the ADBL report

Issue #96, May 2017

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 24, 2017 and March 21 & 22, 2017. The Committee reviewed Manufacturer submissions for forty-two (42) and forty-four (44) Drug Products for potential listing, or change in listing, on the *ADBL,* respectively. The Committee also considered information for a number of supplementary assessments of the coverage status of fifteen (15) and thirty-one (31) Drug Products, respectively.

In addition to Drug Products reviewed by the Expert Committee, four (4) Drug Products underwent Expedited Review for listing on the *ADBL* effective March 1, 2017, and fourteen (14) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 1, 2017.

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 Products Originally Reviewed via the Common Drug Review (CDR)

The following Drug Products were reviewed by CDR and added to the *ADBL* via Special Authorization (SA) effective April 1, 2017:

- **DAKLINZA*** (daclatasvir dihydrochloride) (BMS) **30 mg & 60 mg tablets**
- **EPCLUSA*** (sofosbuvir/velpatasvir) (GIL) **400 mg/100 mg tablet**
- **GRASTOFIL*** (filgrastim) (APX) **0.3 mg/syringe injection**
- **SUNVEPRA*** (asunaprevir) (BMS) **100 mg capsule**
- **ZEPATIER*** (elbasvir/grazoprevir) (MFC) **50 mg/100 mg tablet**

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Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

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The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Step Therapy/SA effective April 1, 2017:

- **FORXIGA*** (dapagliflozin propanediol monohydrate) (AZC) **5 mg & 10 mg tablets**
- **KOMBOGLYZE*** (saxagliptin HCL/metformin HCL) (AZC) **2.5 mg/500 mg, 2.5 mg/850 mg & 2.5 mg/1,000 mg tablets**
- **ONGLYZA***(saxagliptin HCL) (AZC) **2.5 mg tablet**

The following Drug Products were also reviewed by CDR and the Expert Committee and added to the *ADBL* via SA for the indication of Ulcerative Colitis effective May 1, 2017:

- **SIMPONI*** (golimumab) (JAI) **50 mg/0.5 mL & 100 mg/1 mL injection auto injectors & syringes**

Highlights of Drug Products Added

The following Line Extension Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective April 1, 2017:

- **GRASTOFIL*** (filgrastim) (APX) **0.48 mg/syringe injection** listed via SA
- **JANUMET XR*** (sitagliptin phosphate monohydrate/metformin HCL) (MFC) **50 mg/500 mg, 50 mg/1,000 mg & 100 mg/1,000 mg extended-release tablets** listed via Step Therapy/SA

The following Non-Interchangeable Old Drug Product was reviewed by the Expert Committee and added to the *ADBL* as a Regular Benefit effective May 1, 2017:

- **APO-METHYLPHENIDATE** (methylphenidate HCL) (APX) **5 mg tablet**

Highlights of Interchangeable (IC) Drug Products Reviewed

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective May 1, 2017:

- **CHOLESTYRAMINE-ODAN LIGHT** (cholestyramine resin) (ODN) **4 G/powder packet**
- **ODAN-FLUOXETINE** (fluoxetine HCL) (ODN) **4 mg/mL liquid**

The following Drug Product was also reviewed by the Expert Committee and added via Optional Special Authorization effective May 1, 2017:

- **MED-MOXIFLOXACIN*** (moxifloxacin HCL) (GMP) **400 mg tablet**

Highlights of Other Products Reviewed but Not Added

The following Non-Interchangeable Old Drug Products were reviewed but not added as they failed to demonstrate a therapeutic advantage:

- **EURO-DOCUSATE & EURO-DOCUSATE C** (docusate sodium) (SDZ) **100 mg capsules**
- **EURO-SENNA S** (sennosides/docusate sodium) (SDZ) **8.6 mg/50 mg tablet**

The following Natural Health Products were also reviewed but not added as they failed to demonstrate a therapeutic advantage:

- **EURO-HYDROCORTISONE** (hydrocortisone) (SDZ) **1% cream**
- **EURO-SENNA** (sennosides) (SDZ) **8.6 mg tablet**
- **JAMP-MAGNESIUM** (magnesium glucoheptonate) (JPC) **100 mg/mL solution**

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective April 1, 2017:

- **HARVONI*** (sofosbuvir/ledipasvir) (GIL) **400 mg/90 mg tablet**
- **IBAVYR*** (ribavirin) (PPH) **200 mg, 400 mg & 600 mg tablets**
- **SOVALDI*** (sofosbuvir) (GIL) **400 mg tablet**

The Special Authorization criteria for coverage for the following Drug Products have been revised effective May 1, 2017:

- **PEGASYS***(peginterferon alfa-2a) (HLR) **180 mcg/0.5 mL syringe injection**
- **PEGASYS RBV (KIT)*** (peginterferon alfa-2a/ribavirin) (HLR) **180 mcg/200 mg injection syringe/tablet**
- **PEGETRON CLEARCLICK (KIT)*** (peginterferon alfa-2b/ribavirin) (MFC) **100 mcg/200 mg & 150 mcg/200 mg injection syringes/tablets**
- **RITUXAN*** (rituximab) (HLR) **10 mg/mL injection**

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