the ADBL report

Issue #78, March 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)

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Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 23, 2014. The Committee reviewed Manufacturer submissions for thirty (30) 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 eleven (11) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-seven (37) Drug Products underwent Expedited Review for listing on the *ADBL* effective March 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 March 1, 2014 after a Full Review by the Expert Committee:

- **CLINDOXYL ADV*** (clindamycin phosphate/benzoyl peroxide) (GSK) **1%/3% topical gel** was submitted as a line extension to the currently listed Clindoxyl 1%/5% topical gel. This Drug Product has been recommended for listing via Special Authorization for severe, scarring acne, as it offers a therapeutic advantage. Clindoxyl ADV offers an alternative to the currently listed Clindoxyl 1%/5% topical gel and Benzaclin 1%/5% topical gel.

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Drug Products to the *ADBL* after a Full Review has resulted in the creation of New IC Groupings, effective March 1, 2014:

- **APO-IMIQUIMOD*** (imiquimod) (APX) **5% topical cream**
- **CEFOXITIN*** (cefoxitin sodium) (APX**) 1 gram & 2 gram vials for injection**
- **CEFOXITIN SODIUM*** (cefoxitin sodium) (TEV**) 1 gram & 2 gram vials (Base) for injection**

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

- **MED-RIVASTIGMINE*** (rivastigmine hydrogen tartrate) (GMP) **1.5 mg, 3 mg, 4.5 mg & 6 mg capsules**
- **MIRVALA** (desogestrel/ethinyl estradiol) (APX) **21 & 28 tablets**

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 Expedited IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective March 1, 2014:

- **APO-DONEPEZIL*** (donepezil hydrochloride) (APX) **5 mg & 10 mg tablets**
- **CO DONEPEZIL*** (donepezil hydrochloride) (COB) **5 mg & 10 mg tablets**
- **DONEPEZIL HYDROCHLORIDE*** (donepezil hydrochloride) (AHI) **5 mg & 10 mg tablets**
- **JAMP-DONEPEZIL*** (donepezil hydrochloride) (JPC) **5 mg & 10 mg tablets**
- **MAR-DONEPEZIL*** (donepezil hydrochloride) (MAR) **5 mg & 10 mg tablets**
- **PMS-DONEPEZIL*** (donepezil hydrochloride) (PMS) **5 mg & 10 mg tablets**
- **RAN-DONEPEZIL*** (donepezil hydrochloride) (RAN) **5 mg & 10 mg tablets**
- **SANDOZ DONEPEZIL*** (donepezil hydrochloride) (SDZ) **5 mg & 10 mg tablets**
- **TEVA-DONEPEZIL*** (donepezil hydrochloride) (TEV) **5 mg & 10 mg tablets**
- **ZOLEDRONIC ACID-Z*** (zoledronic acid) (SDZ**) 4 mg/5 mL injection**

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

The following Drug Products will be added to the *ADBL* effective March 1, 2014 for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older:

- **VYVANSE*** (lisdexamfetamine dimesylate) (SHB) **20 mg, 30 mg, 40 mg, 50 mg & 60 mg capsules**

Neupogen and Neulasta Special Authorization (SA) Criteria Changes

The criteria for coverage via Special Authorization have been revised for:

- **NEUPOGEN*** (filgrastim) (AMG) **0.3 mg/mL injection**
- **NEULASTA*** (pegfilgrastim) (AMG) **6 mg/0.6 mL injection syringe**

The new criteria for these two Drug Products will read as follows:

Neupogen:

"In patients with non-myeloid malignancies, receiving myelosuppresive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

"Following induction and consolidation treatment for acute myeloid leukemia, for the reduction in the duration of neutropenia, fever, antibiotic use and hospitalization."

"In patients with a diagnosis of congenital, cyclic or idiopathic neutropenia, to increase neutrophil counts and to reduce the incidence and duration of infection."

"For the treatment of patients undergoing Peripheral Blood Progenitor Cell (PBPC) collection and therapy when prescribed by a designated prescriber."

All requests for filgrastim must be completed using the Filgrastim/Pegfilgrastim Special Authorization Request Form (ABC 31150).

Please note for the first criterion: Coverage cannot be considered for palliative patients.

Neulasta:

"In patients with non-myeloid malignancies, receiving myelosuppresive anti-neoplastic drugs with curative intent, to decrease the incidence of infection, as manifested by febrile neutropenia."

All requests for pegfilgrastim must be completed using the Filgrastim/Pegfilgrastim Special Authorization Request Form (ABC 31150).

Please note: Coverage cannot be considered for palliative patients.

Eliquis Listing Status Update

The listing status for the following Drug Product has been changed from Restricted Benefit to Special Authorization for the indication of venous thromboembolism prophylaxis due to the addition of coverage for a second indication on the *ADBL*:

- **ELIQUIS*** (apixiban) (BMS) **2.5mg tablet**

The following Drug Products will be added to the *ADBL* via Step Therapy/Special Authorization effective March 1, 2014 for the treatment of Atrial Fibrillation:

- **ELIQUIS*** (apixiban) (BMS) **2.5 mg & 5 mg tablets**

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).*