the DBL report

Issue #32, July 2004

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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ABC 81171 (07/2004)

Highlights of New Products Added

■ **APO-CIPROFLOX (APX), CO CIPROFLOXACIN (COB), GEN-CIPROFLOXACIN (GPM), NOVO-CIPROFLOXACIN (NOP), PMS-CIPROFLOXACIN (PMS), RATIO-CIPROFLOXACIN (RPM)** and **RHOXAL-CIPROFLOXACIN (RXP)** (ciprofloxacin hydrochloride) 250 mg, 500 mg & 750 mg tablets are first-entry generic products that have been deemed interchangeable with the innovator, CIPRO 250 mg, 500 mg & 750 mg tablets. The Committee recommended that these products be added to the *AHWDBL* as they offer 30% savings over the innovator products and anticipated savings of over $600,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Furthermore, as these products met criteria for FAST-TRACK addition, they were added to the *AHWDBL* **effective May 1, 2004**.

■ **DOM-PAROXETINE** (paroxetine hydrochloride) (DPC) 10 mg tablet is the first of this strength of paroxetine to be listed on the *AHWDBL*. Accordingly, it has been listed as a single source product. A dose of 10 mg is indicated in certain instances, as an initial starting dose for specific indications, as well as for the elderly and/or debilitated, or patients with hepatic or renal impairment. In addition, the availability of this strength may aid in dosage adjustments. The Committee recommended that **DOM-PAROXETINE 10 mg tablet** be added to the *AHWDBL* as it provides a therapeutic advantage.

■ **APO-CALCITONIN** (synthetic calcitonin salmon (salcatonin)) (APX) 200 iu/dose metered nasal spray is a first-entry generic product that was deemed interchangeable with the innovator, MIACALCIN nasal spray. This product is priced 26% less than the innovator, and therefore, the addition of this product to the *AHWDBL* could offer potential savings of over $150,000 in the first year of listing. The Committee recommended this product be listed in the *AHWDBL*, subject to the same special authorization criteria applied to MIACALCIN nasal spray (please refer to the current *AHWDBL* for a full listing of special authorization criteria for **APO-CALCITONIN** nasal spray).

■ **PMS-MIRTAZAPINE** (mirtazapine) (PMS) 30 mg tablet was deemed interchangeable with the innovator, REMERON 30 mg. The Committee recommended that this first-entry generic product be added to the *AHWDBL* as it offers 26% savings over REMERON and anticipated savings of approximately $118,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

Highlights of Products Not Added

■ **HUMATROPE** (somatropin) (LIL) – The 24 mg/cartridge injection is a line extension of **HUMATROPE** 6 mg and 12 mg cartridges, which are currently listed via special authorization. The Committee examined the utilization trends of the strengths of **HUMATROPE** used in the population covered by Alberta Health and Wellness, and concluded that there did not appear to be a clinical need for the 24 mg cartridge at this time. Accordingly, the Committee indicated that this product should not be added to the *AHWDBL* as it fails to offer a therapeutic advantage.

■ **REMERON RD** (mirtazapine) (ORG) – This new orally disintegrating tablet is available in 15 mg, 30 mg & 45 mg strengths, as line extensions to the currently listed REMERON 30 mg tablet. While the concept of quick dissolve drug delivery is a novel approach in antidepressant therapy, the Committee questioned the need for an orally disintegrating tablet in the treatment of depression. In addition, the Committee noted that while **REMERON RD** is priced less than REMERON, greater potential savings may be realized with the listing of the current first-entry interchangeable product. Therefore, the Committee recommended that this product not be added as it fails to offer a therapeutic and/or cost advantage.

Enbrel for Polyarticular Juvenile Rheumatoid Arthritis

■ **ENBREL** (etancercept) (AMG) 25 mg/vial injection has received approval from the Therapeutic Products Directorate of Health Canada for use in active polyarticular Juvenile Rheumatoid Arthritis (JRA). The Expert Committee reviewed a request from the manufacturer to have this indication added to the current special authorization criteria for **ENBREL**. The Committee recognized that there is a role for this product in the treatment of such a severe illness. As a result, following consultation with Alberta specialists in Pediatric Rheumatology, the Committee recommended that **ENBREL** be covered for the treatment of polyarticular JRA, for those patients meeting the published special authorization criteria. As **ENBREL** is also currently covered via special authorization for the treatment of severely active Rheumatoid Arthritis, please refer to the current *AHWDBL* for a full listing of special authorization criteria for **ENBREL** and the applicable special authorization form.

Changes to Special Authorization Coverage of Select Products for the Treatment of Hepatitis C

With recent and ongoing advances in the treatment of chronic hepatitis C, and the availability of newer and more effective therapies such as the pegylated interferons, the Expert Committee has recommended the following changes to the special authorization coverage of specific products on the *AHWDBL*.

■ **INTRON A** (interferon alfa-2b) (SCH) and **ROFERON-A** (interferon alfa-2a) (HLR) – The special authorization criteria for these products has been revised to read: "For the treatment of chronic active hepatitis B."

■ **REBETRON** (interferon alfa-2b/ribavirin) (SCH) – The Expert Committee has recommended that this product be removed from the *AHWDBL*.

An adequate transition period will be allowed in order to provide those patients currently receiving coverage of the above products, for the treatment of chronic hepatitis C, with ample opportunity to finish their current course of therapy or to request special authorization coverage for alternative therapy. New requests for special authorization coverage of these products for the treatment of chronic hepatitis C can no longer be considered **effective July 1, 2004**.