the DBL report

Issue #62, July 2011

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 17 and 18, 2011. The Committee reviewed Manufacturer submissions for 11 Drug Products. The Committee also considered information for a number of supplementary assessments of the coverage status of 43 Drug Products.

In addition to Drug Products reviewed by the Expert Committee, 12 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective June 1, 2011, and another 6 generic Drug Products underwent Expedited Review for listing effective July 1, 2011. The following are highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Products Originally Reviewed via the Common Drug Review (CDR)

ULORIC 80 MG TABLET (febuxostat) (TAK) was reviewed via the CDR process. In keeping with the recommendations from the CDR, this product has been added to the *AHWDBL* with a listing via special authorization as it offers a therapeutic advantage for select patients who are unable to take allopurinol and who cannot tolerate or experience a lack of response to other presently accepted therapies. The special authorization criteria for this Drug Product will read: "For patients with symptomatic gout who have documented hypersensitivity or severe intolerance to allopurinol, AND intolerance or lack of response to sulfinpyrazone AND probenecid. Special authorization may be granted for 6 months." This product is eligible for auto-renewal.

ACTEMRA 80 MG/4 ML, 200 MG/10 ML & 400 MG/20 ML INTRAVENOUS SOLUTIONS (tocilizumab) (HLR) was reviewed via the CDR process. In keeping with the recommendations from the CDR, this product has been added to the *AHWDBL* with a listing via special authorization. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (7/2011)

Products Not Added

LITHMAX 300 MG SUSTAINED RELEASE TABLET (lithium carbonate) (AAP) The Expert Committee recommended that Lithmax 300 mg sustained-release tablet not be added to the *AHWDBL* as it failed to satisfy the published requirements of Critical Dose Drug Products.

RAN-CLARITHROMYCIN 500 MG TABLET (clarithromycin) (RAN) The Expert Committee recommended that RAN-Clarithromycin 500 mg tablet not be added to the *AHWDBL* as it failed to satisfy the published requirements of Non-Linear Drug Products. For Non-Linear Drug Products, it is required they meet all criteria in the Non-Linear Drug Product Appendix to the Interchangeable Drug Products - Additional Criteria in the *AHWDBL* (i.e., the bioavailability of at least the highest dose be studied and that all requirements be met in the fasted and fed state, except where it has been demonstrated that food does not modify bioavailability at doses within the range of strengths to be marketed).

Highlights of New Interchangeable (IC) Groupings

Addition of the following products to the *AHWDBL* has resulted in the creation of New IC Groupings, effective July 1, 2011:

- **APO-CANDESARTAN** (APO) and **SANDOZ CANDESARTAN** (SDZ) (candesartan) **8 MG & 16 MG TABLETS**

Osteoporosis

In their May 17 and 18 meetings, the Expert Committee on Drug Evaluation and Therapeutics discussed osteoporosis therapy in association with a Review of Benefit Status (ROBS) of bisphosphonates in the treatment of osteoporosis, as well as consideration of special authorization criteria for Prolia (denosumab).

ROBS Review: The ROBS review was undertaken to examine the place of bisphosphonates in osteoporosis therapy and if any changes in the present listing status of these agents should be proposed. The ROBS Sub-Committee considered recent literature, as well as several new Canadian and International Guidelines. Following discussion, the Expert Committee on Drug Evaluation and Therapeutics recommended that the listing status and criteria for each of the bisphosphonates should remain unchanged.

PROLIA 60 MG/ML SOLUTION FOR INJECTION (denosumab) (AMG) was reviewed via the CDR process. In keeping with the recommendations from the CDR, this product has been added to the *AHWDBL* with a listing via special authorization as it offers a therapeutic advantage for select high risk patients who are unable to take bisphosphonates due to hypersensitivity or to abnormalities of the esophagus that cannot be corrected. The special authorization criteria for this Drug Product will read: "For the treatment of postmenopausal osteoporosis in women for whom oral bisphosphonates are contraindicated due to hypersensitivity or an endoscopically or radiographically confirmed untreatable abnormality of the esophagus which delays esophageal emptying (e.g., stricture or achalasia), AND who have at least two of the following:
- Age greater than or equal to 75 years
- A prior fragility fracture
- A bone mineral density (BMD) T-score of less than or equal to -2.5

Special authorization may be granted for 12 months.

Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy.

Coverage cannot be provided for two or more osteoporosis medications (alendronate, calcitonin, denosumab, etidronate, raloxifene, risedronate) when these medications are intended for use as combination therapy."

This product is eligible for auto-renewal.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****