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:*



# *Products for Osteoporosis Added via Special Authorization*

Physicians are now provided with new coverage options for their patients with osteoporosis who are unable to be effectively treated with etidronate (DIDROCAL) because of intolerance or unresponsiveness. The following products for the treatment of osteoporosis have been made available via Special Authorization: **ACTONEL 5 mg** (risedronate sodium) (PGA), **EVISTA** (raloxifene hydrochloride) (LIL), **MIACALCIN** (salmon calcitonin, nasal spray) (NOV). These products have shown significant increases in bone mineral density and reductions in the incidence of vertebral fractures in post-menopausal women. The SA criteria for coverage read the same for all products: *For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a >2% loss in bone mineral density in one year).*

# *Products for Type 2 Diabetes Mellitus Added via Special Authorization*

Two agents of the new class of antidiabetic drugs known as "glitazones", **AVANDIA** (rosiglitazone maleate) (BMJ) and **ACTOS** (pioglitazone hydrochloride) (LIL) have been added to the AHWDBL effective December 1, 2000.

These products have been shown to be effective in improving glycemic parameters in Type 2 diabetic patients by reducing insulin resistance, the underlying condition of NIDDM (Non-Insulin Dependent Diabetes Mellitus). Glycemic control is obtained without an increase in circulating insulin or insulin precursors levels and because these agents exert their activity only in the presence of insulin, they are not indicated in the treatment of Type 1 diabetes (IDDM, Insulin-Dependent Diabetes Mellitus). It would appear that patients who are not adequately controlled by conventional therapy with oral hypoglycemic agents (metformin and sulfonylureas), would benefit the most from treatment with AVANDIA or ACTOS. As a result, the SA criteria are as follows: *For the treatment of Type 2 diabetes mellitus in patients who are not adequately controlled by optimum doses or who are intolerant to metformin or sulfonylureas or for whom these products are contraindicated*. Please note that while AVANDIA is indicated for combination therapy, at the current time, ACTOS has obtained approval from the TPP only for use as monotherapy.

*continued on reverse*

# *Highlights of New Products Added*

■ **ESTALIS** (norethindrone acetate/ estradiol-17b) (NOV) is the first combination estrogen/progestin transdermal patch developed for use in a continuous-wear dosage regimen. It offers an alternative to the sequential-wear (2 weeks of estrogen alone + 2 weeks of estrogen/progestin) transdermal patches for post-menopausal women. It has shown efficacy in relieving menopausal and post-menopausal symptoms with suppression of endometrial hyperplasia and uterine bleedings.

■ **NASONEX** (mometasone furoate) (SCH) is the only nasal corticosteroid now indicated for use in children as young as 3 years of age. Data have shown no evidence of growth suppression in children treated with NASONEX. This product has been added as a restricted benefit *for patients 3 to 12 years of age inclusive for the treatment of seasonal allergic rhinitis or perennial allergic rhinitis*. Less expensive alternatives (e.g. budesonide, beclomethasone, flunisolide) are available as unrestricted benefits on the AHWDBL for patients in whom the risk of growth suppression is not a concern.

## *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:*

*Scientific and Research Services*
*Clinical Drug Services and Evaluation*
*Alberta Blue Cross*
*10009 - 108 St.*
*Edmonton, AB T5J 3C5*
*Fax (780) 498-8384*

# *Additional Products Added via Special Authorization*

■ **ARAVA** (leflunomide) (AVE) has been added to the AHWDBL effective November 1, 2000 for the treatment of refractory rheumatoid arthritis (RA).

Leflunomide is the first of a new class of DMARDs (Disease-Modifying Anti-Rheumatic Drugs) that has been shown to be effective in slowing the rate of progression of joint damage in patients with RA. Clinical response is obtained in about 40 to 65% of patients with active disease. Since the efficacy of leflunomide appears to be superior to that of sulfasalazine but comparable to that of methotrexate, ARAVA represents a therapeutic alternative for patients with refractory disease unresponsive to methotrexate or for patients who are intolerant to methotrexate or in whom methotrexate is contraindicated.

SA criteria are the following: *For the treatment of refractory rheumatoid arthritis in patients who have failed an adequate trial of methotrexate. For patients who are unable to tolerate or with a contraindication to methotrexate. This drug product must be prescribed by a specialist in Rheumatology. Initial SA is granted for a maximum of 4 months. Renewal requests may be granted for a period of 12 months.*

■ **DOSTINEX** (cabergoline) (PHD) is a new agent used for the treatment of hyperprolactinemia. Cabergoline is well tolerated and is administered according to a convenient weekly dosing regimen. It has been added via SA according to the following criteria: *For the treatment of hyperprolactinemia in patients who are intolerant to or who have failed bromocriptine. This drug product must be prescribed by a specialist in Internal Medicine or Endocrinology*.

■ **ZANAFLEX** (tizanidine hydrochloride) (DAX) is an antispasticity agent that has been shown to be as efficacious as diazepam and baclofen in the treatment of severe spasticity associated with multiple sclerosis and spinal cord injury. Tizanidine has a good tolerability profile and represents an alternative for patients not able to tolerate baclofen or diazepam at antispasticity dosages. SA criteria are as follows: *For the treatment of spasticity in patients with documented evidence of intolerance or lack of response to diazepam or baclofen.*

# *Highlights of Products Not Added*

■ **TAMIFLU** (oseltamivir phosphate) (HLR) is indicated for the treatment of uncomplicated acute illness due to influenza virus. This product was re-reviewed at the request of the manufacturer. While new data have shown a reduction in secondary illness treated with antibiotics in the elderly population receiving TAMIFLU, the duration of illness was not significantly different in patients treated with TAMIFLU compared to those treated with placebo. There remains a lack of data to show a significant impact on major complications arising from influenza or on morbidity and mortality endpoints. In conclusion, there is insufficient benefit to justify the magnitude of expenditure the listing of this drug would entail.