the ADBL report

Issue #77, February 2014

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) 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 November 26 & 27, 2013. The Committee reviewed Manufacturer submissions for fifteen (15) Drug Products for potential listing, or change in listing, on the *ADBL*. The Committee also considered information for a number of supplementary assessments of the coverage status of seventy-one (71) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, seventy-one (71) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2013 and ten (10) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2014.

The following are highlights of recent changes to the *ADBL* and other topics of general interest. A complete list of changes, as well as the full *ADBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of a Line Extension Drug Product Added to the ADBL

The following Drug Product was added to the *ADBL* effective February 1, 2014 after a Full Review by the Expert Committee:

- **VAL-VANCOMYCIN** (vancomycin hydrochloride) (VAL) **10 g/vial injection** was submitted as a line extension to the currently listed 500 mg and 1 g vials. This Drug Product has been recommended for listing for use by Home Parenteral Therapy (HPT) Programs only, as it offers a therapeutic and/or cost advantage.

Highlights of Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendations from the CDR, the following Drug Product has not been added to the *ADBL:*

- **XIAFLEX** (collagenase clostridium histolyticum) (ACT) **0.9 mg/vial injection** will not be listed as it fails to provide a therapeutic or cost advantage. At the current price for a 3-injection treatment course, this Drug Product does not appear to be cost-effective compared to current treatment modalities such as percutaneous needle fasciotomy (PNF) and open partial fasciotomy (OPF).

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

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Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective February 1, 2014:

- **TEVA-ALENDRONATE/ CHOLECALCIFEROL** (alendronate/ cholecalciferol) (TEV) **70 mg/5600 IU tablet**

The following Drug Products will be added to the *ADBL* effective February 1, 2014 in already Established IC groupings, after a Full Review by the Expert Committee:

- **APO-RAMIPRIL/HCTZ** (ramipril/hydrochlorothiazide) (APO) **2.5 mg/12.5 mg, 5 mg/12.5 mg, 5 mg/25 mg, 10 mg/12.5 mg & 10 mg/25 mg tablets**
- **APO-ALMOTRIPTAN** (almotriptan malate) (APO) **6.25 mg & 12.5 mg tablets***
  **Coverage criteria may apply. Please refer to the full ADBL.*

Highlights of Non-Interchangeable Old Drug Products Added

- **PMS-ACETAMINOPHEN WITH CODEINE** (acetaminophen/codeine phosphate) (PMS) **160 mg/8 mg/5 mL elixir** will be restricted to patients 12 years of age and older, in keeping with recent Health Canada recommendations that Drug Products containing codeine should not be used in children less than 12 years of age due to safety concerns.

Highlights of Deferrals

- **HUMIRA** (adalimumab) (ABB) **40 mg/0.8 mL injection syringe** for the indication of polyarticular Juvenile Idiopathic Arthritis (pJIA) has been deferred pending consultation on Special Authorization criteria with Alberta experts in the field of pJIA.

Benefit Coverage and Special Authorization (SA) Criteria Changes for Osteoporosis Medications:

In response to the discontinuation of calcitonin nasal spray from the Canadian market, and to reflect current clinical practice guidelines, the Expert Committee considered modifications to the coverage status and SA criteria of agents used to treat osteoporosis. As a result of their deliberations, the Expert Committee recommended that the benefit status of the following Drug Products be changed to an unrestricted listing:

- **ALENDRONATE SODIUM** 70 mg tablets (all brands)
- **RISEDRONATE SODIUM** 35 mg tablets (all brands)
- **ALENDRONATE/CHOLECALCIFEROL** (all brands)

In addition, the Expert Committee recommended that the criteria for SA coverage be revised for the following Drug Products:

- **ALENDRONATE SODIUM** 10 mg tablets (all brands)
- **RALOXIFENE HYDROCHLORIDE** 60 mg tablets (all brands)
- **RISEDRONATE SODIUM** 5 mg tablets (all brands)

The revised SA criteria for osteoporosis read as follows:

"For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk who have documented intolerance to alendronate 70 mg or risedronate 35 mg.
Special authorization may be granted for 6 months."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/mL injection."

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

In order to facilitate calculation of the 10-year fracture risk, the following links are available for the FRAX tool and the CAROC table:
http://www.shef.ac.uk/FRAX/tool.jsp?country=19
http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf

ROBS Review of Beta-Blockers

As part of the Review of Benefit Status (ROBS) process, comprehensive clinical reviews of the beta-blockers were undertaken. The Expert Committee gave due consideration to the information available and recommended de-listing a number of beta-blockers from the *ADBL* as they were found to no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments, and to enable broader coverage of higher priority products. In order to minimize the impact these changes will have on patient care, health professionals will be receiving information regarding the implementation of these changes, and will have an opportunity to communicate these changes to their patients.

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