the DBL report

Issue #84, April 2015

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 January 15, 2015. The Committee reviewed Manufacturer submissions for forty-two (42) 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 twenty-four (24) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty (20) Drug Products underwent Expedited Review for listing on the *ADBL* effective April 1, 2015.

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

Updates to the Manufacturer Submission Requirements in the ADBL

Please be advised as of April 1, 2015 updates to the Manufacturer Submission Policy were published; this policy can be found at:

https://idbl.ab.bluecross.ca/idbl/PDFS/dbl_sec1_drug.pdf

Prior to publication, Alberta Health and Alberta Blue Cross held teleconferences with our pharmaceutical industry partners to discuss these updates. Should Manufacturers require additional clarification regarding the published Manufacturer Submission Policy please contact Alberta Blue Cross, Scientific and Research Services at:

submissions@ab.bluecross.ca

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

The following Drug Product was reviewed by CDR and the Expert Committee and was added to the *ADBL* effective April 1, 2015 as a Restricted Benefit:

- **JETREA*** (ocriplasmin) (ALC) **0.5 mg/vial injection**

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).

ABC 81171 (04/2015)

The following Drug Product was reviewed by CDR and the Expert Committee and was added to the *ADBL* effective April 1, 2015 via Special Authorization (SA) as it offers a therapeutic advantage:

- **SOVALDI*** (sofosbuvir) (GIL) **400 mg tablet**

The following Drug Products were reviewed by CDR and the Expert Committee, and were added to the *ADBL* effective April 1, 2015 with Step Therapy and SA criteria:

- **JANUVIA*** (sitagliptin phosphate monohydrate) (MFC) **25 mg & 50 mg tablets**

The following Drug Product was reviewed by CDR and was added to the *ADBL* effective April 1, 2015 via Special Authorization:

- **HARVONI*** (sofosbuvir/ ledipasvir) (GIL) **400 mg/90 mg tablet**

Highlights of Drug Products Added

The following Drug Products were added to the *ADBL* effective April 1, 2015 after a Full review by the Expert Committee:

- **IBAVYR*** (ribavirin) (PPH) **400 mg & 600 mg tablets** were submitted and reviewed as single entity products. The Expert Committee recommended these Drug Products be listed on the *ADBL* via Special Authorization as they offer a therapeutic advantage.

Highlights of Line Extension Drug Products Added to the ADBL

The following Drug Products were added to the *ADBL* effective April 1, 2015 after a Full review by the Expert Committee:

- **ECL-CITALOPRAM** (citalopram hydrobromide) (ECL) **10 mg tablet**
- **JAYDESS** (levonorgestrel) (BAI) **13.5 mg intrauterine insert**
- **LATUDA*** (lurasidone hydrochloride) (SUN) **20 mg & 60 mg tablets**

Highlights of Line Extension Drug Products Not Added to the ADBL

The following Drug Product was reviewed by the Expert Committee and has not been added to the *ADBL* because it does not offer a cost or therapeutic advantage:

- **LOLO** (norethindrone acetate/ethinyl estradiol/ethinyl estradiol) (ASC) **28 day tablets**

Highlights of Interchangeable Drug Products Not Added

At the time these Drug Products were reviewed by the Expert Committee there were no published criteria in the *ADBL* specific to use of Canadian Non-Innovator Reference Products (CNIRPs) and the Expert Committee was unable to consider demonstration of bioequivalence with a CNIRP as evidence of interchangeability. Therefore, each of the following Drug Products was not added to the *ADBL:*

- **JAMP-CYANOCOBALAMIN** (cyanocobalamin) (JPC) **1000 mcg/mL injection**
- **MINT-HYDROCHLOROTHIAZIDE** (hydrochlorothiazide) (MPI) **25 mg & 50 mg tablets**
- **TEVA-AMITRIPTYLINE** (amitriptyline hydrochloride) (TEV) **10 mg, 25 mg & 50 mg tablets**

As noted previously, updates to the Manufacturer Submission Policy were published April 1, 2015. These updates include criteria surrounding the use of a CNIRP. Manufacturers should review these updates and if appropriate provide a resubmission of their drug product(s) for review by the Expert Committee.

The following Old Drug Product has not been added to the *ADBL* as it fails to offer a cost advantage:

- **EURO-HYDROCORTISONE** (hydrocortisone) (EUP) **1% topical cream**

Special Authorization Criteria Changes

The criteria for coverage via Special Authorization for the following Drug Products have been revised effective March 1, 2015:

- **SOLIRIS*** (eculizumab) (API) **300 mg/vial injection**

The SA criteria for eculizumab were modified in order to provide more clarity with the diagnosis of paroxysmal nocturnal hemoglobinuria (PNH), and to update the immunizations required by patients using eculizumab.

- **XARELTO*** *(*rivaroxaban) (BAI) **15 mg & 20 mg tablets**

The SA criteria for Xarelto have been updated to include the indication of Pulmonary Embolism (PE).

The criteria for coverage via Special Authorization for the following Drug Products have been revised effective April 1, 2015:

- **PEGASYS RBV*** (peginterferon alfa-2a/ribavirin) (MFC) **180 mcg/0.5 mL/200 mg tablet syringe injection kit**

- **PEGETRON*** (peginterferon alfa-2b/ribavirin) (MFC) **80 mcg/0.5 mL/200 mg capsule, 100 mcg/0.5 mL/200 mg capsule, 120 mcg/0.5 mL/200 mg capsule & 150 mcg/0.5 mL/200 mg capsule clearclick injections**

The SA criteria for Pegasys RBV and Pegetron Drug Products have been updated to reflect the addition of Sovaldi (sofosbuvir) to the *ADBL*.

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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