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

■ **TRAVATAN** (travoprost) (ALC) – is a prostaglandin analogue indicated for the reduction of intraocular pressure in patients who are intolerant or insufficiently responsive to another intraocular pressure lowering medication. This product has the potential to be cost saving due to the lower cost/drop for TRAVATAN vs. **XALATAN**, another prostaglandin analogue listed on the AHWDBL. XALATAN must be refrigerated until dispensing and discarded 42 days after opening, whereas TRAVATAN does not have the same storage limitations. Accordingly, TRAVATAN may offer a convenient alternative for a patient that, depending on patient dosing, also offers additional cost savings.

■ **METADOL-D** (methadone hydrochloride) (PMS) – is indicated for the detoxification, treatment and maintenance of opioid addiction. The manufacturer has introduced METADOL-D in an effort to clearly differentiate between their methadone products when used for the indications of opioid dependence and analgesia. **METADOL**, an identical product that is intended for the analgesia indication, is currently a benefit on the AHWDBL. As a result, the ECDET recommended that METADOL-D be listed on AHWDBL in an interchangeable grouping with METADOL.

■ **ROSASOL** (metronidazole cream) (STI) – 1% cream has been added to the AHWDBL as an unrestricted listing. This product is indicated for the treatment of inflammatory lesions, erythema and telangectasia associated with rosacea. The addition of ROSASOL may present a slight cost advantage as it is priced equivalently or slightly less than other metronidazole topical preparations that are listed on the AHWDBL.

UPDATE: Removal of the LCA Policy from Methotrexate Sodium 25mg/mL Preserved and Unpreserved Injectable Products on the AHWDBL

Following the receipt of substantial input from health care providers and patients requesting that LCA not be applied to preserved and unpreserved injectable methotrexate products, the ECDET reconsidered their recommendation to reinstate LCA for these products. Concerns stemmed from the potential for increased product wastage and cost to the patient as a result of having to discard unused portions of the unpreserved product, which is the current LCA. After considering all input, the customary doses used in rheumatoid arthritis and the relative costs of each agent vis-à-vis anticipated program savings, the ECDET recommended that LCA be removed from the interchangeable grouping of methotrexate sodium 25mg/mL preserved and unpreserved injection products on the AHWDBL.

Highlights of Products Not Added

■ **FUCITHALMIC** (fusidic acid) (LEO) – 1% viscous eye drops (available with and without preservative) were not recommended for addition to the AHWDBL, as they did not offer a therapeutic or cost advantage. These ophthalmic preparations are indicated for the treatment of superficial eye infections caused by fusidic acid susceptible strains of bacteria. It was noted that conjunctivitis is usually a self-limiting condition; therefore, it is generally treated empirically and broad-spectrum antibiotics are often preferred. The ECDET expressed concern about the potential for treatment failure if a gram-negative organism is the causative agent. In addition, it was taken into consideration that there are several agents available on the AHWDBL that provide a broader spectrum of coverage than FUCITHALMIC**.**

■ **STARNOC** (zaleplon) (SEV) – is a non-benzodiazepine hypnotic that is intended for the short-term treatment and symptomatic relief of insomnia in patients who have difficulty falling asleep. This product was not recommended for addition to the AHWDBL as it failed to offer a cost or therapeutic advantage. Only a limited number of clinical studies were conducted in the elderly (>65 years); therefore, the results may not be generalizable to the population covered by the Alberta Health and Wellness seniors' drug program. Finally, given that STARNOC is considerably more expensive than other hypnotics, its addition to the AHWDBL would increase costs without providing significant therapeutic advantage.

Highlights of Changes to SA Criteria

■ **DOSTINEX** (cabergoline) (PHD) –The special authorization (SA) criteria for this product were revised to read: "For the treatment of hyperprolactinemia in patients who are intolerant to or who have failed bromocriptine." This change results in the removal of the restriction to physician specialty that could request coverage for DOSTINEX. The ECDET recommended this change in recognition of the fact that a variety of physicians treat individuals with hyperprolactinemia.

■ **RILUTEK** (riluzole) (AVE) –The SA criteria will now read: "For use in patients who have probable or definite Amyotrophic Lateral Sclerosis (ALS) as defined by the World Federation of Neurology (WFN) criteria, who have a vital capacity of >60% predicted and do not have a tracheostomy for invasive ventilation. This drug must be prescribed by a physician in the ALS Consortium." These changes result in differentiation between those patients who have a tracheostomy for the purpose of airway protection vs. those patients who require invasive ventilation. The clarification of SA criteria resulted from consultations with physicians in the ALS Consortium who advised that there was little data to support that patients received clinical benefit from RILUTEK once they required invasive ventilation.

Highlights of Deferred Products

■ **ENBREL** (etanercept) (WAY) and **REMICADE** (infliximab) (SCH) – continue to be considered in an ongoing review. As these products represent an unprecedented approach to the treatment of inflammatory disease, the ECDET has elected to conduct a class review that has entailed consultation with Alberta gastroenterologists and rheumatologists, the manufacturers, Health Canada and other provinces. The ECDET continues to deliberate and at the present time they are awaiting additional information requested through the consultation process.

■ **PROTOPIC** (tacrolimus) (TBB) – 0.03% and 0.1% ointments are indicated for short and long term intermittent treatment of patients with moderate to severe atopic dermatitis (AD) in whom conventional therapies are deemed inadvisable, or who are not adequately responsive to or intolerant of conventional therapies. Prior to making a recommendation, the ECDET deemed that consultation with Alberta Dermatologists would be prudent.

■ **RENAGEL** (sevelamer hydrochloride) (GZM) – 403 mg capsule is indicated for the control of hyperphosphatemia in patients with end stage renal disease on hemodialysis. The ECDET was advised that the manufacturer intends to replace the capsule formulation with a 400 mg and 800 mg tablet. As new clinical data will be presented by the manufacturer in the tablet submission, the ECDET opted to defer discussion pending the review of the new submission for the tablet formulation.