the ADBL report

Issue #75, September 2013

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 July 25, 2013. The Committee reviewed Manufacturer submissions for fifty-two (52) 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 seven (7) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, forty-four (44) Drug Products underwent Expedited Review for listing on the *ADBL*.

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 Line Extension Drug Products Added to the ADBL

The following are Drug Products, added to the *ADBL*, effective September 1, 2013 after a Full Review by the Expert Committee:

- **ACCEL-CITALOPRAM** (citalopram hydrobromide) (ACP) **10 mg tablet** was submitted as a Line Extension to the currently listed 20 mg & 40 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic and/or cost advantage.
- **SANDOZ AMLODIPINE** (amlodipine besylate) (SDZ) **2.5 mg tablet** was submitted as a Line Extension to the currently listed 5 mg & 10 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic advantage.
- **CEFAZOLIN** (cefazolin sodium) (PPC) **100 G/SmartPak Bulk Package injection** was submitted as a Line Extension to the currently listed 500 mg/vial & 10 g/vial injections. This Drug Product has been recommended for listing as a Restricted Benefit for use by Home Parenteral Therapy (HPT) programs only as it offers a cost and/or therapeutic advantage.
- **STELARA** (ustekinumab) (JAI) **90 mg/1.0 mL vial or syringe injection** was submitted as a Line Extension to the currently listed 45 mg/0.5 mL syringe. The Expert Committee recommended this Drug Product be listed via Special Authorization with criteria similar to Stelara 45 mg. However the 90 mg dose is available for patients over 100 kg as it provides a therapeutic advantage.

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 Expedited Interchangeable (IC) Drug Products Added

Addition of the following IC Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective September 1, 2013:

- **APO-VALGANCICLOVIR** (valganciclovir hydrochloride) (APX) **450 mg tablet**

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*:

- **ALOXI** (palonosetron) (EIS) **0.05 mg/mL injection**

Highlights of Drug Products Not Added

The following Drug Products have not been recommended for addition to the *ADBL*:

- **EPURIS** (isotretinoin) (CIP) **10 mg, 20 mg, 30 mg & 40 mg capsules** will not be listed on the *ADBL* as they do not provide a therapeutic advantage over currently listed products.
- **HEPARIN** (heparin sodium) (PFI) **1,000 unit/mL, 5,000 unit/mL & 10,000 unit/mL injections** will not be listed as these Drug Products fail to offer a therapeutic or cost advantage.

Highlights of Criteria Changes

The criteria for coverage via Special Authorization have been revised for the following Drug Product:

- **STELARA** (ustekinumab) (JAI) **45 mg/0.5 mL vial or syringe injection** criteria for Special Authorization were modified to indicate that patients weighing over 100 kg may receive the new 90 mg dose.

Risk of Hypoglycemia with Anti-diabetic Agents

Currently published Step Therapy/Special Authorization coverage criteria for DPP-4 inhibitor agents, JANUVIA/JANUMET (sitagliptin), ONGLYZA (saxagliptin) and TRAJENTA (linagliptin) position these Drug Products in a stepped approach after metformin, sulfonylureas, and insulin.

Inquiries from concerned health care practitioners prompted the Expert Committee to specifically discuss the relative risks of hypoglycemia with the various agents. The risk of hypoglycemia is one factor considered in the review for potential coverage of any anti-diabetic agent. It was noted that both insulins and sulfonylureas show an increased risk of hypoglycemia over DPP-4 inhibitors. However, the literatures show that severe hypoglycemic events in patients with type 2 diabetes are rare across all drug classes, including the insulins and sulfonylureas.[1] Accordingly, special authorization requests for DPP-4 inhibitor agents citing that insulin, metformin or sulfonylureas are contraindicated due to risk of hypoglycemia will not be considered.

[1] Canadian Agency for Drugs and Technologies in Health. Second-line pharmacotherapy for type 2 diabetes — Update. Ottawa: The Agency; July 2013. (CADTH optimal use report; vol.3, no. 1a).

Bloomfield HE, Greer N, Newman D, et al. Predictors and Consequences of Severe Hypoglycemia in Adults with Diabetes - A Systematic Review of the Evidence [Internet]. Washington (DC): Department of Veterans Affairs; 2012 Apr. http://www.ncbi.nlm.nih.gov/books/NBK114893/pdf/TOC.pdf

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