the DBL report

Issue #136, February 2024

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 November 23, 2023. The Committee reviewed Manufacturer submissions for thirty-five (35) 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-six (26) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-four (34) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective December 1, 2023, and seventy (70) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective February 1, 2024.

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 by the Canadian Agency for Drugs and Technologies in Health (CADTH)

The following Drug Products were reviewed by CADTH and the Expert Committee and added to the *ADBL* effective December 1, 2023:

- **IMVEXXY 4 mcg & 10 mcg vaginal inserts** (17 beta-estradiol) (KTI)
- **KERENDIA* 10 mg & 20 mg tablets** (finerenone) (BAI) via Special Authorization (SA)
- **QULIPTA* 10 mg, 30 mg & 60 mg tablets** (atogepant) (ABV) via SA

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ABC 81171 (02/2024)

- **SAPHNELO* 300 mg/vial injection** (anifrolumab) (AZC) via SA

The following Drug Products were reviewed by CADTH and added to the *ADBL* effective December 13, 2023:

- **TRIKAFTA* 80 mg/40 mg/60 mg & 59.5 mg and 100 mg/50 mg/75 mg & 75 mg granules** (elexacaftor/tezacaftor/ivacaftor) (ivacaftor) (VER) via SA

The following Drug Products were reviewed by CADTH and the Expert Committee and added to the *ADBL* effective February 1, 2024:

- **ZEPOSIA* 0.23 mg/0.46 mg capsule initiation pack & 0.92 mg capsule** (ozanimod hydrochloride/ ozanimod hydrochloride) (ozanimod hydrochloride) (BMS) via SA

Highlights of Drug Products Added

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2024:

- **MEZERA 500 mg delayed-release tablet** (mesalazine) (AVP)
- **METHOTREXATE 7.5 mg/0.3 mL, 10 mg/0.4 mL, 15 mg/0.6 mL, 20 mg/0.8 mL & 25 mg/1 mL injection syringes BP** (methotrexate sodium) (PMS)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective February 1, 2024:

- **AURO-VALGANCICLOVIR 50 mg/mL oral suspension** (valganciclovir hydrochloride) (AUR)
- **PMS-METHYLPHENIDATE CR 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg & 80 mg controlled-release capsules** (methylphenidate hydrochloride) (PMS) via Restricted Benefit
- **RIVAROXABAN* 2.5 mg tablet** (various brands: APX, DRL, PMS, SDZ, SIV, TAR) via SA
- **RIVAROXABAN* 10 mg tablet** (various brands: APX, DRL, PMS, SDZ, SIV, TAR, TEV) via Restricted Benefit
- **RIVAROXABAN* 15 mg & 20 mg tablets** (various brands: APX, DRL, PMS, SDZ, SIV, TAR, TEV) via Step Therapy/SA

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective February 1, 2024:

- **HADLIMA* 40 mg/0.4 mL auto-injector pen & injection syringe** (adalimumab) (SSB) via SA for Rheumatoid Arthritis (RA), Polyarticular Juvenile Idiopathic Arthritis (pJIA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Crohn's Disease (CD), Ulcerative Colitis (UC), Plaque Psoriasis (PsO) and adult Hidradenitis Suppurativa (HS)
- **YUFLYMA* 40 mg/0.4 mL injection syringe** (adalimumab) (CHC) via SA for RA, pJIA, PsA, AS, CD, UC, PsO and adult HS
- **YUFLYMA* 80 mg/0.8 mL injection pen & syringe** (adalimumab) (CHC) via SA for CD, UC, PsO and adult HS

Special Authorization Criteria Changes

Due to extension of the approval period for subsequent renewals from one year to two years, the Special Authorization criteria for coverage for the following Drug Products have been revised effective December 1, 2023:

- **ABRILADA* 20 mg/0.4 mL injection syringe & 40 mg/0.8 mL injection pen and syringe** (adalimumab) (PFI) for all listed indications
- **AMGEVITA* 20 mg/0.4 mL injection syringe & 40 mg/0.8 mL autoinjector pen and injection syringe** (adalimumab) (AMG) for all listed indications
- **AVSOLA* 100 mg/vial injection** (infliximab) (AMG) for all listed indications
- **BRENZYS* 50 mg/mL auto injector syringe & injection syringe** (etanercept) (SSB) for all listed indications
- **ERELZI* 25 mg/0.5 mL & 50 mg/mL injection syringes and 50 mg/mL sensoready auto injector syringe** (etanercept) (SDZ) for all listed indications
- **HADLIMA* 40 mg/0.8 mL auto-injector pen & injection syringe** (adalimumab) (SSB) for all listed indications
- **HULIO* 20 mg/0.4 mL injection syringe & 40 mg/0.8 mL injection pen and syringe** (adalimumab) (BGP) for all listed indications
- **HYRIMOZ* 20 mg/0.4 mL injection syringe & 40 mg/0.8 mL injection pen and syringe** (adalimumab) (SDZ) for all listed indications

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ABC 81171 (02/2024)

- **IDACIO* 40 mg/0.8 mL injection pen and syringe** (adalimumab) (FKC) for all listed indications
- **INFLECTRA* 100 mg/vial injection** (infliximab) (CHH) for all listed indications
- **RENFLEXIS* 100 mg/vial injection** (infliximab) (SSB) for all listed indications
- **SIMLANDI* 40 mg/0.4 mL auto-injector pen and prefilled syringe & 80 mg/0.8 mL prefilled syringe** (adalimumab) (JPC) for all listed indications)
- **YUFLYMA* 40 mg/0.4 mL injection pen** (adalimumab) (CHC) for all listed indications

Due to changes to the requirement criteria of trying both mesalamine AND a glucocorticoid, to patients having to try at least one of these Drug Products, the Crohn's Disease Special Authorization criteria for coverage for the following Drug Products have been revised effective December 1, 2023:

- **ABRILADA* 40 mg/0.8 mL injection pen and syringe** (adalimumab) (PFI)
- **AMGEVITA* 40 mg/0.8 mL autoinjector pen and injection syringe** (adalimumab) (AMG)
- **AVSOLA* 100 mg/vial injection** (infliximab) (AMG)
- **ENTYVIO* 108 mg/0.68 mL injection pen & syringe and 300 mg/vial injection** (vedolizumab) (TAK)
- **HADLIMA* 40 mg/0.8 mL auto-injector pen & injection syringe** (adalimumab) (SSB)
- **HULIO* 40 mg/0.8 mL injection pen and syringe** (adalimumab) (BGP)
- **HYRIMOZ* 40 mg/0.8 mL injection pen and syringe** (adalimumab) (SDZ)
- **IDACIO* 40 mg/0.8 mL injection pen and syringe** (adalimumab) (FKC)
- **INFLECTRA* 100 mg/vial injection** (infliximab) (CHH)
- **RENFLEXIS* 100 mg/vial injection** (infliximab) (SSB)
- **SIMLANDI* 40 mg/0.4 mL auto-injector pen and prefilled syringe & 80 mg/0.8 mL prefilled syringe** (adalimumab) (JPC)
- **YUFLYMA* 40 mg/0.4 mL injection pen** (adalimumab) (CHC)

Due to modifying the requirements of second generation long-acting antipsychotic products to only require a trial of one antipsychotic therapy, rather than for patients to have experienced extrapyramidal symptoms with a first generation antipsychotic agent or to have tried two other prerequisite antipsychotic therapies, the Special Authorization criteria for coverage for the following Drug Products have been revised effective December 1, 2023:

- **ABILIFY MAINTENA* 300 mg/mL & 400 mg/mL vial injections** (aripiprazole) (OTS)
- **INVEGA SUSTENNA* 50 mg/0.5 mL, 75 mg/0.75 mL, 100 mg/mL & 150 mg/1.5 mL injection syringes** (paliperidone palmitate) (JAI)
- **INVEGA TRINZA* 175 mg/0.875 mL, 263 mg/1.315 mL, 350 mg/1.75 mL & 525 mg/2.625 mL injection syringes** (paliperidone palmitate) (JAI)
- **RISPERDAL CONSTA* 25 mg, 37.5 mg & 50 mg vial injections** (risperidone) (JAI)

The Special Authorization criteria for coverage for the following Drug Products have been revised effective December 13, 2023, due to addition of the Trikafta granules for patients 2 to 5 years old to the *ADBL*:

- **TRIKAFTA* 50 mg/25 mg/37.5 mg & 75 mg and 100 mg/50 mg/75 mg & 150 mg tablets** (elexacaftor/tezacaftor/ivacaftor) (ivacaftor) (VER)

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