to the *AHWDBL* via special authorization, effective July 1, 2005, in keeping with the recommendation by CEDAC. The Expert Committee recommended that further restriction was prudent and therefore the special authorization criteria have been revised to the following:

"For the treatment of invasive aspergillosis for post-hospital discharge only. This medication must be prescribed in consultation with a specialist in Infectious Diseases."