the ADBL report

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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 May 14 & 15, 2020. The Committee reviewed Manufacturer submissions for thirty-three (33) 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 sixteen (16) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, fourteen (14) Drug Products underwent Expedited Review for listing on the *ADBL* effective June 1, 2020, and nine (9) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 1, 2020.

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.php

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

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective June 1, 2020:

- **MAVENCLAD* 10 mg tablet** (cladribine) (SRO) via Special Authorization (SA)
- **RADICAVA* 0.3 mg/mL injection** (edaravone) (MIT) via SA
- **SUBLOCADE* 100 mg/0.5 mL & 300 mg/1.5 mL extended-release injection syringes** (buprenorphine) (IUK) via SA
- **XARELTO* 2.5 mg tablet** (rivaroxaban) (BAI) via SA

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective July 1, 2020:

- **ADLYXINE* 0.05 mg/mL & 0.1 mg/mL prefilled pen injections** (lixisenatide) (SAV) via Step Therapy/SA

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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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Highlights of Drug Products Added

The following Line Extension Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective July 1, 2020:

- **NUCALA* 100 mg/mL prefilled autoinjector & prefilled syringe injection** (mepolizumab) (GSK) via SA

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective June 1, 2020:

- **ASPEN-DIENOGEST* 2 mg tablet** (dienogest) (APC) via SA

Addition of the following Entry IC Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective July 1, 2020:

- **TARO-CLOTRIMAZOLE/BETAMETHASONE 0.05%/1% topical cream** (betamethasone dipropionate/clotrimazole) (TAR)

Highlights of Biosimilar Drug Product Added

The following Biosimilar Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective June 1, 2020:

- **TRUXIMA* 10 mg/mL (10 mL & 50 mL) injections** (rituximab) (CTC) via SA

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective June 1, 2020:

- **AUBAGIO* 14 mg tablet** (teriflunomide) (GZM) for the indication of Relapsing Remitting Multiple Sclerosis (RRMS)
- **AVONEX PS/PEN* (30 mcg/0.5 mL) 6 million IU/syringe/pen** (interferon beta-1a) (BIO) for the indication of RRMS
- **BETASERON* (0.3 mg) 9.6 million IU/vial injection** (interferon beta-1b) (BAI) for the indication of RRMS
- **COPAXONE* 20 mg/mL injection syringe** (glatiramer acetate) (TMP) for the indication of RRMS
- **ENBREL* 25 mg/vial injection & 50 mg/syringe injection** (etanercept) (AMG) for the indication of Plaque Psoriasis (PsO)
- **EXTAVIA* (0.3 mg) 9.6 million IU/vial injection** (interferon beta-1b) (NOV) for the indication of RRMS
- Fingolimod hydrochloride* **0.5 mg capsule** (APX, JPC, MAR, MYP, PMS, SDZ, TAR, TEV) for the indication of RRMS
- **GILENYA* 0.5 mg capsule** (fingolimod hydrochloride) (NOV) for the indication of RRMS
- **GLATECT* 20 mg/mL injection syringe** (glatiramer acetate) (PMS) for the indication of RRMS
- **HUMIRA* 40 mg/m0.8 mL injection syringe** (adalimumab) (ABV) for all indications listed on the *ADBL*
- **LEMTRADA* 12 mg/1.2 mL injection** (alemtuzumab) (GZM) for the indication of RRMS
- **OCREVUS* 30 mg/mL (10 mL vial) injection** (ocrelizumab) (HLR) for the indication of RRMS
- **PLEGRIDY* 63 mcg/94 mcg PS/pen injection starter pack & 125 mcg/0.5 mL PS/pen injection** (peginterferon beta-1a) (BIO) for the indication of RRMS
- **REBIF 66 mcg/1.5 mL & 132 mcg/1.5 mL cartridge injections and 22 mcg/0.5 mL (6 million IU) & 44 mcg/0.5 mL (12 million IU) injection syringes** (interferon beta-1a) (SRO) for the indication of RRMS
- **RITUXAN* 10 mg/mL injection** (rituximab) (HLR) for the indication of Rheumatoid Arthritis (RA)
- **STELARA* 45 mg injection vial & 45 mg & 90 mg injection syringes** (ustekinumab) (JAI) for the indication of PsO
- **TECFIDERA* 120 mg delayed-release capsule** (dimethyl fumarate) (BIO) for the indication of RRMS
- **TYSABRI* 20 mg/mL (15 mL vial) injection** (natalizumab) (BIO) for the indication of RRMS

The Special Authorization criteria for coverage for the following Drug Product has been revised effective July 1, 2020:

- **PHEBURANE* 483 mg/g oral granules** (sodium phenylbutyrate) (MDK) via SA

Methadone Products

Due to a Health Canada safety advisory regarding 'Methadone Treatment of Opioid Dependence and Potential Differences in Product Effect', the Expert Committee has temporarily suspended the designation of interchangeability of methadone 10 mg/mL oral solutions for the treatment of opioid dependence on the *Alberta Drug Benefit List*. Interchangeability designation of the affected methadone products will be re-visited once the Health Canada review is completed.

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