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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ABC 81171 (04/2003)

Highlights of New Products Added

■ **FXT 40** (fluoxetine hydrochloride) (ORY) – is a capsule that delivers 40mg of fluoxetine hydrochloride. This product was reportedly introduced to meet the needs of patients requiring 40 mg of fluoxetine daily. The manufacturer indicated that the use of **FXT 40** would facilitate patient dosing and would represent potential cost savings as the cost of **FXT 40** is less than that of a patient taking 2 x 20 mg capsules of fluoxetine. Accordingly, the Committee recommended that this product be added as it offers a cost advantage.

■ **LUMIGAN** (bimatoprost) (ALL) – 0.03% ophthalmic solution is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension who are intolerant or insufficiently responsive to another intraocular pressure lowering medication. In their resubmission, the manufacturer provided additional clinical and economic data that asserted that this product offers both a therapeutic and economic advantage. After reviewing the information provided, the Committee indicated that **LUMIGAN** appeared to offer a therapeutic advantage over select therapies available on the AHWDBL. Accordingly, the Committee recommended that this product be added.

■ **UNIDET** (tolterodine L-tartrate) (PHD) – A resubmission for the 2 mg and 4 mg extended release capsules was provided by the manufacturer for the Committee's consideration. In their resubmission, the manufacturer requested that the Committee consider delisting DETROL and placing **UNIDET** on the AHWDBL in its place. The Committee indicated that **UNIDET** appears to possess similar efficacy as DETROL, but may offer a therapeutic advantage due to its once daily dosing regimen. Accordingly, the Committee recommended that DETROL be delisted. In addition, the Committee recommended that **UNIDET** be made available via special authorization with criteria that read: "For patients who are intolerant to oxybutynin. Special authorization is granted for 24 months."

■ **ZYPREXA** (olanzapine) (LIL) – This 15 mg tablet is an extension of the Zyprexa line of products that offers a dosage form for patients requiring a higher dosage of olanzapine. The Committee indicated that the addition of this strength to the AHWDBL may facilitate patient compliance by decreasing potential confusion associated with using different strengths of Zyprexa tablets to obtain a 15 mg dose. In addition, there is a potential to realize incremental savings via the removal of one dispensing fee, as patients are no longer required to obtain multiple prescriptions to achieve the 15 mg dose (i.e., 1 x 5 mg tablet plus 1 x 10 mg tablet).

Changes to the Benefit Status of Detrol

Effective April 1, 2003, **DETROL** will no longer be eligible for special authorization. In its place, UNIDET (tolterodine L-tartrate) extended-release capsules will be available via special authorization on the AHWDBL. To facilitate transition to UNIDET, all patients with existing special authorization for **DETROL** will continue to receive coverage of **DETROL** until September 30, 2003. Effective October 1, 2003, **DETROL** will no longer be an eligible benefit and will not be eligible for consideration through special authorization.

In addition, to facilitate transition of existing **DETROL** patients to UNIDET, patients with existing special authorization for **DETROL** automatically receive special authorization for UNIDET as of April 1, 2003.

Changes to the Special Authorization Criteria for Evista

The Committee received a request from the manufacturer to expand special authorization criteria for **EVISTA**. After giving due consideration to the evidence provided, the Committee indicated that the special authorization criteria for Evista be revised to include: "For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures."

Highlights of Deferred Products

■ **ZOMETA** (zoledronic acid) (NOV) – The manufacturer submitted a request to change the special authorization criteria for this product to include its newly granted indication of treatment of bone metastases due to prostate cancer. The Committee indicated that further information was required from both Alberta specialists and the manufacturer regarding this product. Accordingly, the Committee recommended that any changes to the special authorization criteria of **ZOMETA** be deferred pending receipt and review of the requested information.

Highlights of Products Not Added

■ **AMARYL** (glimepiride) (AVE) – 1 mg, 2 mg and 4 mg tablets were resubmitted by the manufacturer. The Committee gave due consideration to the information provided; however, the Committee maintained that the evidence provided in the resubmission does not support a therapeutic advantage commensurate with the increase in cost over available sulfonylureas on the AHWDBL. Accordingly, the Committee recommended that this product not be added as it fails to offer a cost and/or therapeutic advantage.

■ **BENZAMYCIN** (erythromycin/benzoyl peroxide) (DER) - 30 mg/g and 50 mg/g topical gel is indicated for the topical treatment of Grade II to III acne. The Committee noted that the data provided did not appear to support a therapeutic or economic advantage over available alternatives on the AHWDBL. Accordingly, the Committee recommended that **BENZAMYCIN** not be added.

■ **TARKA** (trandolapril/verapamil hydrochloride) (ABB) - is indicated for the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate. Since, according to utilization data, it appears that trandolapril (MAVIK) is not being used by patients within the Alberta Health and Wellness sponsored drug program, the current clinical need for **TARKA** is questionable in this population. Accordingly, the Committee recommended that this product not be added as it fails to offer a cost and/or therapeutic advantage over currently listed products on the AHWBDL.

■ **XALACOM** (latanoprost/timolol) (PHD) – ophthalmic solution is a product intended to decrease intraocular pressure. **XALACOM** was not added to the AHWDBL as it fails to offer a cost and/or therapeutic advantage. Specifically, the Committee indicated that there was a lack of evidence provided in the submission demonstrating therapeutic advantage over other products currently available on the AHWDBL. Furthermore, the Committee expressed concern that the addition of this agent may present a potential negative cost impact if the addition of this agent serves to expand the market inappropriately.

Changes to the Special Authorization Criteria for Nitoman

In Fall 2002, the Committee received several requests from clinicians requesting that the special authorization criteria for **NITOMAN** be broadened to other specialists, as well as specialists practicing outside of Movement Disorder Clinics. After a consultation process involving Alberta Neurologists, the Committee indicated that the special authorization criteria for **NITOMAN** be changed to read: " For the treatment of hyperkinetic movement disorders when prescribed by specialists in Neurology, Psychiatry or Geriatric Medicine."