the DBL report

Issue #21, October 2001

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

In this issue:

Highlights of New Products Added

■ **DDAVP** (desmopressin acetate) (FEI) 0.1 and 0.2 mg tablets—the ECDET recommended DDAVP tablets be added after taking into consideration additional clinical information and a new budget impact analysis provided by the manufacturer. The new formulation will provide therapeutic advantage compared to the traditional nasal formulation particularly in patients with diabetes insipidus.

■ **REMERON** (mirtazapine) (ORG) is indicated for the symptomatic relief of depressive illness. This product has shown efficacy comparable to that of amitriptyline and has a favorable safety and side effect profile compared to other antidepressants already listed in the AHWDBL.

■ **SINGULAIR** (montelukast sodium) (MFC)—as the indication for SINGULAIR was expanded to include children 2 to 5 years of age, the 4 mg chewable tablet has been added to the AHWDBL to facilitate administration of SINGULAIR to this age group. This new formulation will be available as a "**Restricted Benefit**" for patients 2 to 18 years of age. *Please note that even though this strength is primarily designed for children 2 to 5 years of age, there may be a small number of children over 5 who are still managed on lower doses; therefore, the 4 mg chewable tablet shall be made available for patients 2 to 18 years of age to enable access to lower doses where appropriate*.

■ **TEVETEN** (eprosartan mesylate) (SLO)—this product appears to provide similar therapeutic benefits compared to other agents already listed at an apparent slightly lower price.

■ **ZYPREXA ZYDIS** (olanzapine) (LIL)—this new formulation may be advantageous when compliance or difficulty in swallowing is an issue. This product has been added to the AHWDBL because it offers cost and therapeutic advantage for the treatment of patients who cannot/will not swallow traditional oral tablets or for the treatment of patients where an injectable is either contraindicated or cannot be tolerated.

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Highlights of Products Not Added

■ **TAMIFLU (**oseltamivir phosphate) (HLR)—this product was re-reviewed by the ECDET as requested by the manufacturer. The recommendation was not to add this product to the AHWDBL since the clinical data presented failed to show a therapeutic benefit for the population covered by the AHW drug programs.

■ **XENICAL** (orlistat) (HLR)—this product was re-reviewed by the ECDET as requested by the manufacturer. The ECDET maintains that the clinical evidence supporting the impact of XENICAL on morbidity and mortality endpoints remains weak therefore the recommendation was not to add this product to the AHWDBL.

Suggest a Topic

Requests for topics or information on reviewed drug products to appear in The DBL Report are welcome and can be forwarded to:

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Highlights of Products Added via Special Authorization (SA)

■ **PEG-INTRON** (peginterferon alfa-2b) (SCH) is indicated as monotherapy in case of intolerance or contraindication to ribavarin, for the treatment of adult patients with chronic hepatitis C without liver decompensation. Coverage of PEG-INTRON will be provided according to the following criteria: "For the treatment of chronic hepatitis C in patients with evidence of active liver disease who are 18 years of age or older with documented evidence of intolerance or contraindication to ribavirin." Confirmation of the diagnosis of chronic hepatitis C with active liver disease is required. Information must include the patient's pre-treatment anti-HCV and serum HCV RNA (by PCR) status. Information is also required regarding whether liver enzymes (ALT/AST) are elevated, or the results of a liver biopsy. Specific information is required regarding why ribavirin cannot be used.

■ **RILUTEK** (riluzole) (AVE), the first agent indicated for use in amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), has been added via SA for patients 18 to 75 years of age who have probable or definite ALS as defined by World Federation of Neurology (WFN) criteria with onset within 5 years, who have a vital capacity of >60% predicted and do not have a tracheostomy. This drug must be prescribed by a physician in the ALS consortium. Patients who previously received RILUTEK and were not eligible for the Phase IV study can be considered for coverage if they meet the SA criteria. This listing is transitional pending RILUTEK receiving a full NOC from Health Canada.

SA Criteria for Antiplatelet Agents

■ **AGGRENOX** (dipyridamole/ASA) (BOE)—published clinical data have shown that the combination of dipyridamole and ASA significantly decreases the incidence of strokes in patients that have already experienced a cerebrovascular event. As a consequence, AGGRENOX has been made available to patients in Alberta, via SA, effective August 1, 2001.

With the addition of AGGRENOX to the AHWDBL, the ECDET has also recommended that the SA criteria for PLAVIX (clopidogrel bisulfate) (BMS) be revised to reflect the most appropriate use of these agents in the treatment of cerebrovascular and non-cerebrovascular ischemic events, respectively. As a result, the SA criteria are as follows:

AGGRENOX (dipyridamole/ASA) (BOE)

- "For use in patients who have experienced a cerebrovascular ischemic event (e.g. stroke, TIA)."

PLAVIX (clopidogrel bisulfate) (BMS)

- "For the prevention of thrombosis, for one month, when prescribed following intravascular stent placement."
- "For the prevention of cerebrovascular (e.g. stroke, TIA) and non-cerebrovascular ischemic events in patients who have a contraindication to ASA."
- "For use in patients who have experienced a non-cerebrovascular ischemic event while on ASA."
- "For use in patients who have experienced a cerebrovascular ischemic event (e.g. stroke, TIA) while on dipyridamole/ASA (AGGRENOX) or for whom dipyridamole/ASA (AGGRENOX) is contraindicated."