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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Highlights of New Products Added

■ **COVERSYL** (perindopril erbumine) (SEV) – This 8 mg tablet is a line-extension of the currently listed 2 mg and 4 mg tablets. The Expert Committee indicated that **COVERSYL 8 mg** may be more convenient for patients taking a dose of 8 mg daily (i.e., patients may take only one tablet rather than 2 x 4 mg). In addition, it was noted that the 8 mg tablet provides a cost advantage, as it is less expensive than the cost of 2 x 4 mg tablets. Accordingly, the Committee recommended that this product be added to the *AHWDBL,* as it possesses a therapeutic and/or cost advantage.

■ **KEPPRA** (levitiracetam) (VLH), a new anti-epileptic drug (AED) and member of the pyrrolidine class, is chemically unrelated to existing AEDs. **KEPPRA** is indicated as adjunctive therapy in the management of patients with epilepsy who are not satisfactorily controlled by conventional therapy. Due to its different mechanism of action, Committee members indicated that this product may have a place in therapy for select patients who are refractory. Accordingly, the Committee recommended that **KEPPRA** be added to the *AHWDBL*, via the following special authorization criteria:

"For use in combination with other anti-epileptic medication(s) in the treatment of partial seizures in patients who are refractory to adequate trials of three anti-epileptic medications used either as monotherapy or in combination. This drug must be prescribed in consultation with a specialist in Neurology. Special authorization may be granted for 24 months."

■ **MAVIK** (trandolapril) (ABB) 4 mg capsule is an extension of the currently listed **MAVIK** line of products. The Committee noted that the longer half-life of this angiotensin converting enzyme inhibitor (ACEI) may offer a therapeutic advantage. The Committee also indicated that the availability of **MAVIK 4mg** may be advantageous as it makes it more convenient for patients to obtain a higher dose of drug. In addition, it was noted that this product provides a cost advantage, as the cost of one 4 mg capsule is less expensive than the cost of 2 x 2 mg capsules. Accordingly, the Committee recommended addition of **MAVIK 4mg** as it offers a therapeutic and/or cost advantage.

■ **RISPERDAL M-TAB** (risperidone) (JOI) – This new formulation is a quick-dissolve tablet, produced using freeze-drying technology that results in highly porous tablets, which rapidly disintegrate upon contact with saliva. The Committee indicated this product may offer a therapeutic advantage in select patient populations, and recommended that it be added to the *AHWDBL*. **RISPERDAL M-TAB** 0.5 mg, 1 mg and 2 mg orally disintegrating tablets were listed **effective February 1, 2004**.

Changes to Special Authorization Criteria for Drugs used in Alzheimer's Disease

■ **ARICEPT, EXELON & REMINYL** – The Committee indicated that physicians who have completed the Care of the Elderly Six-Month/One-Year Fellowship Program will be added to those physicians already deemed designated prescribers, as defined within the current special authorization criteria for these products. Please refer to the appropriate section of the *AHWDBL* for further details.

Changes to Special Authorization Criteria for Pegetron

■ **PEGETRON** (peginterferon alfa-2b/ ribavirin) (SCH) – After extensive consultation with Alberta specialists in Hepatology and Infectious Diseases, the Expert Committee has recommended several changes to the special authorization criteria for **PEGETRON**. Effective April 1, 2004, these changes will include, for example, the availability of **PEGETRON** for use in a select group of patients who have previously not responded to, or relapsed following, interferon monotherapy; or who have relapsed following combination therapy with non-pegylated interferon and ribavirin. Please refer to the current *AHWDBL* for a full listing of special authorization criteria for **PEGETRON**, and the applicable special authorization form.

Highlights of Interchangeable Products Added

■ **GEN-CITALOPRAM** (citalopram hydrobromide) (GPM) is a first-entry interchangeable product. The 10 mg and 20 mg tablets were deemed interchangeable with the innovator, CELEXA 10 mg and 20 mg tablets, respectively. 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 $1,000,000 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 February 1, 2004**.

■ **NOVO-FOSINOPRIL** (fosinopril sodium) (NOP) 10 mg and 20 mg tablets were deemed interchangeable with MONOPRIL 10 mg and 20 mg tablets, respectively. NOVO-FOSINOPRIL was added to the *AHWDBL* **effective February 1, 2004**, as it met criteria for FAST-TRACK addition by offering 30% savings over the innovator product and anticipated savings of approximately $925,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

Highlights of Products Not Added

■ **ALPHAGAN P** (brimonidine tartrate) (ALL) 0.15% ophthalmic solution is a line-extension to ALPHAGAN 0.2% ophthalmic solution. **ALPHAGAN P** contains Purite®, a novel preservative. The Committee recommended that this product not be added as it fails to offer a therapeutic and/or cost advantage over other presently accepted therapies available on the *AHWDBL*.

■ **TRILEPTAL** (oxcarbazepine) (NOV) is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy and as adjunctive therapy in the treatment of partial seizures in children ages 6 years and over with epilepsy. The Committee noted that this agent is structurally related to carbamazepine and possesses pharmacokinetic properties that may offer an advantage with respect to fewer drug interactions; however, they expressed the opinion that these potential advantages do not merit the higher cost of the agent. In addition, the Committee asserted that **TRILEPTAL** has not demonstrated a clear therapeutic advantage over currently available products on the *AHWDBL*. Accordingly, the Committee recommended that this product not be added as it fails to offer a therapeutic and/or cost advantage.

The Rationale Behind Special Authorization (SA)

A version of the following article first appeared in* The DBL Report*, Issue #9, October 1997.

Physicians, pharmacists and patients often question the rationale behind limiting the coverage of a drug to SA. Limiting of coverage of a product to SA according to specific criteria is done when there is a concern that the potential for inappropriate use of a product is high, when the cost impact to the drug program of an unrestricted listing is prohibitive or when there are safety considerations. If there is evidence that a specific subgroup of patients will benefit from a product, SA is a means to ensure access for those patients. The criteria for SA coverage of products are developed by the Expert Committee through consultation with specialists and the review of clinical practice guidelines and pharmacoeconomic evaluations that aid to identify subgroups of patients in which a product is cost-effective. Information from the physician may be required regarding previous medications, patient's response to therapy and parameters that have been monitored in order to properly evaluate the SA request for certain products. The recommendation to limit coverage of a product to SA is not made lightly as the process is resource intensive and administratively costly. In addition, while SA is often criticized for being somewhat cumbersome and bureaucratic, it may serve as a means by which physicians can pause and consider the appropriate use of the cost-effective therapies that are available.