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 (R2002/12)

Highlights of New Products Added

■ **ANDRODERM** (testosterone) (PAL) –is a transdermal testosterone delivery system that has been demonstrated to provide more physiological plasma levels of testosterone as compared to IM testosterone. The Committee noted that although such levels were not shown to translate into improved clinical outcomes, the availability of a transdermal testosterone formulation may be more palatable for patients than other available products offering some therapeutic advantage. As a result, it was recommended that **ANDRODERM** be added to the AHWDBL via special authorization with the following criteria for coverage: "For the treatment of congenital and acquired primary and secondary hypogonadism. Coverage will not be considered when used for the treatment of male andropause."

■ **FOSAMAX 70 mg** (alendronate sodium) (MSD) – The Committee considered additional information supplied by the manufacturer regarding improved compliance and preference for the once weekly vs. once daily dosing regimen. In addition, the Committee was advised that the price of this product had been reduced to $8.85/tablet, thereby providing a 28% savings over the cost of treating patients with FOSAMAX 10 mg tablets daily. Accordingly, the Committee recommended that **FOSAMAX 70 mg** be added via special authorization with criteria for coverage at parity with that of FOSAMAX 10 mg tablets as it offers both a cost and therapeutic advantage. In addition, it should be noted that those patients with current special authorization approval for FOSAMAX for the treatment of osteoporosis will not be required to submit new special authorization requests to receive coverage for **FOSAMAX 70 mg** (i.e., such patients may switch to **FOSAMAX 70 mg**, depending on their preference of dosing regimen).

■ **NOVORAPID** (insulin aspart) (NNA) – The Committee considered clinical information supporting that **NOVORAPID** is at least as effective as HUMALOG in reducing HgbA1c and has a favorable impact on post-prandial hyperglycemia. In addition, the Committee considered economic information indicating **NOVORAPID** 100 U/mL vials and 100 U/mL penfill cartridges are slightly less expensive than HUMALOG vials and cartridges. Hence, the Committee recommended that **NOVORAPID** vials and penfill cartridges be added to the AHWDBL as they offer some cost advantage vis-à-vis HUMALOG.

Changes to the Benefit Status of Andriol

The Committee recommended that **ANDRIOL** (testosterone undecanoate) (ORG) change to a special authorization benefit with the following criteria for coverage: "For the treatment of congenital and acquired primary and secondary hypogonadism. Coverage will not be considered when used for the treatment of male andropause." To provide patients who are currently receiving treatment with **ANDRIOL** with ample opportunity to request special authorization coverage via the AHWDBL, a three-month transition period has been recommended. Accordingly, **ANDRIOL** will change to a special authorization benefit effective April 1, 2003.

Highlights of Interchangeable Products Added

■ **APO-LAMOTRIGINE** (lamotrigine) (APX) – The 25 mg, 100 mg and 150 mg strengths were deemed interchangeable with LAMICTAL 25 mg, 100 mg and 150 mg tablets, respectively. The Committee recommended that these products be added to the AHWDBL as they offer 32% savings over the innovator products and anticipated savings of approximately $93,000 to the Alberta Health and Wellness sponsored drug programs in the first year of listing.

■ **RATIO- IPRA SAL UDV** (ipratropium bromide/salbutamol sulfate) (RPH) – inhalation solution is a first-entry interchangeable product that is cross-licensed with the innovator product, COMBIVENT. **RATIO-IPRA SAL UDV** was added to the AHWDBL on November 1, 2002 as it met criteria for FAST-TRACK addition by offering 30% savings over the innovator product and anticipated savings of approximately $428,000 to the Alberta Health and Wellness sponsored drug programs in the first year of listing.

■ **RATIO-BRIMONIDINE** (brimonidine tartrate) (RPH) – 0.2% ophthalmic drops is a first-entry interchangeable product that is cross-licensed with the innovator product, ALPHAGAN. The Committee recommended that this product be added to the AHWDBL as it offers a 37.5% savings over ALPHAGAN and anticipated savings of approximately $143,000 to the Alberta Health and Wellness sponsored drug programs in the first year of listing.

Highlights of Deferred Products

■ **ARIXTRA** (fondaparinux sodium) (ORG) - is the first product in a new class of antithrombotic agents which is a selective, indirect inhibitor of factor Xa. During their review of the submission, the Committee noted that while **ARIXTRA** may be effective in the prophylaxis of asymptomatic deep vein thrombosis (DVT), it does not appear to be as effective for prophylaxis of symptomatic DVT and appears to have an increased bleeding risk. In addition, the Committee indicated that **ARIXTRA** is not economically attractive when compared to either FRAGMIN or INNOHEP, which appear to be the products predominantly used by AHWDBL beneficiaries. Accordingly, the Committee recommended that this product be deferred pending the receipt and review of additional information from the manufacturer pertaining to clinical and economic comparisons with agents commonly used in Alberta.

■ **PEGETRON** (ribavirin/peginterferon alfa-2b) (SCH) – is indicated for the treatment of adult patients with histologically proven chronic hepatitis C who have elevated transaminases without liver decompensation and who are positive for HCV-RNA or anti-HCV. The Committee acknowledged that the once weekly dosing of **PEGETRON** may impact on patient compliance and, in turn, improve patient outcomes. However, the Committee questioned the dose equivalencies between **PEGETRON** and REBETRON and how these translate into the cost differences between agents. In addition, the Committee had several questions surrounding the potential use of **PEGETRON** in clinical practice. Hence, the Committee recommended that this product be deferred pending the receipt and review of additional information from the manufacturer and Alberta hepatologists.

Highlights of Products Not Added

■ **THYROGEN** (thyrotropin alfa) (GZM) – is indicated as an adjunctive tool for serum thyroglobulin (Tg) testing with or without radioactive imaging in the follow-up of patients with well-differentiated thyroid cancer. The Committee noted that this agent is used as a component of diagnostic testing and diagnostic testing aids are generally not considered for potential funding on the AHWDBL. Furthermore, based on the clinical data provided and as per the **THYROGEN** product monograph, withdrawal of thyroid hormone therapy prior to Tg testing achieves superior results and thus, remains the standard of care. While the manufacturer asserted that the use of **THYROGEN** in place of withdrawal of thyroid therapy would result in a positive impact on patient quality of life, no data was provided to support this assertion. Therefore, the Committee recommended that this product not be added to the AHWDBL as it fails to offer a cost or therapeutic advantage.

■ **XATRAL** (alfuzosin hydrochloride) (WIN) - The Committee considered a resubmission from the manufacturer for the coverage of the 10 mg tablets on the AHWDBL. The Committee advised that no additional information had been provided which would clearly delineate a therapeutic advantage of **XATRAL** over other currently available alternatives on the AHWDBL. Accordingly, the Committee elected to uphold their previous recommendation not to list **XATRAL** on the AHWDBL as it fails to offer a therapeutic advantage.