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

In this issue:

Highlights of the Review of SA Drugs Used in the Treatment of Osteoporosis

As part of its ongoing consideration of new evidence, the ECDET completed a comprehensive review of drugs available via special authorization (SA) that are used in the treatment of osteoporosis. The special authorization criteria for coverage of alendronate and risedronate for those patients who have experienced a fracture has been changed as follows:

> "For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. Special authorization for this criteria is granted for 24 months."

The change in criteria resulted from consideration of physician input and published clinical data that supports that treatment with alendronate over a 7-year period leads to a progressive increase in bone mineral density over and above that experienced in the first 12-months of therapy. In addition, the ECDET emphasized that **ACTONEL**, **EVISTA**, **FOSAMAX** and **MIACALCIN** are not indicated for use in combination and that such special authorization requests will be denied.

Highlights of New Products Added

■ **COMTAN** (entacapone) (NOV) is indicated as an adjunct to levodopa/carbidopa or levodopa/benserazide preparations to treat patients with idiopathic Parkinson's Disease who experience the signs and symptoms of end-of-dose "wearing-off." COMTAN is a specific, reversible inhibitor of catechol-o-methyltransferase (COMT) that does not appear to possess the hepatic toxicity associated with **TASMAR** (tolcapone), another medication within this class. In light of the availability of COMTAN, TASMAR will be delisted. As of April 1, 2002, patients currently on TASMAR will no longer be able to receive coverage for this drug.

■ **ZYVOXAM** (linezolid) (PHD) - the 600 mg oral tablet was recommended for coverage via SA with criteria that reads: "For the treatment of vancomycin resistant Enterococcus Infections. For the treatment of methacillin-resistant Staphylococcus aureus (MRSA)/methacillin-resistant Staphylococcus epidermidis (MRSE) infections in patients who are unresponsive to, or intolerant of, vancomycin. The SA criteria require that this drug be prescribed in consultation with a specialist in Infectious Diseases." The ECDET identified ZYVOXAM as a "high priority" drug and therefore, every attempt will be made to deal with requests for this medication via the SA process within one working day of the request being received by Alberta Blue Cross.

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Highlights of Products Not Added

■ **DIAMICRON MR** (gliclazide) (SEV) – the 30 mg modified release tablet was not recommended for addition to the AHWDBL. This modified release formulation mimics the circadian glycemic profile of patients with type 2 diabetes and requires once daily dosing. Despite these changes to the original formulation, clinical evidence showed no improvements in glycemic control compared to patients receiving regular-release (RR) gliclazide. Gliclazide RR is available as an unrestricted benefit on the AHWDBL.

■ **NEXIUM** (esomeprazole magnesium trihydrate) (AZC) – this product is the single S-enantiomer of **LOSEC** (omeprazole), which is a racemate or a 50:50 mixture of R- and S- enantiomers. The ECDET considered studies that compared 40 mg and 20 mg doses of esomeprazole with 20 mg doses of omeprazole. These studies failed to show any significant differences between **NEXIUM** and **LOSEC** on many measures of healing, resolution of symptoms and maintenance therapy of reflux esophagitis, acute and long-term treatment of GERD and the eradication of H. pylori infection when used in a regimen with clarithromycin and amoxicillin. The results are surprising given that patients in the **NEXIUM** arms of the trials received more active drug than those who received **LOSEC** (i.e., a higher dose of the S-enantiomer was used which also has greater bioavailability than the R-enantiomer)

Highlights of Changes to SA Criteria

■ **EPREX** (epoetin alfa) (JOI) – The SA criteria for this product were revised to facilitate the screening of SA requests. Specifically, the criteria have been changed to reflect the Therapeutic Products Directorate approved indication for EPREX. The SA criteria for coverage will now read: "For the treatment of anemia of nonmyeloid malignancies in patients with low hemoglobin (<100g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20g/L per month, the dose of EPREX should be reduced by about 25%. If hemoglobin exceeds 120g/L, therapy should be discontinued until hemoglobin falls below 100g/L, at which time EPREX should be reinstituted at a dose 25% below the previous dose." If the patient has iron overload the physician must state this in the request or alternatively, information is required regarding the patient's transferrin saturation, along with the results of liver function tests if applicable.

■ **RILUTEK** (riluzole) (AVE) – This product was added via SA effective October 1, 2001. At their October meeting, the ECDET recommended that the SA criteria be altered to remove the age restrictions and duration of illness in the original criteria in an effort to ensure that Albertans suffering from ALS have appropriate access to this drug. The 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. This drug must be prescribed by a physician in the ALS Consortium." RILUTEK has received a conditional NOC from the Therapeutic Products Directorate; therefore, this product may only be prescribed by physicians of the ALS Consortium who are experienced in the diagnosis and management of ALS.

Highlights of Deferred Products

■ **RENAGEL** (sevalamer 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. In addition, new clinical data will be presented by the manufacturer in the tablet submission. Therefore, the ECDET elected to defer further discussion on this product pending the review of the new submission for the tablet formulation.

Interchangeability and application of LCA to Methotrexate Sodium 25mg/mL (base) Injection

Alberta Blue Cross has received a number of enquiries from pharmacies following the application of the LCA price policy to methotrexate sodium 25mg/mL (base) injection on the AHWDBL. It should be noted that unpreserved and preserved versions of these products have always been designated as interchangeable products on the AHWDBL, and that the LCA price policy was applied prior to 1997. Following a comprehensive review of the LCA pricing criteria for the AHWDBL, a decision was made to reinstate the LCA price policy to this interchangeable grouping of drugs. Concerns regarding wastage and discarding of unused drug if the unpreserved product is used have been raised; however, it is expected that the cost savings expected by the application of the LCA policy will outweigh the expense of the discarded product. Pharmacies will continue to be reimbursed by Alberta Blue Cross for the cost of the entire vial that is dispensed to a maximum of the LCA price per mL.