DBL Report

Issue #144 | May 2025

An Official Accompaniment to the *Alberta Drug Benefit List (ADBL)* produced by Alberta Blue Cross®

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS

Margaret Gray, BSP, FCSHP (Chair)

Micheal Guirguis, BScPharm, PhD (Vice-Chair)

Caitlin A. Clarke, BScPhm, PharmD

Nicholas Myers, BSc, MB, BS, MRCGP (UK)

ALBERTA HEALTH LIAISON

Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT

Amina Babar, BSc (Pharm)

Julia Chan, BSc (Pharm), MHA, CHE

Amanda Chung, BSc (Pharm)

Sherry Dieleman, BSc (Pharm), MSc

Stephanie Parcasio, BSc (Pharm)

The following are highlights of recent changes to the *ADBL* and other topics of general interest. Please refer to the current *ADBL* for explanations of coverage, including a listing of coverage criteria (where applicable) DBL Publications | Alberta.ca.

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 18, 2025. The Committee reviewed Manufacturer submissions for fourteen (14) Drug Products for potential listing, or change in listing, on the *ADBL*. The Committee also considered information for a number of supplementary assessments related to the coverage status of thirteen (13) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, forty-four (44) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective May 1, 2025.

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 Canada's Drug Agency (CDA-AMC)

The following Drug Products were reviewed by CDA-AMC and the Expert Committee and added to the *ADBL*:

EFFECTIVE DATE	PRODUCT DESCRIPTION	LISTING STATUS
April 1, 2025	REMSIMA SC 120 MG/ML INJECTION PEN (INFLIXIMAB) CELLTRION HEALTHCARE CANADA LTD	Special Authorization
May 1, 2025	SOHONOS 1 MG, 1.5 MG, 2.5 MG, 5 MG & 10 MG CAPSULES (PALOVAROTENE) IPSEN BIOPHARM LIMITED	Special Authorization

Classification: Protected A

Highlights of Drug Products Added to the *ADBL*

The following Drug Products were added to the *ADBL*:

EFFECTIVE DATE	PRODUCT DESCRIPTION	DETAILS	LISTING STATUS
April 1, 2025	IXIFI 100 MG/VIAL INJECTION (INFLIXIMAB) PFIZER CANADA ULC	Biosimilar Drug Product	Special Authorization
April & May 1, 2025	FLUTICASONE HFA 50 MCG/DOSE METERED AEROSOL DRUG PRODUCTS (FLUTICASONE PROPIONATE) APOTEX INC. & PHARMASCIENCE INC.	Establishment of New Interchangeable (IC Grouping)	Regular Benefits
May 1, 2025	APO-LEVOTHYROXINE 88 MCG & 137 MCG TABLETS (LEVOTHYROXINE SODIUM) APOTEX INC.		Regular Benefits
	TARO-DEFERIPRONE 1000 MG TABLET (DEFERIPRONE) TARO PHARMACEUTICALS INC.		Special Authorization
	TARO-TOFACITINIB XR 11 MG EXTENDED-RELEASE TABLET (TOFACITINIB CITRATE) TARO PHARMACEUTICALS INC.		

Highlights of Changes to the *ADBL*

The following Drug Products on the *ADBL* incurred changes:

EFFECTIVE DATE	PRODUCT DESCRIPTION	UPDATES
April 1, 2025	INFLECTRA 100 MG/VIAL INJECTION (INFLIXIMAB) PFIZER CANADA ULC	Pfizer's agreement with Celltrion Healthcare for Inflectra ended March 31, 2025, with Pfizer ceasing to promote Inflectra as of April 1, 2025. Pfizer will distribute remaining inventory and continue patient support through September 30, 2025. Healthcare professionals must transition patients to an alternative infliximab product before that date. Due to this change, an administrative note for coverage has been added to all listed Inflectra indications to communicate that all new Special Authorization requests for Pfizer labelled Inflectra for treatment naïve patients will no longer be approved. Infliximab naive patients will need to be assessed for coverage with other currently listed infliximab biosimilars and will require an appropriate prescription.
May 1, 2025	JUBBONTI 60 MG/ML INJECTION SYRINGE	Preamble in the Special Authorization criteria has been removed due to the Alberta Biosimilar Initiative.

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	(DENOSUMAB) SANDOZ CANADA INC.	
	PROLIA 60 MG/ML INJECTION SYRINGE (DENOSUMAB) AMGEN CANADA INC.	Delisted due to the Alberta Biosimilar Initiative.

Listing Status Changes

As part of the Review of Benefit Status (ROBS) process, a comprehensive clinical review of Triptan Drug Products was undertaken by the Expert Committee. Following this review, the Expert Committee recommended the coverage status of Triptan Drug Products be revised. Effective May 1, 2025, the listing status for Triptan Drug Products (Various brands will be revised from **Restricted Benefit/Special Authorization benefits to Regular Benefits**.

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Classification: Protected A

the DBL report

Issue #143, March 2025

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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Julia Chan, BSc (Pharm), MHA
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Stephanie Parcasio, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 21, 2025. The Committee reviewed Manufacturer submissions for eighteen (18) 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 eighteen (18) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, forty-four (44) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective March 1, 2025.

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

Special Authorization Criteria Change

Due to removal of the Health Assessment Questionnaire (HAQ) score from the ongoing coverage section, the Psoriatic Arthritis and/or Rheumatoid Arthritis Special Authorization criteria for coverage for the following Drug Products have been revised effective March 1, 2025:

- **ABRILADA* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (PFI)
- **ACTEMRA* 162 mg/0.9 mL auto injector & syringe and 80 mg/4 mL, 200 mg/10 mL & 400 mg/20 mL vial injections** (tocilizumab) (HLR)
- **AMGEVITA* 40 mg/0.8 mL autoinjector pen & syringe** (adalimumab) (AMG)
- **AVSOLA* 100 mg/vial injection** (infliximab) (AMG)
- **BRENZYS* 50 mg/mL auto injector & injection syringes** (etanercept) (SSB)
- **CIMZIA* 200 mg/mL auto-injector pen & injection syringe** (certolizumab pegol) (UCB)
- **COSENTYX* 150 mg/mL injection syringe** (secukinumab) (NOV)
- **ERELZI* 25 mg/0.5 mL & 50 mg/mL injection syringes and 50 mg/mL sensoready auto injector syringe** (etanercept) (SDZ)

- **HADLIMA* 40 mg/0.4 mL and 40 mg/0.8 mL auto-injector pens & injection syringes** (adalimumab) (SSB)
- **HULIO* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (BBC)
- **HYRIMOZ* 40 mg/0.4 mL and 40 mg/0.8 mL injection pens & syringes** (adalimumab) (SDZ)
- **IDACIO* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (FKC)
- **INFLECTRA* 100 mg/vial injection** (infliximab) (CHH)
- **KEVZARA* 150 mg/1.14 mL injection pen and 200 mg/1.14 mL injection pen & syringe** (sarilumab) (SAV)
- **KINERET* 100 mg injection syringe** (anakinra) (BVM)
- **OLUMIANT* 2 mg tablet** (baricitinib) (LIL)
- **ORENCIA* 125 mg/mL injection syringe & 250 mg/vial injection** (abatacept) (BMS)
- **RENFLEXIS* 100 mg/vial injection** (infliximab) (SSB)
- **RINVOQ* 15 mg extended-release tablet** (upadacitinib) (ABV)
- **RYMTI* 50 mg/mL auto-injector pen & injection syringe** (etanercept) (LPC)
- **SIMLANDI* 40 mg/0.4 mL auto-injector pen & injection syringe** (adalimumab) (JPC)
- **SIMPONI* 50 mg/0.5 mL injection auto injector & syringe** (golimumab) (JAI)
- **TALTZ* 80 mg/mL autoinjector & injection syringe** (ixekizumab) (LIL)
- **TOFACITINIB CITRATE* 5 mg tablet** (Various brands: AUR, JPC, PMS, TAR & PFI)
- **TREMFYA* 100 mg/mL injection syringe & TREMFYA ONE-PRESS* 100 mg/mL auto-injector syringe** (guselkumab) (JAI)
- **XELJANZ XR* 11 mg extended-release tablet** (tofacitinib citrate) (PFI)
- **YUFLYMA* 40 mg/0.4 mL injection pen & syringe** (adalimumab) (CHC)

the ADBL report

Issue #142, February 2025

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Sherry Dieleman, BSc (Pharm), MSc
Stephanie Parcasio, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 18 & 19, 2024. The Committee reviewed Manufacturer submissions for thirty-two (32) 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 fifty-nine (59) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, nine (9) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective December 1, 2024, and twenty-one (21) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective February 1, 2025.

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 Canada's Drug Agency (CDA-AMC)

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

- **AMVUTTRA* 25 mg/0.5 mL injection syringe** (vutrisiran sodium) (ANT) via Special Authorization (SA)
- **ORLADEYO* 150 mg capsule** (berotralstat hydrochloride) (BCR) via SA
- **SLYND 4 mg oral tablet** (drospirenone) (DUI)
- **QULIPTA* 10 mg, 30 mg & 60 tablets** (atogepant) (ABV) via SA for the indication of chronic migraine

The following Drug Products were reviewed by CDA-AMC and the Expert Committee and added to the *ADBL* effective February 1, 2025:

- **KOSELUGO* 10 mg & 25 mg capsules** (selumetinib) (APG) via SA

Highlights of Drug Products Added

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

- **MEZERA 1 g delayed-release tablet** (mesalazine) (AVP)

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2025:

- **MK 20 A LIBERATION PROLONGEE 20 mEq tablet** (potassium chloride (K+)) (MTR)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.

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

ABC 81171 (02/2025)

- **PRALUENT* 150 mg/mL (300 mg/2 mL) injection pen** (alirocumab) (SAV) 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 February 1, 2025:

- **ICATIBANT* 30 mg injection syringe** (icatibant acetate) (JPC) via SA

Highlights of Diabetes Supplies

Effective December 16, 2024, continuous glucose monitors (CGMs) for adult patients (≥18 years of age) were added to the *ADBL*. The following Devices were added to the *ADBL* via Restricted Benefit:

- **FREESTYLE LIBRE 2 SENSOR*** (glucose monitoring sensor) (ABD)
- **FREESTYLE LIBRE 2 READER*** (glucose monitoring receiver) (ABD)
- **DEXCOM G7 SENSOR*** (glucose monitoring sensor) (COM)
- **DEXCOM G7 RECEIVER*** (glucose monitoring receiver) (COM)

The following Devices were added to the *ADBL* via Restricted Benefit/SA effective December 16, 2024:

- **GUARDIAN 4 SENSOR (780G PUMP) *** (glucose monitoring sensor) (MET)
- **GUARDIAN 4 TRANSMITTER (780G PUMP) *** (glucose monitoring transmitter) (MET)

The following Devices criteria were expanded to include adult patients (≥18 years of age) via SA effective December 16, 2024:

- **GUARDIAN LINK TRANSMITTER (670G PUMP)*** (glucose monitoring transmitter) (MET)
- **GUARDIAN LINK TRANSMITTER (770G)*** (glucose monitoring transmitter) (MET)
- **GUARDIAN SENSOR*** (glucose monitoring transmitter sensor) (MET)
- **GUARDIAN CONNECT TRANSMITTER*** (glucose monitoring transmitter) (MET)

The following Devices criteria were expanded to include adult patients (≥18 years of age) via Restricted Benefit effective December 16, 2024:

- **DEXCOM G6 SENSOR*** (glucose monitoring transmitter sensors) (COM)
- **DEXCOM G6 TRANSMITTER*** (glucose monitoring transmitter) (COM)

The following Devices Restricted Benefit criteria were changed to include an administrative preamble, that details patients that chose to use a CGM will continue to be eligible for diabetes supplies up to a maximum of $320 for Alberta Health Programs and 400 test strips for Alberta Human Services Programs, effective December 16, 2024:

- **BLOOD GLUCOSE TEST STRIPS** (Various brands: ABD, ADC, ARP, BNE, LIF, RDC, SEN, TTC)

The following Devices Restricted Benefit criteria were changed to include an administrative preamble, that details patients that chose to use a CGM will continue to be eligible for diabetes supplies up to a maximum of $320 for Alberta Health Programs and 400 test strips for Alberta Human Services Programs, effective December 16, 2024:

- **BLOOD GLUCOSE TEST STRIPS** (Various brands: ABD, ADC, ARP, BNE, LIF, RDC, SEN, TTC)
- **BLOOD KETONE & URINE KETONE TEST STRIPS**
- **BLOOD LETTING LANCET**
- **INSULIN PEN NEEDLES & SYRINGES**

Coverage Status Changes to Currently Listed Products

The coverage status of the following Drug Products has been changed from SA to Regular Benefit effective February 1, 2025:

- **CELECOXIB 100 mg & 200 mg capsules** (Various brands: AGP, APX, AUR, BGP, BMD, JPC, MAR, MPI, MTR, NRA, PMS, SIV & SNS)

The coverage status of the following Drug Products has been changed from Step Therapy/SA to Regular Benefit effective February 1, 2025:

- **ANORO ELLIPTA 62.5 mcg/25 mcg inhalation powder** (umeclidinium bromide /vilanterol trifenatate) (GSK)
- **DUAKLIR GENUAIR 400 mcg/12 mcg inhalation powder** (aclidinium bromide/ formoterol fumarate dihydrate) (COV)
- **INSPIOLTO RESPIMAT 2.5 mcg/2.5 mcg inhalation solution** (tiotropium bromide monohydrate/ olodaterol hydrochloride) (BOE)
- **ULTIBRO BREEZHALER 110 mcg/50 mcg inhalation capsule** (indacaterol maleate/ glycopyrronium bromide) (NOV)

Special Authorization Criteria Change

The Special Authorization criteria for coverage for the following Drug Products have been revised effective November 5, 2024:

- **TRIKAFTA* 50 mg/25 mg/37.5 mg & 75 mg and 100 mg/50 mg/75 mg & 150 mg tablets and 80 mg/40 mg/60 mg & 59.5 mg and 100 mg/50 mg/75 mg & 75 mg granules** (elexacaftor/tezacaftor/ivacaftor) (ivacaftor) (VER)

Due to the Alberta Biosimilar Initiative, a SA administrative preamble has been added to the following Drug Product, effective November 1, 2024:

- **PROLIA 60 MG/ML INJECTION SYRINGE*** (denosumab) (AMG)

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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Issue #141, November 2024

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Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 17, 2024. The Committee reviewed Manufacturer submissions for thirty-eight (38) 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 five (5) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, eight (8) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective October 1, 2024, and twenty-one (21) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective November 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 Canada's Drug Agency (CDA-AMC)

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

- **OMVOH* 100 mg/mL injection pen & syringe and 300 mg/15 mL (20 mg/mL) vial injection** (mirikizumab) (LIL) via Special Authorization (SA)

Highlights of Drug Products Added

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

- **SANDOZ BISOPROLOL 1.25 mg & 2.5 mg tablets** (bisoprolol fumarate) (SDZ)
- **VYEPTI* 300 mg/3 mL vial injection** (eptinezumab) (LBC) via SA

The following Natural Health Product was reviewed by the Expert Committee and added to the *ADBL* effective November 1, 2024:

- **PHARMARIS K8 8 MEQ sustained-release tablet** (potassium chloride (K+)) (PCI)

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 October 1, 2024:

- **JAMP IPRATROPIUM HFA 20 mcg/dose metered-dose aerosol** (ipratropium bromide) (JPC)

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

- **APO-BRIVARACETAM* 10 mg, 25 mg, 50 mg, 75 mg & 100 mg tablets** (brivaracetam) (APX) via SA
- **AURO-BRIVARACETAM* 50 mg & 100 mg tablets** (brivaracetam) (AUR) via SA
- **ETHOSUXIMIDE 250 mg capsule** (ethosuximide) (various brands: MAR, ODN)
- **LISDEXAMFETAMINE DIMESYLATE* 10 mg capsule** (various brands: SDZ, TEV) via Restricted Benefit (RB)

Highlights of Biosimilar Drug Products Added

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

- **STEQEYMA* 45 mg/0.5 mL & 90 mg/1 mL injection syringes** (ustekinumab) (CHC) via SA for the indication of Plaque Psoriasis (PsO)
- **JUBBONTI* 60 mg/mL injection syringe** (denosumab) (SDZ) via SA

Special Authorization Criteria Changes

Due to the listing of Rinvoq (upadacitinib) for Ulcerative Colitis, to note that combination therapy with other Janus kinase inhibitors or a sphingosine 1-phosphate receptor modulator will not be allowed, the Special Authorization criteria for coverage for the following Drug Products have been revised effective October 1, 2024:

- **XELJANZ* 5 mg & 10 mg tablets** (tofacitinib citrate) (PFI) via SA
- **TOFACITINIB CITRATE* 5 mg & 10 mg tablets** (various brands: AUR, TAR) via SA
- **TOFACITINIB CITRATE* 5 mg tablet** (various brands: JPC & PMS) via SA

Due to removal of the administrative note, the Plaque Psoriasis Special Authorization criteria for coverage for the following Drug Products have been revised effective November 1, 2024:

- **JAMTEKI* 45 mg/0.5 mL & 90 mg/1 mL injection syringes** (ustekinumab) (JPC) via SA
- **WEZLANA* 45 mg/0.5 mL & 90 mg/1 mL injection syringes & 45 mg/0.5 mL vial injection** (ustekinumab) (AMG) via SA

Delisted Products

The following Drug Products were delisted from the *ADBL* effective November 1, 2024 due to the Alberta Biosimilar Initiative:

- **STELARA 45 mg/0.5 mL injection vial or syringe & 90 mg/1 mL injection syringe** (ustekinumab) (JAI)

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 (11/2024)

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Sherry Dieleman, BSc (Pharm), MSc

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Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 23, 2024. The Committee reviewed Manufacturer submissions for seventeen (17) 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 ten (10) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-seven (27) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective August 1, 2024, and sixteen (16) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective September 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 Canada's Drug Agency (CDA-AMC)

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

- **BRINEURA* 30 mg/mL injection** (cerliponase alfa) (BMI) via Special Authorization (SA)
- **CAMZYOS* 2.5 mg, 5 mg, 10 mg & 15 mg capsules** (mavacamten) (BMS) via SA
- **NUCALA* 100 mg/mL prefilled autoinjector & prefilled syringe injection** (mepolizumab) (GSK) via SA for the indication of chronic rhinosinusitis with nasal polyps

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

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- **OXLUMO* 94.5 mg/0.5 mL vial injection** (lumasiran sodium) (ANT) via SA
- **RINVOQ* 15 mg extended-release tablet** (upadacitinib) (ABV) via SA for the indication of Ankylosing Spondylitis
- **RINVOQ* 15 mg, 30 mg & 45 mg extended-release tablets** (upadacitinib) (ABV) via SA for the indications of Ulcerative Colitis & Crohn's Disease
- **VASCEPA* 1 g capsule** (icosapent ethyl) (HLS) via SA

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

- **VERQUVO* 2.5 mg, 5 mg & 10 mg tablets** (vericiguat) (BAI) via SA

Highlights of Drug Products Added

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

- **SUBOXONE 2 mg/0.5 mg, 8 mg/2 mg & 12 mg/3 mg sublingual/buccal films** (buprenorphine hydrochloride/ naloxone hydrochloride dihydrate) (IUK)

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 August 1, 2024:

- **SANDOZ LISDEXAMFETAMINE 20 mg, 40 mg, 50 mg & 60 mg capsules** (lisdexamfetamine dimesylate) (SDZ) via Restricted Benefit
- **TEVA-LISDEXAMFETAMINE 20 mg, 30 mg, 40 mg, 50 mg & 60 mg capsules** (lisdexamfetamine dimesylate) (TEV) via Restricted Benefit

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

- **AURO-RUFINAMIDE* 200 mg & 400 mg tablets** (rufinamide) (AUR) via SA
- **TARO-FUSIDIC ACID 2% topical cream** (fusidic acid) (TAR)

Special Authorization Criteria Changes

Due to removal of the requirement criteria for a timed 25-foot walk (T25W) score, along with the renewal criteria regarding disease progression, the SA criteria for coverage for the following Drug Products have been revised effective August 1, 2024:

- **MAYZENT* 0.25 mg & 2 mg oral tablets** (siponimod) (NOV)

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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Issue #139, July 2024

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The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Margaret Gray, BSP, FCSHP (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amina Babar, BSc (Pharm)
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 13 & 14, 2024. The Committee reviewed Manufacturer submissions for twenty-four (24) Drug Products for potential listing, or change in listing, on the *ADBL*.

In addition to Drug Products reviewed by the Expert Committee, twenty-two (22) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective June 1, 2024, and eighteen (18) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective July 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 Canada's Drug Agency (CDA-AMC)

The following Drug Products were reviewed by CDA-AMC and the Expert Committee and added to the *ADBL* effective May 24, 2024:

- **PAXLOVID* 150 mg/100 mg tablet pack & 150 mg/100 mg tablet pack (for moderate renal impairment)** (nirmatrelvir/ritonavir) (PFI) via Restricted Benefit/Special Authorization (SA)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (07/2024)

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

- **LIVTENCITY* 200 mg tablet** (maribavir) (TAK) via SA
- **VYALEV* 12 mg/mL/ 240 mg/mL injection** (foslevodopa/ foscarbidopa) (ABV) via SA

The following Drug Product was reviewed by CDA-AMC and the Expert Committee and added to the *ADBL* effective June 13, 2024:

- **VABYSMO* 6 mg/0.05 mL vial injection** (faricimab) (HLR) via Restricted Benefit for the indications of Diabetic Macular Edema (DME) & Neovascular (wet) Age-related Macular Degeneration (nAMD)

Highlights of Drug Products Added

The following Drug Product was added to the *ADBL* effective June 1, 2024:

- **GLATIRAMER ACETATE* 20 mg/mL injection syringe** (glatiramer acetate) (MYP) via SA

Highlights of Biosimilar Drug Products Added

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

- **NYPOZI* 300 mcg/0.5 mL & 480 mcg/0.8 mL injection syringes** (filgrastim) (TNX) via SA
- **RYMTI* 50 mg/mL auto injector syringe & injection syringe** (etanercept) (LPC) via SA for the indications of Ankylosing Spondylitis (AS), Plaque Psoriasis (PsO), Polyarticular Juvenile Idiopathic Arthritis (pJIA), Psoriatic Arthritis (PsA) and Rheumatoid Arthritis (RA)

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

- **HYRIMOZ* 20 mg/0.2 mL injection syringe** (adalimumab) (SDZ) via SA for the indication of pJIA
- **HYRIMOZ* 40 mg/0.4 mL injection pen & syringe** (adalimumab) (SDZ) via SA for the indications of AS, adult Hidradenitis Suppurativa (HS), adult Crohn's Disease (CD), PsO, pJIA, PsA, RA & adult Ulcerative Colitis (UC)
- **HYRIMOZ* 80 mg/0.8 mL injection pen & syringe** (adalimumab) (SDZ) via SA for the indications of adult HS, adult CD, PsO & adult UC

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 (07/2024)

the ADBL report

Issue #138, May 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)

EXPERT COMMITTEE MEMBERS:
Margaret Gray, BSP, FCSHP (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amina Babar, BSc (Pharm)
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 19, 2024. The Committee reviewed Manufacturer submissions for sixteen (16) 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 nine (9) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, fifty-three (53) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective May 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 April 1, 2024:

BENLYSTA* 120 mg/vial & 400 mg/vial injections and 200 mg/mL autoinjector (belimumab) (GSK) via Special Authorization (SA)

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

- **ENSPRYNG* 120 mg/mL injection syringe** (satralizumab) (HLR) via SA
- **VIMIZIM* 5 mg/5 mL (1 mg/mL) intravenous infusion** (elosulfase alfa) (BMI) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (05/2024)

Highlights of Drug Products Added

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

- **ACT METHYLPHENIDATE ER* 18 mg, 27 mg, 36 mg & 54 mg extended-release tablets** (methylphenidate hydrochloride) (TEV) via Restricted Benefit
- **OCTASA 800 mg & 1600 mg delayed-release tablets** (mesalazine) (TAG)
- **PRZ-K20 mEq extended-release tablet** (potassium chloride (K+)) (PCI)
- **UCERIS 2 mg/actuation rectal foam** (budesonide) (VCL)

Highlights of Biosimilar Drug Products Added

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

- **JAMTEKI* 45 mg/0.5 mL & 90 mg/1 mL syringe injections** (ustekinumab) (JPC) via SA for the indication of Plaque Psoriasis (PsO)
- **WEZLANA* 45 mg/0.5 mL & 90 mg/1 mL injection syringes and 45 mg/0.5 mL vial injection** (ustekinumab) (AMG) via SA for the indication of PsO

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 May 1, 2024:

- **APO-METHADONE 1 mg, 5 mg, 10 mg & 25 mg tablets** (methadone hydrochloride) (APX)
- **AURO-TOFACITINIB* 10 mg tablet** (tofacitinib citrate) (AUR) via SA
- **LUPIN-TIOTROPIUM 18 mcg inhalation capsule** (tiotropium bromide monohydrate) (LPC)
- **PMS-METHOTREXATE 10 mg/0.2 mL & 12.5 mg/0.25 mL injection syringes** (methotrexate sodium) (PMS)
- **TARO-TOFACITINIB* 10 mg tablet** (tofacitinib citrate) (TAR) via SA

Special Authorization Criteria Changes

Due to the listing of Ultomiris (ravulizumab) for paroxysmal nocturnal hemoglobinuria (PNH), to note that combination therapy and switching between Soliris and Ultomiris will not be allowed, the Special Authorization criteria for coverage for the following Drug Product has been revised effective May 1, 2024:

- **SOLIRIS INTRAVENOUS INFUSION* 300 mg/vial injection** (eculizumab) (APG) via SA

The Special Authorization criteria for coverage for the following Drug Products have been revised effective May 1, 2024, due to addition of an administrative preamble along with the removal of tiering requirements:

- **STELARA* 45 mg/0.5 ml vial or syringe injection & 90 mg/1 mL injection syringe** (ustekinumab) (JAI) via SA

Due to expansion of coverage to include patients 12 to 17 years of age, the Restricted Benefit/SA criteria for coverage for the following Drug Products have been revised effective May 1, 2024:

- **ALMOTRIPTAN* 12.5 mg tablet** (almotriptan malate) (SNS) via Restricted Benefit/SA
- **MYLAN-ALMOTRIPTAN* 6.25 mg & 12.5 mg tablets** (almotriptan malate) (MYP) via Restricted Benefit/SA
- **SANDOZ ALMOTRIPTAN* 12.5 mg tablet** (almotriptan malate) (SDZ) via Restricted Benefit/SA
- **TEVA-ALMOTRIPTAN* 12.5 mg tablet** (almotriptan malate) (TEV) via Restricted Benefit/SA

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 (05/2024)

the DBL report

Issue #137, March 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)

EXPERT COMMITTEE MEMBERS:
Margaret Gray, BSP, FCSHP (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amina Babar, BSc (Pharm)
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 16, 2024. The Committee reviewed Manufacturer submissions for fourteen (14) 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 fifteen (15) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-two (22) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective March 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 March 1, 2024:

- **BIJUVA 1 mg/100 mg capsule** (estradiol hemihydrate/ progesterone) (KTI)
- **EMPAVELI* 1080 mg/20 mL (54 mg/mL) vial injection** (pegcetacoplan) (BVM) via Special Authorization (SA) for the indication of Paroxysmal Nocturnal Hemoglobinuria (PNH)
- **SKYRIZI* 360 mg/dose injection cartridge & 600 mg/10 mL vial injection** (risankizumab) (ABV) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (03/2024)

for the indication of Moderately to Severely Active Crohn's Disease

- **ULTOMIRIS* 100 mg/mL (1100 mg/11 mL & 300 mg/3 mL) and 10 mg/mL injections** (ravulizumab) (APG) via SA for the indications of PNH & atypical Hemolytic Uremic Syndrome (aHUS)
- **XOLAIR* 75 mg/0.5 mL injection syringe** (omalizumab) (NOV) via SA for the indication of Asthma
- **XOLAIR* 150 mg/mL injection syringe** (omalizumab) (NOV) via SA for the indications of Chronic Idiopathic Urticaria (CIU) and Asthma

Highlights of Drug Products Added

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

- **PRZ-METFORMIN 1000 mg tablet** (metformin hydrochloride) (PCI)
- **TREMFYA ONE-PRESS* 100 mg/1 mL auto-injector syringe** (guselkumab) (JAI) via SA for the indication of Plaque Psoriasis

Highlights of Changes to Currently Listed Products

The benefit listing status of the following Drug Products have been changed from Restricted or Step Therapy/Special Authorization Benefits to a Regular Benefit effective March 1, 2024:

- **RIVAROXABAN 2.5 mg, 10 mg, 15 mg & 20 mg tablets** (various brands: APX, BAI, PMS, DRL, SDZ, SIV & TAR)
- **TEVA-RIVAROXABAN 10 mg, 15 mg & 20 mg tablets** (rivaroxaban) (TEV)

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 March 1, 2024:

- **TARO-PERAMPANEL* 2 mg, 4 mg, 6 mg, 8 mg, 10 mg & 12 mg tablets** (perampanel) (TAR) via SA

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 (03/2024)

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)

EXPERT COMMITTEE MEMBERS:
Margaret Gray, BSP, FCSHP (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)
Tony Nickonchuk, BScPharm

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amina Babar, BSc (Pharm)
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc

In this issue:

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

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.

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

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

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 (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)

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).*

the ADBL report

Issue #135, November 2023

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Micheal Guirguis, BScPharm, PhD (Acting Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)
Tony Nickonchuk, BScPharm

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amina Babar, BSc (Pharm)
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 21, 2023. The Committee reviewed Manufacturer submissions for fifteen (15) 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 thirty-five (35) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-two (32) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective October 1, 2023, and thirty-five (35) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective November 1, 2023.

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 October 1, 2023:

- **TREMFYA* 100 mg/1 mL injection syringe** (guselkumab) (JAI) via Special Authorization (SA) for the indication of Plaque Psoriasis

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (11/2023)

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

- **RINVOQ* 15 mg & 30 mg extended-release tablets** (upadacitinib) (ABV) via SA for the indication of Atopic Dermatitis
- **TEZSPIRE* 210 mg/1.91 mL (110 mg/mL) injection pen & syringe** (tezepelumab) (AZC) via SA

Highlights of Drug Products Added

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

- **FOQUEST* 25 mg, 35 mg, 45 mg, 55 mg, 70 mg, 85 mg & 100 mg controlled-release capsules** (methylphenidate hydrochloride) (ELV) via Restricted Benefit
- **TRESIBA 100 unit/mL penfill cartridge** (insulin degludec) (NNA)

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 October 1, 2023:

- **ATOMOXETINE HYDROCHLORIDE* 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg & 100 mg capsules** (brands: APX, SDZ) via Step Therapy/SA
- **PMS-ATOMOXETINE* 10 mg, 18 mg, 25 mg, 40 mg & 60 mg capsules** (atomoxetine hydrochloride) (PMS) via Step Therapy/SA

Addition of Single Source Drug Products

The following Drug Products were added to the *ADBL* effective October 1, 2023:

- **APO-AMPHETAMINE XR* 5 mg, 10 mg, 15 mg, 20 mg, 25 mg & 30 mg extended-release capsules** (amphetamine sulfate/ amphetamine aspartate/ dextroamphetamine sulfate/ dextroamphetamine saccharate) (APX) via Restricted Benefit

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective October 1, 2023:

- **AVONEX PS/PEN* (30 mcg/0.5 mL) 6 million IU/syringe/pen** (interferon beta-1A) (BIO)
- **BETASERON* (0.3 mg) 9.6 million IU/vial injection** (interferon beta-1B) (BAI)
- **DIMETHYL FUMARATE* 120 mg & 240 mg delayed-release capsules** (brands: APX, JPC, PMS, SDZ)
- **DIMETHYL FUMARATE* 120 mg delayed-release capsule** (brands: AHI, BIO, GLM, MAR)
- **FINGOLIMOD HYDROCHLORIDE* 0.5 mg capsule** (brands: APX, JPC, MAR, MYP, NOV, PMS, SDZ, TAR, TEV)
- **GLATECT* 20 mg/mL injection syringe** (glatiramer acetate) (PMS)
- **KESIMPTA* 20 mg/0.4 mL pen injection syringe** (ofatumumab) (NOV)
- **MAYZENT* 0.25 mg & 2 mg tablets** (siponimod) (NOV)
- **OCREVUS* 30 mg/mL (10 mL vial) injection** (ocrelizumab) (HLR)
- **PLEGRIDY* 63 mcg/94 mcg PS/pen injection starter pack & 125 mcg/0.5 mL PS/pen injection** (peginterferon beta-1A) (BIO)
- **REBIF* 22 mcg/0.5 mL (6 million IU) & 44 mcg/0.5 mL (12 million IU) injection syringes and 66 mcg/1.5 mL & 132 mcg/1.5 mL cartridge injections** (interferon beta-1A) (SRO)
- **STELARA* 45 mg/0.5 mL injection vial or syringe & 90 mg/1 mL injection syringe** (ustekinumab) (JAI)
- **TERIFLUNOMIDE* 14 mg tablet** (brands: AHI, APX, GZM, JPC, MAR, MTR, NTP, PMS, SDZ, TEV)
- **TYSABRI* 20 mg/mL (15 mL vial) injection** (natalizumab) (BIO)

The Special Authorization criteria for coverage for the following Drug Products have been revised effective November 1, 2023:

- **DUPIXENT* 200 mg & 300 mg injection pens and syringes** (dupilumab) (SAV)

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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the ADBL report

Issue #134, September 2023

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)
Tony Nickonchuk, BScPharm

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Amina Babar, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 20, 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 ninety-six (96) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, ten (10) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective August 1, 2023, and ten (10) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective September 1, 2023.

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 August 1, 2023:

- **ALBRIOZA* 3 g/1 g oral powder packet** (sodium phenylbutyrate/ ursodoxicoltaurine) (AYX) via Special Authorization (SA)
- **RADICAVA* 105 mg/5 mL oral suspension** (edaravone) (MIT) via SA
- **VYEPTI* 100 mg/1 mL vial injection** (eptinezumab) (LBC) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
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 CADTH and the Expert Committee and added to the *ADBL* effective September 1, 2023:

- **CIBINQO* 50 mg, 100 mg & 200 mg tablets** (abrocitinib) (PFI) via SA
- **TREMFYA* 100 mg/mL injection syringe & TREMFYA ONE-PRESS* 100 mg/mL auto-injector syringe** (guselkumab) (JAI) via SA

Highlights of Drug Products Added

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

- **ACUVAIL 0.45% ophthalmic solution** (ketorolac tromethamine) (ABV)
- **M-HC 1% urea 10% topical cream** (hydrocortisone acetate/ urea) (MTR)

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 September 1, 2023:

- **DAPAGLIFLOZIN 5 mg & 10 mg tablets** (various brands: APX, AUR, GLM, JPC, MTR, PMS & SDZ)
- **AURO-DAPAGLIFLOZIN/ METFORMIN 5 mg/850 mg & 5 mg/1000 mg tablets** (dapagliflozin/ metformin hydrochloride) (AUR)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Product was added to the *ADBL* effective September 1, 2023:

- **LAPELGA* 6 mg/0.6 mL pre-filled autoinjector** (pegfilgrastim) (APX) via SA

Highlights of Changes to Currently Listed Products

The coverage status of the following Drug Products have been revised from Step Therapy/Special Authorization to a Regular Benefit effective September 1, 2023:

- **FORXIGA 5 mg & 10 mg tablets** (dapagliflozin) (AZC)
- **XIGDUO 5 mg/850 mg & 5 mg/1000 mg tablets** (dapagliflozin/ metformin hydrochloride) (AZC)

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective September 1, 2023:

- **RADICAVA* 105 mg/5 mL oral suspension & 0.3 mg/mL injection** (edaravone) (MIT)

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 (09/2023)

the ADBL report

Issue #133, July 2023

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)
Tony Nickonchuk, BScPharm

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 18, 2023. The Committee reviewed Manufacturer submissions for twenty-one (21) 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 two (2) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirteen (13) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective June 1, 2023, and eleven (11) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective July 1, 2023.

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 June 1, 2023:

- **BEOVU* 6 mg/0.05 mL injection syringe** (brolucizumab) (NOV) via Restricted Benefit for the indication of Diabetic Macular Edema (DME)
- **DUPIXENT* 200 mg & 300 mg injection syringes** dupilumab) (SAV) via SA for the indication of Asthma ages 6-11

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

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- **DUPIXENT* 200 mg & 300 mg injection pens and injection syringes** (dupilumab) (SAV) via SA for the indication of Asthma ages 12+
- **GIVLAARI* 189 mg/mL injection** (givosiran sodium) (ANT) via Special Authorization (SA)

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

- **FIRDAPSE* 10 mg tablet** (amifampridine phosphate) (KYE) via SA

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 July 1, 2023:

- **SANDOZ ALFACALCIDOL 0.25 mcg & 1 mcg capsules** (alfacalcidol) (SDZ)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Product was added to the *ADBL* effective June 1, 2023:

- **ABRILADA 20 mg/0.4 mL injection syringe** (adalimumab) (PFI) via SA for the indication of Polyarticular Juvenile Idiopathic Arthritis (pJIA)

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective June 1, 2023:

- **DUPIXENT* 200 mg & 300 mg injection pens and injection syringes** (dupilumab) (SAV) for the indication of Atopic Dermatitis (AD)

The Special Authorization criteria for coverage for the following Drug Product has been revised effective July 1, 2023:

- **RUZURGI* 10 mg tablet** (amifampridine) (MDK)

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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the DBL report

Issue #132, May 2023

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)
Tony Nickonchuk, BScPharm

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 23, 2023. The Committee reviewed Manufacturer submissions for twenty-four (24) 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 seventeen (17) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, forty-seven (47) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective May 1, 2023.

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 May 1, 2023:

- **DOJOLVI* oral liquid** (triheptanoin) (UGX) via Special Authorization (SA)
- **INCRELEX* 40 mg/4 mL vial injection** (mecasermin) (ISP) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (05/2023)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective May 1, 2023:

- **ELONOX 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL & 100 mg/mL injection syringes and ELONOX HP 120 mg/0.8 mL & 150 mg/mL injection syringes** (enoxaparin sodium) (FKC)

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective May 1, 2023:

- **FEBUXOSTAT* 80 mg tablets** (various brands: JPC, MAR & TEV)

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 (05/2023)

the DBL report

Issue #131, March 2023

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Nicholas Myers, BSc, MB, BS, MRCGP (UK)

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 19, 2023. The Committee reviewed Manufacturer submissions for thirty-one (31) 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 seventeen (17) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty (20) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective March 1, 2023.

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 Product was reviewed by CADTH and the Expert Committee and added to the *ADBL* effective March 1, 2023:

- **RUZURGI* 10 mg tablet** (amifampridine) (MDK) via Special Authorization (SA)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (03/2023)

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 March 1, 2023:

- **SANDOZ SITAGLIPTIN* 25 mg, 50 mg & 100 mg tablets** (sitagliptin) (SDZ) via Step Therapy/SA
- **APO-SITAGLIPTIN MALATE* 25 mg, 50 mg & 100 mg tablets** (sitagliptin) (APX) via Step Therapy/SA
- **AURO-HYDROCORTISONE 10 mg & 20 mg tablets** (hydrocortisone) (AUR)

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective March 1, 2023:

- **TEVA-PREDNISONE 50 mg tablet** (prednisone) (TEV)

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 (03/2023)

the DBLreport

Issue #130, February 2023

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Daniel Altman, BSc, MD, FRCPC
Caitlin A. Clarke, BScPhm, PharmD
Michael Kolber, BSc, MD, CCFP, MSc
Nicholas Myers, BSc, MB, BS, MRCGP (UK)

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 17, 2022. The Committee reviewed Manufacturer submissions for ten (10) 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 fifty-seven (57) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, sixteen (16) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective December 1, 2022, and thirty-eight (38) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2023.

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 February 1, 2023:

- **BIMZELX* 160 mg/mL autoinjector & injection syringe** (bimekizumab) (UCB) via Special Authorization (SA)
- **EMGALITY* 120 mg/mL injection syringe & pen injection** (galcanezumab) (LIL) via SA
- **REBLOZYL* 25 mg/vial & 75 mg/vial injections** (luspatercept) (CLG) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (02/2023)

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, 2023:

- **APO-BRIMONIDINE TIMOP 0.2%/0.5% ophthalmic solution** (brimonidine tartrate/ timolol maleate) (APX)
- **TEVA-DILTIAZEM XC 180 mg, 240 mg, 300 mg & 360 mg extended-release tablets** (diltiazem hydrochloride) (TEV)
- **TOFACITINIB CITRATE* 5 mg tablets** (various brands: AUR, PMS & TAR) via SA for the indications of Rheumatoid Arthritis & Ulcerative Colitis

Highlights of Drug Products Added

The following Natural Health Product was reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2023:

- **PMS-POTASSIUM CHLORIDE 1.33 mEq/mL oral solution** (potassium chloride (K+)(CL-)) (PMS)

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

- **DUPIXENT* 200 mg injection pen** (dupilumab) (SAV) via SA for the indication of Atopic Dermatitis
- **PDP-AMLODIPINE 1 mg/mL oral solution** (amlodipine besylate) (PPH)
- **PROPYLTHIOURACIL 50 mg tablet** (propylthiouracil) (PHE)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Product was added to the *ADBL* effective December 1, 2022:

- **SEMGLEE 100 unit/mL pen injection** (insulin glargine) (BGP)

The following Biosimilar Drug Product was added to the *ADBL* effective February 1, 2023:

- **KIRSTY 100 unit/mL pen injection** (insulin aspart) (BGP)

Highlights of Changes to Currently Listed Products

The benefit listing status of the following Drug Products (currently or recently listed) have been revised from Step Therapy/Special Authorization to a Regular Benefit effective February 1, 2023:

- **APIXABAN 2.5 mg & 5 mg tablets** (various brands: AHI, APX, AUR, BMS, JPC, MAR, MTR, NTP, SDZ, SIV & TAR)
- **APIXABAN 5 mg tablet** (MPI)

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Product have been revised effective February 1, 2023:

- **STELARA* 45 mg/0.5 mL vial or syringe injection & 90 mg/1 mL injection syringe** (ustekinumab) (JAI)

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 (02/2023)

the ADBL report

Issue #129, November 2022

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Daniel Altman, BSc, MD, FRCPC
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Nicholas Myers, BSc, MB, BS, MRCGP (UK)

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 23, 2022. The Committee reviewed Manufacturer submissions for twenty-four (24) 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 thirty-one (31) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, ten (10) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective October 1, 2022, and forty-six (46) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 1, 2022.

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 October 1, 2022:

- **KYNMOBI* 10 mg, 15 mg, 20 mg, 25 mg & 30 mg sublingual films** (apomorphine hydrochloride) (SUN) via Special Authorization (SA)
- **PDP-LEVETIRACETAM 100 mg/mL oral solution** (levetiracetam) (PPH)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

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- **RINVOQ* 15 mg extended-release tablet** (upadacitinib) (ABV) via SA for the indications of Rheumatoid Arthritis (RA) & Psoriatic Arthritis (PsA)
- **WAYMADE-TRIENTINE* 250 mg capsule** (trientine hydrochloride) (WYM) via SA

The following Drug Product was reviewed by CADTH and the Expert Committee and added to the *ADBL* effective November 1, 2022:

- **BREZTRI AEROSPHERE* 182/8.2/5.8 mcg inhalation suspension** (budesonide/ glycopyrronium/ formoterol fumarate dihydrate) (AZC) via Step Therapy/SA

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 November 1, 2022:

- **APIXABAN* 2.5 mg tablets** (various brands: APX, JPC, MAR, MTR, NTP, SDZ & TAR) via Step Therapy/SA for the indication of At Risk Patients with Non-valvular Atrial Fibrillation and via SA for the indications of Prophylaxis of Venous Thromboembolism and Venous Thromboembolic Events
- **APIXABAN* 5 mg tablets** (various brands: APX, JPC, MAR, MTR, NTP, SDZ & TAR) via Step/SA for the indication of At Risk Patients with Non-valvular Atrial Fibrillation and via SA for the indication of Venous Thromboembolic Events
- **GLN-ATOVAQUONE 150 mg/mL oral suspension** (atovaquone) (GLM)

Methadone Products

The temporary suspension of the designation of interchangeability for methadone 10 mg/mL oral solutions for the treatment of opioid dependence on the *ADBL* has been lifted, and all applicable methadone 10 mg/mL oral concentrate Drug Products currently listed on the *ADBL* will be deemed interchangeable with their respective Innovator Drug Products.

Highlights of Drug Products Added

The following Natural Health Product was reviewed by the Expert Committee and added to the *ADBL* effective October 1, 2022:

- **POTASSIUM CHLORIDE 1.33 mEq oral liquid** (potassium chloride (K+)(CL-)) (ODN)

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL,* resulting in the creation of a New IC Grouping, effective November 1, 2022:

- **APO-DIMETHYL FUMARATE* 240 mg delayed-release capsule** (dimethyl fumarate) (APX) via SA

The following Drug Products were also reviewed by the Expert Committee and added to the *ADBL* effective November 1, 2022:

- **ARAZLO 0.045% topical lotion** (tazarotene) (VCL)
- **BRYHALI 0.01% topical solution** (halobetasol propionate) (VCL)

Highlights of Changes to Currently Listed Products

The benefit listing status of the following Drug Product has been changed from Restricted Benefit/Special Authorization to Restricted Benefit effective October 1, 2022:

- **PEGASYS* 180 mcg/0.5 mL injection syringe** (peginterferon alfa-2a) (HLR)

The interchangeable status for the following Drug Product on the *Palliative Coverage Drug Benefit Supplement* (*PCDBS*) has been changed effective November 1, 2022:

- **BISACODYL 10 mg rectal suppository** (bisacodyl) (JPC)

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 (11/2022)

the ADBL report

Issue #128, September 2022

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Chair)
Micheal Guirguis, BScPharm, PhD (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Daniel Altman, BSc, MD, FRCPC
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Nicholas Myers, BSc, MB, BS, MRCGP (UK)
Tony Nickonchuk, BScPharm

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 19, 2022. The Committee reviewed Manufacturer submissions for twenty-five (25) 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 three (3) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, fifteen (15) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective August 1, 2022, and ten (10) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 1, 2022.

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 Product was reviewed by CADTH and added to the *ADBL* effective July 11, 2022:

- **TRIKAFTA* 50 mg/25 mg/37.5 mg & 75 mg tablets** (elexacaftor / tezacaftor / ivacaftor) (ivacaftor) (VER) via Special Authorization (SA)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (09/2022)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Product to the *ADBL* has resulted in the creation of New IC Groupings, effective September 1, 2022:

- **BUDESONIDE* 3 mg controlled-release capsule** (budesonide) (TPG) via SA
- **FENTANYL* 50 mcg/mL (100 mcg/2 mL), 50 mcg/mL (250 mcg/5 mL), 50 mcg/mL (1000 mcg/20 mL) & 50 mcg/mL (2500 mcg/50 mL) Injection BP** (fentanyl) (STM) via SA
- **JAMP CALCIUM POLYSTYRENE SULFONATE 999 mg/g oral/rectal powder** (calcium polystyrene sulfonate) (JPC)
- **SANDOZ FESOTERODINE FUMARATE* 4 mg & 8 mg extended-release tablets** (fesoterodine fumarate) (SDZ) via Step Therapy/SA
- **TARO-CALCIPOTRIOL/BETAMETHASONE 50 mcg/0.5 mg/g gel** (calcipotriol monohydrate/betamethasone dipropionate) (TAR)

Highlights of Diabetes Supplies Added

The following device was added to the *ADBL* via Restricted Benefit effective August 1, 2022:

- **MEDISURE EMPOWER BLOOD GLUCOSE TEST STRIPS*** (diabetes supplies) (MDS)

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective August 1, 2022:

- **HALYCIL 50 mg tablet** (propylthiouracil) (ACI)

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective September 1, 2022:

- **DEPO-PROVERA 150 mg/mL prefilled syringe** (medroxyprogesterone acetate) (PFI)
- **DUPIXENT* 300 mg injection pen** (dupilumab) (SAV) via SA
- **SKYRIZI* 150 mg/mL injection pen & injection syringe** (risankizumab) (ABV) via SA

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Product have been revised effective July 11, 2022:

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

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 (09/2022)

the DBL report

Issue #127, July 2022

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Acting Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 16 & 17, 2022. The Committee reviewed Manufacturer submissions for twenty-four (24) 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 fourteen (14) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-seven (27) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective June 1, 2022, and fifty (50) Drug Products and Devices underwent Expedited Review for listing on the *ADBL* effective July 1, 2022.

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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective July 1, 2022:

- **DUPIXENT* 200 mg & 300 mg injection syringes** (dupilumab) (SAV) via Special Authorization (SA) for the indication of Atopic Dermatitis

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (07/2022)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Product to the *ADBL* has resulted in the creation of New IC Groupings, effective June 1, 2022:

- **PMS-FLUTICASONE HFA 125 mcg/dose metered dose aerosol** (fluticasone propionate) (PMS)

Addition of the following Entry IC Drug Products to the *ADBL* have resulted in the creation of New IC Groupings, effective July 1, 2022:

- **APO-SAXAGLIPTIN* 2.5 mg & 5 mg tablets** (saxagliptin hydrochloride) (APX) via Step Therapy/SA
- **CLONIDINE HYDROCHLORIDE 0.025 mg tablets** (various brands: SDZ & MAR)
- **JAMP CLOXACILLIN 250 mg & 500 mg capsules** (cloxacillin sodium) (JPC)
- **LURASIDONE HYDROCHLORIDE 20 mg, 40 mg, 60 mg & 80 mg tablets** (various brands: JPC, PMS, SDZ & TAR)
- **LURASIDONE HYDROCHLORIDE 120 mg tablets** (various brands: PMS & TAR)
- **METHOTREXATE SUBCUTANEOUS 15 mg/0.3 mL, 17.5 mg/0.35 mL, 20 mg/0.4 mL, 22.5 mg/0.45 mL & 25 mg/0.5 mL injection syringes** (methotrexate sodium) (AHI)
- **TARO-TICAGRELOR* 90 mg tablet** (ticagrelor) (TAR) via Restricted Benefit/SA
- **TERIFLUNOMIDE* 14 mg tablets** (various brands: AHI, APX, JPC, MTR, MAR, NTP, PMS, SDZ & TEV) via SA

Highlights of Drug Products Added

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective July 1, 2022:

- **ODAN-SODIUM POLYSTYRENE SULFONATE 250 mg/mL suspension** (sodium polystyrene sulfonate) (ODN)
- **ZENHALE* 100 mcg/5 mcg/dose & 200 mcg/5 mcg/dose metered dose aerosols** (mometasone furoate/ formoterol fumarate dihydrate) (ORC) via Step Therapy/SA

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective June 1, 2022:

- **SIMLANDI* 40 mg/0.4 mL auto-injector pen** (adalimumab) (JPC) via SA for the indications of Rheumatoid Arthritis (RA), Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Hidradenitis Suppurativa (HS), Crohn's Disease (CD), Ulcerative Colitis (UC) and Polyarticular Juvenile Idiopathic Arthritis (pJIA)
- **YUFLYMA* 40 mg/0.4 mL injection pen** (adalimumab) (CHC) via SA for the indications of RA, PsO, PsA, AS, HS, CD, UC and pJIA

The following Biosimilar Drug Products were added to the *ADBL* effective July 1, 2022:

- **HULIO* 20 mg/0.4 mL injection syringe** (adalimumab) (BGP) via SA for the indication of pJIA
- **SIMLANDI* 40 mg/0.4 mL prefilled syringe** (adalimumab) (JPC) via SA for the indications of RA, PsA, AS, HS, CD, PsO, pJIA & UC
- **SIMLANDI* 80 mg/0.8 mL prefilled syringe** (adalimumab) (JPC) via SA for the indications of HS, CD, PsO & UC

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective June 1, 2022:

- **FINGOLIMOD HYDROCHLORIDE* 0.5 mg capsules** (various brands: APX, JPC, MAR, MYP, NOV, PMS, SDZ, TAR & TEV)
- **LEMTRADA* 12 mg/1.2 mL injection** (alemtuzumab) (GZM)
- **MAVENCLAD* 10 mg tablet** (cladribine) (SRO)
- **TYSABRI* 20 mg/mL (15 mL vial) injection** (natalizumab) (BIO)

The Special Authorization criteria for coverage for the following Drug Products have been revised effective July 1, 2022:

- **AJOVY* 225 mg/1.5 mL auto-injector & injection syringes** (fremanezumab) (TMP)

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 (07/2022)

the DBL report

Issue #126, May 2022

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Acting Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 15, 2022. The Committee reviewed Manufacturer submissions for fifteen (15) 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 two (2) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-five (25) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 1, 2022.

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 April 1, 2022:

- **ENTUZITY* 500 unit/mL injection kwikpen** (insulin human biosynthetic (regular)) (LIL) via Special Authorization (SA)
- **OFEV* 100 mg & 150 mg capsules** (nintedanib esilate) (BOE) via SA for the indication of Chronic Fibrosing Interstitial Lung Disease with a Progressive Phenotype

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective May 1, 2022:

- **KESIMPTA* 20 mg/0.4 mL prefilled pen** (ofatumumab) (NOV) via SA
- **MAR-TRIENTINE* 250 mg capsule** (trientine hydrochloride) (MAR) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (05/2022)

Classification: Protected A

Highlights of Diabetes Supplies Added

The following brand of blood glucose test strips was added to the *ADBL* via Restricted Benefit effective May 1, 2022:

- **TYKESS* blood glucose test strips** (TTC)

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective May 1, 2022:

- **SANDOZ DIMETHYL FUMARATE* 240 mg delayed-release capsule** (dimethyl fumarate) (SDZ) via SA

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective May 1, 2022:

- **ABRILADA* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (PFI) via SA for the indications of Ankylosing Spondylitis (AS), Hidradenitis Suppurativa (HS), Crohn's Disease (CD), Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Polyarticular Juvenile Idiopathic Arthritis (pJIA), Rheumatoid Arthritis (RA) and Ulcerative Colitis (UC)

Highlights of Changes to Currently Listed Products

The Restricted Benefit criteria for coverage for the following Devices have been revised effective April 1, 2022:

- **DEXCOM G6* SENSOR & DEXCOM G6* TRANSMITTER** for continuous glucose monitoring (COM)
- **GUARDIAN LINK* TRANSMITTER (670G & 770G PUMPS), GUARDIAN* SENSOR & GUARDIAN CONNECT* TRANSMITTER** for continuous glucose monitoring (MET)

The Special Authorization administrative preamble has been removed for the following Drug Products, effective May 1, 2022:

- **AMGEVITA* 40 mg/0.8 mL injection syringe & autoinjector pen** (adalimumab) (AMG) via SA for the indications of AS, HS, CD, PsO, PsA, pJIA, RA & UC
- **AMGEVITA* 20 mg/0.4 mL prefilled syringe** (adalimumab) (AMG) via SA for the indication of pJIA
- **HADLIMA* 40 mg/0.8 mL autoinjector & injection syringe** (adalimumab) (SSB) via SA for the indications of AS, HS, CD, PsO, PsA, pJIA, RA & UC
- **HULIO* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (BGP) via SA for the indications of AS, HS, CD, PsO, PsA, pJIA, RA & UC
- **HYRIMOZ* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (SDZ) via SA for the indications of AS, HS, CD, PsO, PsA, pJIA, RA & UC
- **HYRIMOZ* 20 mg/0.4 mL injection syringe** (adalimumab) (SDZ) via SA for the indication of pJIA
- **IDACIO* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (FKC) via SA for the indications of AS, HS, CD, PsO, PsA, pJIA, RA & UC

Delisted Products

The following Drug Products were delisted from the *ADBL* effective April 1, 2022 due to the Alberta Biosimilar Initiative:

- **NOVORAPID 100 unit/mL injection vial and cartridge & NOVORAPID FLEXTOUCH 100 unit/mL injection pen** (insulin aspart) (NNA)

The following Drug Products were delisted from the *ADBL* effective May 1, 2022 due to the Alberta Biosimilar Initiative:

- **HUMIRA 20 mg/0.2 mL & 40 mg/0.8 mL injection syringes** (adalimumab) (ABV)

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 (05/2022)

Classification: Protected A

the DBL report

Issue #125, March 2022

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Acting Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 18, 2022. The Committee reviewed Manufacturer submissions for fifteen (15) 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 forty-eight (48) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, fifty-five (55) Drug Products underwent Expedited Review for listing on the *ADBL* effective March 1, 2022.

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 March 1, 2022:

- **ENTYVIO* 108 mg/0.68 mL injection pen & syringe** (vedolizumab) (TAK) via Special Authorization (SA) for the indications of Crohn's Disease and Ulcerative Colitis
- **EVRYSDI* 0.75 mg/mL oral solution** (risdiplam) (HLR) via SA
- **FORXIGA* 5 mg & 10 mg tablets** (dapagliflozin propanediol monohydrate) (AZC) via Step Therapy/SA for the indication of Heart Failure

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (03/2022)

Classification: Protected A

Highlights of Drug Products Added

The following Natural Health Product was reviewed by the Expert Committee and added to the *ADBL* effective March 1, 2022:

- **MK 8 8 MEQ tablet** (potassium chloride (K+)) (MTR)

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective March 1, 2022:

- **PANCREASE MT 2 capsule (enteric-coated pellet)** (lipase/ amylase/ protease) (VPL)
- **VYNDAMAX* 61 mg capsule** (tafamidis) (PFI) via SA

Highlights of Changes to Currently Listed Products

The interchangeable status for the following Drug Product on the *Palliative Coverage Drug Benefit Supplement (PCDBS)* has been changed effective March 1, 2022:

- **JAMP-SENNA 8.6 mg tablet** (sennosides) (JPC)

The Special Authorization criteria for coverage for the following Drug Products have been revised effective March 1, 2022:

- **SPINRAZA* 2.4 mg/mL injection** (nusinersen sodium) (BIO)
- **VYNDAQEL* 20 mg capsule** (tafamidis meglumine) (PFI)

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 (03/2022)

the ADBL report

Issue #124, February 2022

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Acting Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 18 & 19, 2021. The Committee reviewed Manufacturer submissions for twenty-five (25) 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, nineteen (19) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2021, and twenty-two (22) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2022.

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 December 1, 2021:

- **MAYZENT* 0.25 mg & 2 mg tablets** (siponimod) (NOV) via Special Authorization (SA)

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective February 1, 2022:

- **AJOVY* 225 mg/1.5 ml auto-injector & injection syringes** (fremanezumab) (TEV) via SA
- **BAQSIMI 3 mg/dose (single-use) nasal powder** (glucagon) (LIL) via Restricted Benefit
- **BEOVU 6 mg/0.05 mL injection syringe** (brolucizumab) (NOV) via Restricted Benefit
- **CRYSVITA* 10 mg/mL, 20 mg/mL & 30 mg/mL injections** (burosumab) (KKL) via SA
- **DUOBRII* 0.01%/0.045% topical lotion** (halobetasol propionate/ tazarotene) (VCL) via SA
- **ILUMYA* 100 mg/mL injection syringe** (tildrakizumab) (SPF) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (02/2022)

Classification: Protected A

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 December 1, 2021:

- **OCTREOTIDE* 10 mg/vial, 20 mg/vial & 30 mg/vial injections** (octreotide acetate) (TEV) via SA

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective February 1, 2022:

- **BIPAZEN 4 mcg/mL injection** (desmopressin acetate) (KVR)
- **DIMETHYL FUMARATE* (various brands: AHI, APX, JPC, MAR, PMS & SDZ) 120 mg delayed-release capsules** (dimethyl fumarate) via SA

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective December 1, 2021:

- **IDACIO* 40 mg/0.8 mL injection syringe** (adalimumab) (FKC) via SA for the indications of Ankylosing Spondylitis, Hidradenitis Suppurativa, Crohn's Disease, Plaque Psoriasis (PsO), polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Rheumatoid Arthritis (RA), and Ulcerative Colitis
- **RIABNI* 10 mg/mL injection** (rituximab) (AMG) via SA for the indications of Granulomatosis with Polyangiitis or Microscopic Polyangiitis and RA

Highlights of Diabetes Supplies Added

The following devices were added to the *ADBL* via Restricted Benefit effective February 1, 2022:

- **DEXCOM G6 SENSOR & DEXCOM G6 TRANSMITTER** for continuous glucose monitoring (COM)
- **GUARDIAN LINK TRANSMITTER (670G & 770G PUMPS), GUARDIAN SENSOR & GUARDIAN CONNECT TRANSMITTER** for continuous glucose monitoring (MET)

Highlights of Drug Products Added

The following Natural Health Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2022:

- **JAMP-HYDROCORTISONE ACETATE 1% topical cream** (hydrocortisone) (JPC)
- **JAMPOCAINE 5% topical ointment** (lidocaine) (JPC)

Highlights of Changes to Currently Listed Products

The benefit listing status of the following Drug Products have been changed from Special Authorization to Regular Benefit effective December 1, 2021:

- **SUBLOCADE 100 mg/0.5 mL & 300 mg/1.5 mL extended-release injection syringes** (buprenorphine) (IUK)

The Special Authorization criteria for coverage for the following Drug Products have been revised effective February 1, 2022:

- **STELARA* 45 mg/0.5 mL vial or syringe injection & 90 mg/1 mL injection syringe** (ustekinumab) (JAI) for the indication of PsO

Delisted Products

The following Drug Products were delisted from the *ADBL* effective January 10, 2022 due to the Alberta Biosimilar Initiative:

- **LOVENOX 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL, 100 mg/mL & 120 mg/0.8 mL injection syringes & 100 mg/mL vial & LOVENOX HP 150 mg/mL injection syringe** (enoxaparin sodium) (SAV)

The following Drug Products were delisted from the *ADBL* effective February 1, 2022 due to the Alberta Biosimilar Initiative:

- **HUMALOG 100 units/mL vial, cartridge & KwikPen injections** (insulin lispro) (LIL)

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 (02/2022)

Classification: Protected A

the DBLreport

Issue #123, November 2021

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Acting Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Andrea Nagle, BScPharm, LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 21, 2021. The Committee reviewed Manufacturer submissions for twenty-eight (28) 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 eight (8) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-eight (38) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2021, and twenty-six (26) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 1, 2021.

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 added to the *ADBL* effective September 24, 2021:

- **TRIKAFTA* 100 mg/50 mg/75 mg & 150 mg oral tablets** (elexacaftor/tezacaftor/ivacaftor) (ivacaftor) (VER) via Special Authorization (SA)

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective November 1, 2021:

- **ATECTURA BREEZHALER* 150 mcg/80 mcg, 150 mcg/160 mcg & 150 mcg/320 mcg inhalation capsules** (indacaterol acetate/mometasone furoate) (VLP) via Step Therapy/SA
- **ENERZAIR BREEZHALER* 150 mcg/50 mcg/160 mcg inhalation capsule** (indacaterol acetate/glycopyrronium bromide/mometasone furoate) (VLP) via SA
- **NEXPLANON 68 mg subdermal implant** (etonogestrel) (ORC)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (11/2021)

Classification: Protected A

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 November 1, 2021:

- **ACCEL-HYOSCINE 10 mg tablet** (hyoscine butylbromide) (ACP)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective October 1, 2021:

- **TRURAPI 100 unit/mL injection cartridge & TRURAPI SOLOSTAR 100 unit/mL pen injection** (insulin aspart) (SAV)

Highlights of Drug Products Added

The following Drug Product was added to the *ADBL* effective October 1, 2021:

- **ODAN-METHADONE (CHERRY FLAVOUR) 10 mg/mL oral solution** (methadone hydrochloride) (ODN)

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective November 1, 2021:

- **LOSEC MUPS 20 mg delayed-release tablet** (omeprazole) (CAG)
- **SOMATULINE AUTOGEL* 60 mg/0.5 mL, 90 mg/0.5 mL & 120 mg/0.5 mL injection syringes** (lanreotide acetate) (ISP) via SA for control of symptoms in patients with metastatic carcinoid tumors

Highlights of Changes to Currently Listed Products

The benefit listing status of the following Drug Products have been changed from Regular Benefits to Restricted Benefits effective October 1, 2021:

- **NOVORAPID 100 unit/mL injection vial and cartridge & NOVORAPID FLEXTOUCH 100 unit/mL pen injection** (insulin aspart) (NNA)

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 (11/2021)

Classification: Protected A

the ADBL report

Issue #122, September 2021

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Acting Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Stephanie Minnema, PhD, MBA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 20, 2021. The Committee reviewed Manufacturer submissions for twenty (20) 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 seventy-three (73) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, forty-four (44) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2021, and fourteen (14) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 1, 2021.

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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective August 1, 2021:

- **KANUMA* 20 mg/vial injection** (sebelipase alfa) (APG) via Special Authorization (SA)

The following Drug Products were reviewed by CDR and added to the *ADBL* effective August 1, 2021:

- **ORKAMBI* 100 mg/125 mg & 150 mg/188 mg granules and 100 mg/125 mg & 200 mg/125 mg tablets** (lumacaftor/ivacaftor) (VER) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (09/2021)

Classification: Protected A

Highlights of Drug Products Added

The following Natural Health Product was reviewed by the Expert Committee and added to the *ADBL* effective September 1, 2021:

- **JAMP-HYDROCORTISONE ACETATE 1% UREA 10% topical cream** (hydrocortisone acetate/urea) (JPC)

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 August 1, 2021:

- **AA-TELMISARTAN-AMLODIPINE 80 mg/5 mg & 80 mg/10 mg tablets** (telmisartan/amlodipine besylate) (AAP)
- **JAMP PIRFENIDONE* 267 mg capsule** (pirfenidone) (JPC) via SA
- **SANDOZ PIRFENIDONE* 267 mg & 801 mg tablets** (pirfenidone) (SDZ) via SA

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective September 1, 2021:

- **APO-DARIFENACIN* 7.5 mg & 15 mg extended-release tablets** (darifenacin hydrobromide) (APX) via Step Therapy/SA
- **TARO-BUDESONIDE 0.25 mg/mL inhalation suspension** (budesonide) (TAR)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective August 1, 2021:

- **ADMELOG 100 unit/mL injection & injection cartridge and ADMELOG PEN 100 unit/mL injection** (insulin lispro) (SAV)
- **INCLUNOX 30 mg/0.3 mL syringe** (enoxaparin sodium) (SDZ)
- **NOROMBY 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL & 100 mg/mL injection syringes and NOROMBY HP 120 mg/0.8 mL & 150 mg/mL injection syringes** (enoxaparin sodium) (JUN)

The following Biosimilar Drug Product was added to the *ADBL* effective September 1, 2021:

- **RIXIMYO* 10 mg/mL injection** (rituximab) (SDZ) via SA for the indications of Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

Highlights of Changes to Currently Listed Products

The benefit listing status of the following Drug Products have been changed from Regular Benefits to Restricted Benefits effective August 1, 2021:

- **HUMALOG* 100 units/mL vial, cartridge & Kwikpen injections** (insulin lispro) (LIL)

The interchangeable status for the following Drug Product on the ADBL has been changed effective September 1, 2021:

- **JAMP-NYSTATIN 100,000 unit/mL oral suspension** (nystatin) (JPC) is now in an IC grouping with other nystatin 100,000 unit/mL Drug Products.

Highlights of Diabetes Supplies Added

The following brands of blood glucose test strips were added to the *ADBL* via Restricted Benefit effective August 1, 2021:

- **ACCU-CHEK AVIVA, ACCU-CHEK COMPACT, ACCU-CHEK GUIDE and ACCU-CHEK MOBILE blood glucose test strips** (RDC)
- **CARESENS N MULTI blood glucose test strips** (SEN)
- **CONTOUR and CONTOUR NEXT blood glucose test strips** (ADC)
- **FIRST CANADIAN HEALTH SPIRIT blood glucose test strips** (ARP)
- **FREESTYLE LITE and FREESTYLE PRECISION blood glucose test strips** (ABD)
- **GE200 blood glucose test strips** (BNE)
- **MEDISURE blood glucose test strips** (MDS)
- **ONE TOUCH ULTRA and ONE TOUCH VERIO blood glucose test strips** (LIF)
- **RAPID RESPONSE GLUCO-MD blood glucose test strips** (BTN)

Note: With the listing of the above blood glucose test strips, the generic pseudo identification number currently

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 (09/2021)

Classification: Protected A

used by pharmacies to submit claims for blood glucose test strips for members of a government-sponsored drug plan will be removed from the *ADBL*. As of September 1, 2021, claims will no longer be paid under that generic pseudo identification number.

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective August 1, 2021:

- **COSENTYX* 150 mg/mL injection** (secukinumab) (NOV) for the indication of Ankylosing Spondylitis
- **KALYDECO* 150 mg tablet** (ivacaftor) (VER)
- **XELJANZ* 5 mg tablet and XELJANZ XR* 11 mg extended-release tablet** (tofacitinib citrate) (PFI) for the indication of Rheumatoid Arthritis

The Special Authorization criteria for coverage for the following Drug Products have been revised effective September 1, 2021:

- Donepezil hydrochloride*** 5 mg & 10 mg tablets** (AHI, APX, AUR, BMD, JPC, MAR, MPI, NTP, PFI, PMS, RAN, SDZ, SNS, SEP, SIV & TEV)
- Galantamine*** 8 mg, 16 mg & 24 mg extended-release capsules** (AUR, MYP, PMS & SNS)
- Rivastigmine hydrogen tartrate*** 1.5 mg, 3 mg, 4.5 mg & 6 mg capsules** (APX, GMP, JPC, SDZ & NOV) **and 2 mg/mL oral solution** (NOV)

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 (09/2021)

Classification: Protected A

the ADBL report

Issue #121, July 2021

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Acting Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Stephanie Minnema, PhD, MBA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 17, 2021. The Committee reviewed Manufacturer submissions for twenty-five (25) Drug Products for potential listing, or change in listing, on the *ADBL*.

In addition to Drug Products reviewed by the Expert Committee, thirty-three (33) Drug Products underwent Expedited Review for listing on the *ADBL* effective June 1, 2021, and twenty-one (21) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 1, 2021.

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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective July 1, 2021:

- **OLUMIANT* 2 mg tablet** (baricitinib) (LIL) via Special Authorization (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 New IC Groupings, effective July 1, 2021:

- **METHOTREXATE (PRESERVED) 25 mg/mL injection BP** (methotrexate sodium) (AHI)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (07/2021)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective July 1, 2021:

- **INCLUNOX 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL & 100 mg/1 mL injection syringes, & INCLUNOX HP 120 mg/0.8 mL & 150 mg/mL injection syringes** (enoxaparin sodium) (SDZ)
- **REDESCA 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL & 100 mg/mL injection syringes, 300 mg/3 mL injection vial, & REDESCA HP 120 mg/0.8 mL & 150 mg/mL injection syringes** (enoxaparin sodium) (VLP)

Change of Listing Status

The benefit listing status of the following Drug Products have been changed from Regular Benefits to Restricted Benefits effective July 1, 2021:

- **LOVENOX* 30 mg/0.3 mL, 40 mg/0.4 mL, 60 mg/0.6 mL, 80 mg/0.8 mL, 100 mg/mL & 120 mg/0.8 mL injection syringes & 100 mg/mL vial & LOVENOX HP 150 mg/mL injection syringe** (enoxaparin sodium) (SAV) via Restricted Benefit

the DBLreport

Issue #120, May 2021

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Fiona Clement, PhD, (Acting Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 16, 2021. The Committee reviewed Manufacturer submissions for thirteen (13) Drug Products for potential listing, or change in listing, on the *ADBL*. The Committee also considered information for a supplementary assessment of the coverage status of one (1) Drug Product.

In addition to Drug Products reviewed by the Expert Committee, fifty-seven (57) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 1, 2021.

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 April 1, 2021:

- **AERMONY RESPICLICK 55 mcg/dose, 113 mcg/dose & 232 mcg/dose metered inhalation powders** (fluticasone propionate) (TEV)

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective May 1, 2021:

- **MONOFERRIC* 100 mg/mL injection** (iron isomaltoside 1000) (PFI) via Special Authorization (SA)
- **REVESTIVE* 5 mg/vial injection** (teduglutide) (TAK) via SA for the indication of Pediatric Short Bowel Syndrome
- **VYNDAQEL* 20 mg capsule** (tafamidis meglumine) (PFI) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (05/2021)

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 May 1, 2021:

- **TEVA-BETAMETHASONE/CALCIPOTRIOL 50 mcg/g / 0.5 mg/g topical ointment** (calcipotriol monohydrate/betamethasone dipropionate) (TEV)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were added to the *ADBL* effective May 1, 2021:

- **AMGEVITA* 40 mg/0.8 mL prefilled syringe & autoinjector** (adalimumab) (AMG) via SA for the indications of Rheumatoid Arthritis (RA), Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Hidradenitis Suppurativa (HS), Crohn's Disease (CD), Ulcerative Colitis (UC), and Polyarticular Juvenile Idiopathic Arthritis (pJIA)
- **AMGEVITA* 20 mg/0.4 mL prefilled syringe** (adalimumab) (AMG) via SA for the indication pJIA
- **HADLIMA* 40 mg/0.8 mL autoinjector & injection syringe** (adalimumab) (SSB) via SA for the indications of RA, PsO, PsA, AS, HS, CD, UC & pJIA
- **HULIO* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (BGP) via SA for the indications of RA, PsO, PsA, AS, HS, CD, UC & pJIA
- **HYRIMOZ* 40 mg/0.8 mL injection pen & syringe** (adalimumab) (SDZ) via SA for the indications of RA, PsO, PsA, AS, HS, CD, UC & pJIA
- **HYRIMOZ* 20 mg/0.4 mL injection syringe** (adalimumab) (SDZ) via SA for the indication of pJIA
- **IDACIO* 40 mg/0.8 mL injection pen** (adalimumab) (FKC) via SA for the indications of RA, PsO, PsA, AS, HS, CD, UC & pJIA
- **NYVEPRIA* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (PFI) via SA

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective April 1, 2021:

- **ACTEMRA* 162 mg/0.9 mL auto injector** (tocilizumab) (HLR) via SA for the indications of Giant Cell Arteritis (GCA), pJIA & Systemic Juvenile Idiopathic Arthritis (sJIA)

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective May 1, 2021:

- **CREON 35 MINIMICROSPHERES 35,000 unit/ 35,700 unit/ 2,240 unit capsule** (lipase/amylase/protease) (BGP)
- **FASENRA* 30 mg/mL injection pen** (benralizumab) (AZC) via SA
- **TAKHZYRO* 150 mg/mL injection syringe** (lanadelumab) (SHB) via SA

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective May 1, 2021:

- **BRENZYS* 50 mg/mL auto injector & injection syringe** (etanercept) (SSB) for the indications of PsO & pJIA
- **ERELZI* 25 mg/0.5 mL & 50 mg/mL injection syringes and 50 mg/mL sensoready auto injector syringe** (etanercept) (SDZ) for the indications of PsO & pJIA
- **ENBREL* 25 mg/vial injection** (etanercept) (AMG) for the indications of PsO & pJIA
- **HUMIRA* 20 mg/0.2 mL and 40 mg/0.8 mL injection syringes** (adalimumab) (ABV)
- **PROCYSBI* 25 mg & 75 mg delayed-release capsules** (cysteamine bitartrate) (RAP)

Delisted Products

The following Drug Product was delisted from the *ADBL* effective May 1, 2021 due to the Alberta Biosimilar Initiative:

- **ENBREL 50 mg/mL injection syringe** (etanercept) (AMG)

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 (05/2021)

the ADBL report

Issue #119, March 2021

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 19, 2021. The Committee reviewed Manufacturer submissions for twenty-seven (27) Drug Products for potential listing, or change in listing, on the *ADBL*. The Committee also considered information for a supplementary assessment of the coverage status of one (1) Drug Product.

In addition to Drug Products reviewed by the Expert Committee, twenty-seven (27) Drug Products underwent Expedited Review for listing on the *ADBL* effective March 1, 2021.

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 March 1, 2021:

- **ONPATTRO* 2 mg/mL vial injection** (patisiran sodium) (ANT) via Special Authorization (SA)
- **TRINTELLIX 5 mg, 10 mg, 15 mg & 20 mg tablets** (vortioxetine hydrobromide) (LBC)
- **TEGSEDI* 284 mg/1.5 mL injection syringe** (inotersen sodium) (AKC) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (03/2021)

Highlights of Biosimilar Drug Products Added

The following Biosimilar Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective March 1, 2021:

- **AVSOLA* 100 mg/vial injection** (infliximab) (AMG) via SA for the indications of Ankylosing Spondylitis, Moderately to Severely Active Crohn's Disease and Fistulizing Crohn's Disease, Plaque Psoriasis (PsO), Psoriatic Arthritis (PsA), Rheumatoid Arthritis (RA), and Ulcerative Colitis
- **BRENZYS* 50 mg/mL auto injector syringe & injection syringe** (etanercept) (SSB) via SA for the indications of PsO, Polyarticular Juvenile Idiopathic Arthritis (pJIA) and PsA
- **TRUXIMA* 10 mg/mL (10 mL & 50 mL) injections** (rituximab) (CTC) via SA for the indications of Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA)

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 March 1, 2021:

- **TARO-CIPROFLOXACIN/DEXAMETHASONE 0.3/0.1% otic suspension** (ciprofloxacin hydrochloride/ dexamethasone) (TAR)
- **TEVA-LIOTHYRONINE 5 mcg & 25 mcg tablets** (liothyronine sodium) (TEV)

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective March 1, 2021:

- **HUMIRA* 20 mg/0.2 mL injection syringe** (adalimumab) (ABV) via SA for the indication of pJIA

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective March 1, 2021:

- **ENBREL* 25 mg/vial injection & 50 mg/mL injection syringe** (etanercept) (AMG) for the indications of PsO and pJIA
- **ERELZI* 25 mg/0.5 mL injection syringe and 50 mg/mL injection syringe & sensoready auto injector** (etanercept) (SDZ) for the indications of PsO and pJIA
- **MAVIRET* 40 mg/100 mg tablet** (pibrentasvir/ glecaprevir) (ABV)
- **RUXIENCE* 10 mg/mL injection** (rituximab) (PFI) for the indication of GPA/MPA
- **SOVALDI* 400 mg tablet** (sofosbuvir) (GIL)

Due to the Biosimilar Initiative, the following Drug Product has been delisted effective March 1, 2021:

- **RITUXAN* 10 mg/mL injection** (rituximab) (HLR)

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 (03/2021)

the ADBL report

Issue #118, February 2021

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 19 & 20, 2020. The Committee reviewed Manufacturer submissions for eighteen (18) 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 thirty-five (35) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-two (22) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2020, and thirteen (13) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2021.

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 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 December 1, 2020:

- **RIVA LEUCOVORIN 5 mg tablet** (leucovorin calcium) (RIV)

Highlights of Biosimilar Drug Products Added

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

- **NIVESTYM* 0.3 mg/mL & 480 mcg/1.6 mL injections and 300 mcg/0.5 mL & 480 mcg/0.8 mL injection syringes** (filgrastim) (PFI) via Special Authorization (SA)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (02/2021)

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 December 1, 2020:

- **TAKHZYRO* 150 mg/mL injection** (lanadelumab) (SHB) via SA
- **XELJANZ* 5 mg & 10 mg tablets** (tofacitinib citrate) (PFI) via SA for the indication of Ulcerative Colitis (UC)

Highlights of Products Added

The following Non-Interchangeable Old Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2021:

- **EMERADE 0.3 mg/0.3 mL & 0.5 mg/0.5 mL injection pens** (epinephrine) (VCL)

Change of Listing Status

Listing status was reviewed and the Expert Committee recommended that the benefit listing status of the following Drug Products be changed from Special Authorization to Regular benefits effective February 1, 2021:

- **EZETIMIBE 10 mg tablets** (all brands)

Special Authorization Criteria Changes

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

- **STELARA* 45 mg/0.5 mL vial or syringe injection & 90 mg/1.0 mL injection syringe** (ustekinumab) (JAI) for the indication of Plaque Psoriasis
- **GRASTOFIL* 300 mcg/0.5 mL & 480 mcg/0.8 mL injection syringes** (filgrastim) (APX)

Due to the Biosimilar Initiative, the Special Authorization criteria for coverage for the following Drug Products have been revised effective January 15, 2021:

- **ERELZI* 25 mg/0.5 mL & 50 mg/mL injection syringes and 50 mg/mL sensoready auto injector syringe** (etanercept) (SDZ) for the indication of Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA), Ankylosing Spondylitis (AS), Polyarticular Juvenile Idiopathic Arthritis (pJIA) and Plaque Psoriasis (PsO)
- **BRENZYS* 50 mg/mL injector syringe & auto injector syringe** (etanercept) (SSB) for the indication of RA and AS
- **ENBREL* 25 mg/vial injection & 50 mg/mL injection syringe** (etanercept) (AMG) for the indication of pJIA & PsO
- **NIVESTYM* 0.3 mg/1 mL & 480 mcg/1.6 mL vials for injection and 300 mcg/0.5 mL & 480 mcg/0.8 mL injection syringes** (filgrastim) (PFI)
- **GRASTOFIL* 300 mcg/0.5 mL & 480 mcg/0.8 mL injection syringes** (filgrastim) (APX)
- **FULPHILA* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (BGP)
- **LAPELGA* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (APX)
- **ZIEXTENZO* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (SDZ)
- **INFLECTRA* 100 mg/vial injection** (infliximab) (CHH) for the indication of RA, UC, Crohn's Disease, AS, PsO and PsA
- **RENFLEXIS* 100 mg/vial injection** (infliximab) (SSB) for the indication of RA, UC, Crohn's Disease, AS, PsO and PsA
- **RIXIMYO* 10 mg/mL injection** (rituximab) (SDZ) for the indication of RA
- **RUXIENCE* 10 mg/mL injection** (rituximab) (PFI) for the indication of RA
- **TRUXIMA* 10 mg/mL (10 mL) & 10 mg/mL (50 mL) injections** (rituximab) (CTC) for the indication of RA
- **GLATECT* 20 mg/mL injection syringe** (glatiramer acetate) (PMS) for the indication of Relapsing-Remitting Multiple Sclerosis (RRMS)

Due to the Biosimilar Initiative, the following Drug Products have been delisted effective January 15, 2021:

- **COPAXONE 20 mg/mL injection syringe** (glatiramer acetate) (TMP)
- **ENBREL* 25 mg/vial injection & 50 mg/mL injection syringe** (etanercept) (AMG) for the indications of AS, PsA & RA
- **LANTUS 100 unit/mL injection, 100 unit/mL injection cartridge & pen 100 unit/mL injection** (insulin glargine) (SAV)
- **NEULASTA 6 mg/0.6 mL injection syringe** (pegfilgrastim) (AMG)
- **NEUPOGEN 0.3 mg/mL injection** (filgrastim) (AMG)
- **REMICADE 100 mg/vial injection** (infliximab) (JAI)
- **RITUXAN* 10 mg/mL injection** (rituximab) (HLR) for the indication of RA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (02/2021)

the ADBL report

Issue #117, November 2020

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 22, 2020. The Committee reviewed Manufacturer submissions for thirty-nine (39) 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-nine (29) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, eighteen (18) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2020, and thirty-two (32) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 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 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 November 1, 2020:

- **RIVA-PYRIDOSTIGMINE 60 mg tablet** (pyridostigmine bromide) (RIV)
- **TRI-JORDYNA (21 DAY) 0.18 mg/0.035 mg/0.215 mg/0.035 mg/0.25 mg/0.035 mg tablet** (norgestimate/ethinyl estradiol/norgestimate/ethinyl estradiol/norgestimate/ethinyl estradiol) (GLM)
- **ZAMINE (21 DAY & 28 DAY) 3 mg/0.03 mg tablet** (drospirenone/ ethinyl estradiol) (APX)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (11/2020)

Highlights of Biosimilar Drug Products Added

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

- **ERELZI* 25 mg/0.5 mL & 50 mg/mL injection syringes and 50 mg/mL sensoready autoinjector syringe** (etanercept) (SDZ) via Special Authorization (SA) for the indication of Plaque Psoriasis

Highlights of Line Extension Drug Product Added

Addition of the following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective November 1, 2020:

- **FRAGMIN 16500 IU/0.66 mL injection syringe** (dalteparin sodium) (PFI)

Actemra for Giant Cell Arteritis (GCA)

To align with the international value (mg/L) for C-reactive protein (CRP) data used by the Alberta Public Laboratories, the SA criteria for the following Actemra Drug Product indicated for GCA was updated effective October 1, 2020 to include the mg/L value, as well as the current mg/dL value:

- **ACTEMRA* 162 mg/0.9 mL injection syringe** (tocilizumab) (HLR)

Special Authorization Criteria Changes

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

- **ENBREL* 25 mg/vial injection & 50 mg/mL injection syringe** (etanercept) (AMG) for the indication of Plaque Psoriasis
- **STELARA* 45 mg/0.5 mL vial or syringe injection & 90 mg/1.0 mL syringe injection** (ustekinumab) (JAI) for the indication of Plaque Psoriasis

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*
ABC 81171 (11/2020)

the ADBL report

Issue #116, September 2020

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
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Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 21, 2020. The Committee reviewed Manufacturer submissions for twenty-seven (27) 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 ten (10) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, five (5) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2020, and eighteen (18) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 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 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 August 1, 2020:

- **ACCEL-PILOCARPINE 5 mg tablet** (pilocarpine hydrochloride) (ACP)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (09/2020)

Highlights of Biosimilar Drug Product Added

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

- **RUXIENCE* 10 mg/mL injection** (rituximab) (PFI) via Special Authorization (SA) for the indications of Granulomatosis with Polyangiitis (GPA) or Microscopic Polyangiitis (MPA) and Rheumatoid Arthritis (RA)
- **RIXIMYO* 10 mg/mL injection** (rituximab) (SDZ) via SA for the indication of RA
- **ZIEXTENZO* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (SDZ) via SA

Special Authorization Criteria Changes

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

- **ORENCIA* 250 mg/ vial injection** (abatacept) (BMS) for the indication of polyarticular juvenile idiopathic arthritis (pJIA)

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

- **MAVIRET* 40 mg/100 mg tablet** (pibrentasvir/ glecaprevir) (ABV)
- **RITUXAN* 10 mg/mL injection** (rituximab) (HLR) for the indication of GPA/MPA

The Special Authorization criteria for the following Drug Products have been updated, effective September 1, 2020. Wording of the preamble has been revised to remove the statement that patients will not be permitted to switch from one biosimilar to another.

- **BRENZYS* 50 mg/mL injection syringe & auto injector syringe** (etanercept) (SSB)
- **ENBREL* 25 mg/vial injection & 50 mg/syringe injection** (etanercept) (AMG)
- **ERELZI* 25 mg/0.5 mL & 50 mg/mL injection syringes and 50 mg/mL sensoready auto injector syringe** (etanercept) (SDZ)
- **FULPHILA* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (BGP)
- **INFLECTRA* 100 mg/vial injection** (infliximab) (CHH)
- **LAPELGA* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (APX)
- **NEULASTA* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (AMG)
- **REMICADE* 100 mg/vial injection** (infliximab) (JAI)
- **RENFLEXIS* 100 mg/vial injection** (infliximab) (SSB)
- **RITUXAN* 10 mg/mL injection** (rituximab) (HLR) for the indication of RA
- **TRUXIMA* 10 mg/mL (10 mL & 50 mL) injections** (rituximab) (CTC)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*
ABC 81171 (09/2020)

the ADBL report

Issue #115, July 2020

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
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Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
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ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

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

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (07/2020)

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.

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.

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

ABC 81171 (07/2020)

the DBL report

Issue #114, May 2020

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
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Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

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ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 17, 2020. The Committee reviewed Manufacturer submissions for nine (9) 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 three (3) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-eight (38) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 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 April 1, 2020:

- **PREVYMIS* 20 mg/mL (240 mg/12 mL) & 20 mg/mL (480 mg/24 mL) injections and 240 mg & 480 mg tablets** (letermovir) (MFC) via Special Authorization (SA)

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

- **ACTEMRA* 162 mg/0.9 mL auto injector** (tocilizumab) (HLR) for the indication of Rheumatoid Arthritis (RA) via SA
- **ACTEMRA* 162 mg/0.9 mL injection syringe** (tocilizumab) (HLR) for the indication of Systemic Juvenile Idiopathic Arthritis (sJIA) and Polyarticular Juvenile Idiopathic Arthritis (pJIA) via SA
- **TRIAMCINOLONE HEXACETONIDE* 20 mg/mL injection** (triamcinolone hexacetonide) (MDX) via Restricted Benefit

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (05/2020)

Highlights of Line Extension Drug Products Added

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

- **METOJECT SUBCUTANEOUS 10 mg/0.2 mL, 12.5 mg/0.25 mL & 15 mg/0.3 mL injection syringes** (methotrexate sodium) (MDX)

Highlights of Interchangeable (IC) Drug Products Added

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

- **MAR-ACARBOSE 50 mg & 100 mg tablets** (acarbose) (MAR)
- **PMS-FLUTICASONE/SALMETEROL DPI* 100/50 mcg, 250/50 mcg & 500/50 mcg inhalation powders** (salmeterol xinafoate/fluticasone propionate) (PMS) via Step Therapy/SA
- **TRI-JORDYNA (28 DAY) 0.18 mg/0.035 mg/0.215 mg/0.035 mg/0.25 mg/0.035 mg tablet** (norgestimate/ethinyl estradiol/norgestimate/ethinyl estradiol/norgestimate/ethinyl estradiol) (GLM)
- **WIXELA INHUB* 100 diskus, 250 diskus & 500 diskus powders for inhalation** (salmeterol xinafoate/fluticasone propionate) (MYP) via Step Therapy/SA

Special Authorization Criteria Changes

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

- **ACTEMRA* (20 mL) 400 mg/vial injection** (tocilizumab) (HLR) for the indication of sJIA via SA
- **ACTEMRA* (4 mL) 80 mg/vial & (10 mL) 200 mg/vial injections** (tocilizumab) (HLR) for the indication of sJIA and pJIA via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*
ABC 81171 (05/2020)

the DBL report

Issue #113, March 2020

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 21, 2020. The Committee reviewed Manufacturer submissions for eighteen (18) 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 two (2) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, nine (9) Drug Products underwent Expedited Review for listing on the *ADBL* effective March 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 March 1, 2020:

- **FULPHILA* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (BGP) via Special Authorization (SA)
- **KALYDECO* 150 mg tablet** (ivacaftor) (VER) for the indication of cystic fibrosis in patients age 6 years and older who have one of the following mutations in the CFTR gene: G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R, and in patients age 18 years and older with an R117H mutation in the CFTR gene via SA
- **VYZULTA 0.024% ophthalmic solution** (latanoprostene bunod) (VCL)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (03/2020)

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 March 1, 2020:

- **ODAN LEVOCARNITINE* 100 mg/mL oral solution** (levocarnitine) (ODN) via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

the ADBL report

Issue #112, February 2020

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Michael Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 21, 2019. The Committee reviewed Manufacturer submissions for twenty (20) 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-one (21) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-seven (27) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2019, and ten (10) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective December 1, 2019:

- **CYSTADROPS* ophthalmic solution** (cysteamine hydrochloride) (RRD) via Special Authorization (SA)

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

- **CRESEMBA* 100 mg capsule & 200 mg/vial injection** (isavuconazonium sulfate) (AVP) via Restricted Benefit/SA
- **SKYRIZI* 75 mg injection syringe** (risankizumab) (ABV) via SA
- **TRELEGY ELLIPTA* 100 mcg/62.5 mcg/25 mcg inhalation powder** (fluticasone furoate/ umeclidinium bromide/ vilanterol trifenatate) (GSK) via Step Therapy/SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (02/2020)

Highlights of Interchangeable (IC) Drug Products Added

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

- Fingolimod hydrochloride* **0.5 mg capsule** (MYP, PMS, SDZ, TEV) via SA

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective December 12, 2019:

- **ENBREL* 25 mg vial injection & 50 mg injection syringe for Plaque Psoriasis** (etanercept) (AMG)
- **HUMIRA* (40 mg/0.8 mL injection syringe) 40 mg/syringe injection syringe for Plaque Psoriasis, Crohn's Disease, Ankylosing Spondylitis, Psoriatic Arthritis & Rheumatoid Arthritis** (adalimumab) (ABV)
- **RITUXAN* 10 mg/mL injection for Rheumatoid Arthritis** (rituximab) (HLR)
- **STELARA* (0.5 mL vial or syringe) 45 mg injection vial or syringe & (1.0 mL syringe) 90 mg/syringe injection syringe for Plaque Psoriasis** (ustekinumab) (JAI)

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

- **APTIOM* 200 mg, 400 mg, 600 mg & 800 mg tablets for Partial-Onset Seizures** (eslicarbazepine acetate) (SUN)
- **FYCOMPA* 2 mg, 4 mg, 6 mg, 8 mg, 10 mg & 12 mg tablets for Partial-Onset Seizures or Primary Generalized Tonic-Clonic Seizures** (perampanel) (EIS)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*
ABC 81171 (02/2020)

the DBL report

Issue #111, November 2019

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPharm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPharm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 24, 2019. The Committee reviewed Manufacturer submissions for thirteen (13) 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 two (2) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, seven (7) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2019, and seven (7) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 1, 2019.

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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective October 1, 2019:

- **GALAFOLD* 123 mg oral capsule** (migalastat) (AMI) via Special Authorization (SA)

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (11/2019)

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 October 1, 2019:

- **VORICONAZOLE* 200 mg/vial injection** (voriconazole) (JPC) via Restricted Benefit/SA

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective November 1, 2019:

- **ATROPINE 1% ophthalmic solution** (atropine sulfate) (PSL)
- **JAMP ITRACONAZOLE* 10 mg/mL oral solution** (itraconazole) (JPC) via Restricted Benefit/SA
- **METHADONE HYDROCHLORIDE 10 mg/mL oral solution** (methadone hydrochloride) (SDZ)

Addition of Single Source Drug Products

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective November 1, 2019

- **RAN-CEFPROZIL 25 mg/mL & 50 mg/mL oral suspensions** (cefprozil) (RAN)

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 (11/2019)

the DBL report

Issue #110, September 2019

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 23, 2019. The Committee reviewed Manufacturer submissions for seventeen (17) 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 fifteen (15) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, sixteen (16) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2019, and six (6) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 1, 2019.

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 August 1, 2019:

- **FASENRA* 30 mg/mL injection syringe** (benralizumab) (AZC) via Special Authorization (SA)
- **FYCOMPA* 2 mg, 4 mg, 6 mg, 8 mg, 10 mg & 12 mg tablets** (perampanel) (EIS) for the indication of primary generalized tonic-clonic (PGTC) seizures via SA

A complete list of changes, as well as the full ADBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.php.
Please refer to the current ADBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (09/2019)

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective September 1, 2019:

- **OZEMPIC* 1.34 mg/mL (0.25 mg or 0.5 mg dose) & 1.34 mg/mL (1 mg dose) pen injections** (semaglutide) (NNA) via Step Therapy/SA
- **VPRIV* 400 unit/vial injection** (velaglucerase alfa) (SHG) via SA

The following Drug Product was reviewed by CDR and added to the *ADBL* effective September 1, 2019:

- **ELELYSO* 200 unit/vial injection** (taliglucerase alfa) (PFI) via SA

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective August 1, 2019:

- **XELJANZ XR* 11 mg extended-release tablet** (tofacitinib citrate) (PFI) via SA

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective September 1, 2019:

- **KEVZARA* 150 mg/1.14 mL & 200 mg/1.14 mL injection pens** (sarilumab) (SAV) via SA

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 August 1, 2019:

- **APO-DEFERASIROX (TYPE J)* 90 mg, 180 mg & 360 mg tablets** (deferasirox) (APX) via Step Therapy/SA

Addition of the following Entry IC Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective September 1, 2019:

- **MAR-TROSPIUM* 20 mg tablet** (trospium chloride) (MAR) via Step Therapy/SA

Restricted Benefit Criteria Changes

The Restricted Benefit criteria for coverage for the following Drug Product have been revised effective September 1, 2019 to include the indication for intermittent treatment and additional treatment courses:

- **FIBRISTAL* 5 mg tablet** (ulipristal acetate) (ASC)

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Product have been revised effective August 1, 2019:

- **NUCALA* 100 mg/mL vial injection** (mepolizumab) (GSK)

The Special Authorization criteria for coverage for the following Drug Products have been revised effective September 1, 2019:

- **GILENYA* 0.5 mg capsule** (fingolimod) (NOV)
- Lacosamide **50 mg, 100 mg, 150 mg & 200 mg tablets** (AUR, PMS, SDZ, TEV & UCB)
- Febuxostat* **80 mg tablet** (MAR & TAK)

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 (09/2019)

the DBL report

Issue #109, July 2019

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 13, 2019. The Committee reviewed Manufacturer submissions for twelve (12) 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 four (4) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, three (3) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 1, 2019.

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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective July 1, 2019:

- **PROBUPHINE* 80 mg subdermal implant** (buprenorphine hydrochloride) (KTI) via Special Authorization (SA)

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 (07/2019)

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 July 1, 2019:

- **MAR-FEBUXOSTAT* 80 mg tablet** (febuxostat) (MAR) via Special Authorization

Highlights of Line Extension Drug Products Reviewed for the ADBL

Addition of the following Drug Products to the *ADBL* effective July 1, 2019:

- **AA-CLOZAPINE 50 mg & 200 mg tablets** (clozapine) (AAP)

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Product has been revised effective June 17, 2019:

- **SPINRAZA* 2.4 mg/mL injection** (nusinersen sodium) (BIO)

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 (06/2019)

the ADBL report

Issue #108, June 2019

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 19, 2019. The Committee reviewed Manufacturer submissions for nineteen (19) 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 twelve (12) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, fifty (50) Drug Products underwent Expedited Review for listing on the *ADBL* effective June 1, 2019.

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 the Expert Committee and added to the *ADBL* effective April 1, 2019:

- **KEVZARA* 150 mg/1.14 mL & 200 mg/1.14 mL injection syringes** (sarilumab) (SAV) via Special Authorization (SA)
- **KYLEENA 19.5 mg intrauterine insert** (levonorgestrel) (BAI)
- **OCREVUS* 30 mg/mL (10 mL vial) injection** (ocrelizumab) (HLR) via SA
- **REXULTI 0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg & 4 mg tablets** (brexpiprazole) (OTS)

The following Drug Product was reviewed by CDR and added to the *ADBL* via Special Authorization effective April 1, 2019:

- **MAVIRET* 40 mg/100 mg tablet** (pibrentasvir/glecaprevir) (ABV)

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 (06/2019)

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization effective June 1, 2019:

- **DUODOPA* 20 mg/mL/5 mg/mL (100 mL) intestinal gel** (levodopa/ carbidopa) (ABV)
- **LAPELGA* 6 mg/0.6 mL injection syringe** (pegfilgrastim) (APX)
- **MDK-NITISINONE* 20 mg capsule** (nitisinone) (MEN)
- **MOVAPO* 10 mg/mL pre-filled pen injection** (apomorphine hydrochloride) (PAL)

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* via Special Authorization effective June 1, 2019:

- **ERELZI* 25 mg/0.5 mL & 50 mg/mL injection syringes and 50 mg/mL Sensoready auto injector syringe** (etanercept) (SDZ) for the indication of Psoriatic Arthritis (PsA)

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 June 1, 2019:

- **APO-DABIGATRAN* 110 mg & 150 mg capsules** (dabigatran etexilate) (APX) via Step Therapy/Special Authorization
- **AURO-CEFIXIME 20 mg/mL oral suspension** (cefixime) (AUR)

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective April 1, 2019:

- **EPCLUSA* 400 mg/100 mg tablet** (sofosbuvir/ velpatasvir) (GIL)
- **HARVONI* 400 mg/90 mg tablet** (sofosbuvir/ ledipasvir) (GIL)
- **SOVALDI* 400 mg tablet** (sofosbuvir) (GIL)
- **VOSEVI* 400 mg/100 mg/100mg tablet** (sofosbuvir/ velpatasvir/ voxilaprevir) (GIL)
- **ZEPATIER* 50 mg/100 mg tablet** (elbasvir/ grazoprevir) (MFC)

The Special Authorization criteria for coverage for the following Drug Products have been revised effective June 1, 2019:

- **DAKLINZA* 30 mg & 60 mg tablets** (daclatasvir dihydrochloride) (BMS)

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 (06/2019)

the ADBL report

Issue #107, March 2019

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

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Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 21, 2019. The Committee reviewed Manufacturer submissions for six (6) 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 thirteen (13) Drug Products.

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, 2019.

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 the Expert Committee and added to the *ADBL* effective March 1, 2019:

- **ACTEMRA*** (tocilizumab) (HLR) **162 mg/0.9 mL injection syringe** for the indication of Giant Cell Arteritis (GCA) via Special Authorization (SA)
- **IZBA** (travoprost) (NOV) **0.003% ophthalmic solution**
- **LIXIANA*** (edoxaban tosylate monohydrate) (SEV) **15 mg, 30 mg & 60 mg tablets** via Step Therapy/Special Authorization
- **TALTZ*** (ixekizumab) (LIL) **80 mg/mL autoinjector & injection syringe** for the indication of Psoriatic Arthritis (PsA) via SA

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 (03/2019)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective March 1, 2019:

- **APO-TRAVOPROST-TIMOP** (travoprost/timolol maleate) (APX) **0.004%/0.5% ophthalmic solution**
- **MAR-DAPSONE** (dapsone) (MAR) **100 mg tablet**

Highlights of Drug Products Added

The following Line Extension Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective March 1, 2019:

- **BASAGLAR KWIKPEN (80 UNITS PER INJECTION DELIVERY)** (insulin glargine) (LIL) **100 unit/mL injection**

Highlights of Changes to Currently Listed Products

The criteria for coverage via Special Authorization were revised for the following Drug Products effective March 1, 2019:

- **ABILIFY MAINTENA*** (aripiprazole) (OTS) **300 mg/vial & 400 mg/vial injections**
- **INVEGA SUSTENNA*** (paliperidone palmitate) (JAI) **50 mg/0.5 mL, 75 mg/0.75 mL, 100 mg/1 mL & 150 mg/1.5 mL injection syringes**
- **INVEGA TRINZA*** (paliperidone palmitate) (JAI) **175 mg/0.875 mL, 263 mg/1.315 mL, 350 mg/1.75 mL & 525 mg/2.625 mL injection syringes**
- **RISPERDAL CONSTA*** (risperidone) (JAI) **25 mg/vial, 37.5 mg/vial & 50 mg/vial injections**

After assessment by the Expert Committee, the listing status of the following Drug Products will be changed from Restricted Benefits to Regular Benefits effective March 1, 2019:

- **MOMETASONE** (mometasone furoate) **50 mcg/dose aqueous nasal sprays** (all brands)

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 (03/2019)

the DBLreport

Issue #106, February 2019

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 22 and 23, 2018. The Committee reviewed Manufacturer submissions for thirty-four (34) 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, forty-four (44) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2018 and twelve (12) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2019.

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 the Expert Committee and added to the *ADBL* effective December 1, 2018:

- **ACTIKERALL** (5-fluorouracil/salicylic acid) (CIP) **0.5%/10% topical solution**
- **BRIVLERA*** (brivaracetam) (UCB) **10 mg, 25 mg, 50 mg, 75 mg & 100 mg tablets** via Special Authorization (SA)
- **DYSPORT THERAPEUTIC** (abobotulinumtoxinA) (ISP) **300 IU/vial & 500 IU/vial injections**
- **ENSTILAR** (calcipotriol monohydrate/betamethasone dipropionate) (LEO) **50 mcg/g/0.5 mg/g topical foam**
- **HEMANGIOL*** (propranolol hydrochloride) (PIE) **3.75 mg/mL oral solution** via SA
- **LANCORA*** (ivabradine hydrochloride) (SEV) **5 mg & 7.5 mg tablets** via SA
- **QUINSAIR*** (levofloxacin) (RAP) **100 mg/mL inhalation solution** via Step Therapy/SA
- **SPINRAZA*** (nusinersen sodium) (BIO) **2.4 mg/mL injection** via SA
- **TRESIBA FLEXTOUCH PEN** (insulin degludec) (NNA) **100 unit/mL & 200 unit/mL injections**

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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The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* effective January 1, 2019:

- **OCALIVA*** (obeticholic acid) (ICP) **5 mg & 10 mg tablets** via SA
- **RENFLEXIS*** (infliximab) (SSB) **100 mg/vial injection** via SA
- **REVESTIVE*** (teduglutide) (SHB) **5 mg/vial injection** via SA
- **SYNJARDY*** (empagliflozin/metformin hydrochloride) (BOE) **5 mg/500 mg, 5 mg/850 mg, 5 mg/1000 mg, 12.5 mg/500 mg, 12.5 mg/850 mg & 12.5 mg/1000 mg tablets** via Step Therapy/SA

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via SA effective February 1, 2019:

- **MDK-NITISINONE*** (nitisinone) (MEN) **2 mg, 5 mg & 10 mg capsules**
- **NITISINONE*** (nitisinone) (CYC) **2 mg, 5 mg & 10 mg tablets**
- **ORFADIN*** (nitisinone) (BVM) **2 mg, 5 mg, 10 mg & 20 mg capsules**
- **PRALUENT*** (alirocumab) (SAV) **75 mg/mL & 150 mg/mL injection pens & syringes**

Highlights of Drug Products Added

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2019:

- **CAMPRAL*** (acamprosate calcium) (MVP) **333 mg delayed-release tablet** via SA
- **MEZERA** (mesalazine) (AVP) **1 g rectal suppository**

Highlights of Expedited Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective December 1, 2018:

- **APO-HYDROMORPHONE CR** (hydromorphone hydrochloride) (APX) **3 mg, 4.5 mg, 6 mg, 9 mg, 18 mg, 24 mg & 30 mg controlled release capsules**
- **LACOSAMIDE*** (lacosamide) (various brands: AUR, PMS, SDZ, TEV) **50 mg, 100 mg, 150 mg & 200 mg tablets** listed via SA
- **MAR-METHIMAZOLE** (thiamazole) (MAR) **5 mg tablet**

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective February 1, 2019:

- **TARO-DIPYRIDAMOLE/ ASA** (dipyridamole/acetylsalicylic acid) (TAR) **200 mg/25 mg capsule**

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective February 1, 2019:

- **APO-HYDROMORPHONE CR** (hydromorphone hydrochloride) (APX) **12 mg controlled-release capsule**
- **APO-NALTREXONE** (naltrexone hydrochloride) (APX) **50 mg tablet**
- **APO-PINAVERIUM** (pinaverium bromide) (APX) **50 mg & 100 mg tablets**
- **BACKUP PLAN ONESTEP** (levonorgestrel) (APX) **1.5 mg tablet**
- **NALTREXONE HYDROCHLORIDE TABLETS USP** (naltrexone hydrochoride) (JPC) **50 mg tablet**

Step Therapy/Special Authorization Criteria Changes

The Step Therapy/Special Authorization criteria for coverage for the following Drug Product has been revised effective December 1, 2018:

- **CAYSTON*** (aztreonam) (GIL) **75 mg/vial powder for inhalation solution**

The Step Therapy/Special Authorization criteria for coverage for the following Drug Products have been revised effective January 1, 2019:

- **JARDIANCE*** (empagliflozin) (BOE) **10 mg & 25 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).*
ABC 81171 (02/2019)

the DBLreport

Issue #105, November 2018

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 20, 2018. The Committee reviewed Manufacturer submissions for twenty-one (21) 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 four (4) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, six (6) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2018, and sixteen (16) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 1, 2018.

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 Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *Alberta Drug Benefit List (ADBL)* effective October 1, 2018:

- **PLAN B** (levonorgestrel) (TEP) **1.5 mg tablet**

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective November 1, 2018:

- **APO-LANSOPRAZOLE-AMOXICILLIN-CLARITHROMYCIN KIT** (lansoprazole/amoxicillin trihydrate/clarithromycin) (APX)
  30 mg/500 mg/500 mg tablet/capsules
- **JAMP-FOSFOMYCIN** (fosfomycin tromethamine) (JPC) **3 g oral powder packet**

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).*

Changes in Listing Status & Criteria

As part of the Review of Benefit Status (ROBS) process, comprehensive clinical reviews of overactive bladder agents were undertaken by the Expert Committee. Following discussion and examination of all information available, the Committee recommended listing changes to these agents on the *ADBL*. As of October 1, 2018, the listing status of the following Drug Products has been changed from Step Therapy/Special Authorization to Regular Benefits:

- **SOLIFENACIN** (solifenacin succinate) **5 mg & 10 mg tablets** (all brands)
- **TOLTERODINE** (tolterodine l-tartrate) **2 mg & 4 mg long-acting capsules** (all brands)

Accordingly, effective October 1, 2018, the Step Therapy/Special Authorization criteria for coverage for the following Drug Products have been revised:

- **ENABLEX*** (darifenacin hydrobromide) (MLL) **7.5 mg & 15 mg extended-release tablets**
- **TOVIAZ*** (fesoterodine fumarate) (PFI) **4 mg & 8 mg extended-release tablets**
- **MYRBETRIQ*** (mirabegron) (ASP) **25 mg & 50 mg extended-release tablets**
- **TROSEC*** (trospium chloride) (SUN) **20 mg tablet**

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 (11/2018)

the DBL report

Issue #104, September 2018

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
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Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 24, 2018. The Committee reviewed Manufacturer submissions for twenty-two (22) 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 seven (7) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirteen (13) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2018, and seventy (70) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 1, 2018.

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 the Expert Committee and added to the *ADBL* effective September 1, 2018:

- **PROCYSBI*** (cysteamine bitartrate) (RAP) **25 mg & 75 mg delayed-release capsules** via Special Authorization (SA)

Highlights of Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *Palliative Coverage Drug Benefit Supplement* effective September 1, 2018:

- **BISACODYL** (bisacodyl) (JPC) **10 mg rectal suppository**

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 (09/2018)

Highlights of Expedited Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective September 1, 2018:

- **APO-VARENICLINE STARTER PACK*** (varenicline tartrate/varenicline tartrate) (APX) **0.5 mg/1 mg tablets** listed via Restricted Benefit/SA
- Pregabalin (APX, PMS, RAN, SNS, SIV & SDZ) **25 mg, 50 mg, 75 mg, 150 mg & 300 mg capsules**
- Pregabalin (MPI) **25 mg, 50 mg, 75 mg, 150 mg capsules**
- Trandolapril (PMS & SDZ) **0.5 mg, 1 mg, 2 mg, & 4 mg capsules**

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 September 1, 2018:

- **PMS-NITROFURANTOIN** (nitrofurantoin) (PMS) **100 mg capsule**
- **RAN-RAMIPRIL HCTZ** (ramipril/ hydrochlorothiazide) (RAN) **2.5 mg/12.5 mg & 5 mg/25 mg tablets**

Special Authorization Criteria Changes

SA criteria have been revised for the following Drug Products effective August 1, 2018:

- **LEMTRADA*** (alemtuzumab) (GZM) **12 mg/vial injection**
- **TYSABRI*** (natalizumab) (BIO) **20 mg/mL injection**

SA criteria have been revised for the following Drug Product effective September 1, 2018:

- **DIFICID*** (fidaxomicin) (MFC) **200 mg film-coated tablet**

Non-Innovator Policy Review

The Non-Innovator Policy of the *ADBL* provides a mechanism by which Multisource Drug Products may seek a listing designation as interchangeable with a Canadian Innovator Reference Product (CIRP) that is not currently listed on the *ADBL* when that CIRP has been identified by the Minister. The Minister may identify a CIRP that has been considered but never listed on the *ADBL* and where the availability of a Multisource Drug Product(s) may now alter the cost effectiveness of the molecule. Through this process, a comprehensive clinical review of the following Drug Products was undertaken by the Expert Committee and this category will be added in the Non-Innovator Policy effective September 1, 2018. Once published, Submissions for Multisource Drug Products for the following non-listed CIRP will be accepted and considered for addition to the *ADBL* as per current Submission and Price Policy Guidelines:

- **REVIA (NALTREXONE HYDROCHLORIDE) 50 mg tablet**

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).*

the DBL report

Issue #103, July 2018

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 14 and 15, 2018. The Committee reviewed Manufacturer submissions for fifteen (15) 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 nine (9) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, nineteen (9) Drug Products underwent Expedited Review for listing on the *ADBL* effective June 1, 2018, and eight (8) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 1, 2018.

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 the Expert Committee and added to the *ADBL* effective June 1, 2018:

- **COSENTYX*** (secukinumab) (NOV) **150 mg/mL injection** via Special Authorization (SA) for the indications of Ankylosing Spondylitis and Psoriatic Arthritis
- **MICTORYL PEDIATRIC*** (propiverine hydrochloride) (DUI) **5 mg tablet** as a Restricted Benefit
- **REPATHA*** (evolocumab) (AMG) **140 mg/mL autoinjector & 120 mg/mL automated mini-doser injection cartridge** via SA
- **TALTZ*** (ixekizumab) (LIL) **80 mg/mL autoinjector & injection syringe** via SA

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* via SA effective July 1, 2018:

- **GLATECT*** (glatiramer acetate) (PMS) **20 mg/mL injection syringe**

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 (07/2018)

Highlights of Drug Products Added

The following Line Extension Drug Products were reviewed by the Expert Committee and added to the *ADBL* via SA effective July 1, 2018:

- **CUBICIN RF*** (daptomycin) (CUB) **500 mg/vial injection**
- **INVEGA TRINZA*** (paliperidone palmitate) (JAI) **175 mg/0.875 mL, 263 mg/1.315 mL, 350 mg/1.75 mL & 525 mg/2.625 mL injection syringes**

Highlights of Expedited Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective June 1, 2018:

- **APO-ARIPIPRAZOLE*** (aripiprazole) (APX) **2 mg & 5 mg tablets** listed via Restricted Benefit and **10 mg, 15 mg, 20 mg & 30 mg tablets** as Regular Benefits
- **ACT DEXTROAMPHETAMINE SR*** (dextroamphetamine sulfate) (APH) **10 mg sustained-release capsule**
- **AURO-ZIPRASIDONE** (ziprasidone hydrochloride monohydrate) (AUR) **20 mg, 40 mg, 60 mg & 80 mg capsules**

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective July 1, 2018:

- **MINT-EPLERENONE*** (eplerenone) (MPI) **25 mg & 50 mg tablets** listed via SA
- **APO-VARENICLINE*** (varenicline tartrate) (APX) **0.5 mg & 1 mg tablets** listed via Restricted Benefit/SA

Special Authorization Criteria Changes

The SA criteria have been revised for the following Drug Product effective June 1, 2018:

- **PROLIA*** (denosumab) (AMG) **60 mg/mL injection syringe**

Changes in Listing Status

The following Drug Products have been changed from listing via Special Authorization to Regular Benefits effective July 1, 2018:

- **JAMP-VANCOMYCIN** (vancomycin hydrochloride) (JPC) **125 mg & 250 mg capsules**
- **VANCOCIN** (vancomycin hydrochloride) (MLI) **125 mg & 250 mg capsules**

Non-Innovator Policy Review

The Non-Innovator Policy of the *ADBL* provides a mechanism by which Multisource Drug Products may seek a listing designation as interchangeable with a Canadian Innovator Reference Product (CIRP) that is not currently listed on the *ADBL* when that CIRP has been identified by the Minister. The Minister may identify a CIRP that has been considered but never listed on the *ADBL* and where the availability of a Multisource Drug Product(s) may now alter the cost effectiveness of the molecule. Through this process, a comprehensive clinical review of the following Drug Products was undertaken by the Expert Committee and this category will be added in the Non-Innovator Policy effective July 1, 2018. Once published, Submissions for Multisource Drug Products for the following non-listed CIRP will be accepted and considered for addition to the *ADBL* as per current Submission and Price Policy Guidelines:

- **Lyrica (PREGABALIN) 25 mg, 50 mg, 75 mg, 150 mg & 300 mg capsules**

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 (07/2018)

the DBL report

Issue #102, May 2018

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
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Tony Nickonchuk, BScPharm
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Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 20, 2018. The Committee reviewed Manufacturer submissions for twenty-three (23) 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 (30) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 1, 2018.

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 the Expert Committee and added to the *ADBL* via Special Authorization (SA) effective April 1, 2018:

- **HUMIRA*** (adalimumab) (ABV) **40 mg/0.8 mL injection syringe** for the indication of Hidradenitis Suppurativa (HS)
- **XOLAIR*** (omalizumab) (NOV) **150 mg vial injection** for the indication of chronic idiopathic urticaria (CIU)

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via SA effective May 1, 2018:

- **NUCALA*** (mepolizumab) (GSK) **100 mg/mL vial injection**
- **PHEBURANE*** (sodium phenylbutyrate) (MDK) **483 mg/g granules**
- **RAVICTI*** (glycerol phenylbutyrate) (HZN) **1.1 g/mL liquid**

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 (05/2018)

The following Drug Product was reviewed by CDR and added to the *ADBL* via SA effective May 1, 2018:

- **VOSEVI*** (sofosbuvir /velpatasvir /voxilaprevir) (GIL) **400 mg/100 mg/100 mg tablet**

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 April 1, 2018:

- **ACT DEXTROAMPHETAMINE SR** (dextroamphetamine sulfate) (APH) **15 mg sustained-release capsule**

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective May 1, 2018:

- **TEVA-BUDESONIDE** (budesonide) (TEV) **0.125 mg/mL & 0.5 mg/mL inhalation suspensions**

Highlights of Drug Products Added

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective April 1, 2018:

- **METOJECT SUBCUTANEOUS** (methotrexate sodium) (MDX) **17.5 mg/0.35 mL, 20 mg/0.4 mL, 22.5 mg/0.45 mL & 25 mg/0.5 mL injection syringes**

The following Line Extension Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective May 1, 2018:

- **ESBRIET*** (pirfenidone) (HLR) **267 mg & 801 mg tablets** listed via SA

Highlights of Expedited Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective May 1, 2018:

- **MINT-ACITRETIN** (acitretin) (MPI) **10 mg & 25 mg capsules**
- **TARO-ACITRETIN** (acitretin) (TAR) **10 mg capsule**
- **PERINDOPRIL** (perindopril erbumine) (APX, AUR, PMS, SDZ and TEV) **2 mg, 4 mg & 8 mg tablets**
- **PERINDOPRIL/INDAPAMIDE** (perindopril erbumine/indapamide hemihydrate) (SDZ and TEV) **4 mg/1.25 mg & 8 mg/2.5 mg tablets**

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective April 1, 2018:

- **DAKLINZA*** (daclatasvir dihydrochloride) **30 mg & 60 mg tablets**
- **EPCLUSA*** (sofosbuvir/velpatasvir) **400 mg/100 mg tablet**
- **HARVONI*** (sofosbuvir/ledipasvir) **400 mg/90 mg tablet**
- **SOVALDI*** (sofosbuvir) **400 mg tablet**
- **ZEPATIER*** (elbasvir/grazoprevir) **50 mg/100 mg tablet**

The Special Authorization criteria for coverage for the following Drug Products have been revised effective May 1, 2018:

- **DIFLUCAN*** (fluconazole) (PFI) **10 mg/mL oral suspension**
- **Zoledronic Acid*** (ACLASTA, Dr. Reddys & Taro brands) **0.05 mg/mL injections**

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 (05/2018)

the DBL report

Issue #101, March 2018

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 22, 2018. The Committee reviewed Manufacturer submissions for twenty-nine (29) 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 thirty-three (33) Drug Products.

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, 2018.

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 the Expert Committee and added to the *ADBL* via Special Authorization effective March 1, 2018:

- **ERELZI*** (etanercept) (SDZ) **25 mg/0.5 mL & 50 mg/mL prefilled syringes and 50 mg/mL Sensoready prefilled autoinjector** for the indications of Ankylosing Spondylitis (AS), Polyarticular Juvenile Idiopathic Arthritis (pJIA) and Rheumatoid Arthritis (RA).
- **STRENSIQ*** (asfotase alfa) (APG) **18 mg/vial, 28 mg/vial, 40 mg/vial & 80 mg/vial injections**

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 (03/2018)

Highlights of Interchangeable (IC) Drug Products Added

The following IC Drug Products were added to the *ADBL* effective March 1, 2018:

- **ACT BUPRENORPHINE/NALOXONE** (buprenorphine hydrochloride/naloxone hydrochloride dihydrate) (APH) **2 mg/0.5 mg & 8 mg/2 mg sublingual tablets**

Highlights of Drug Products Added

The following Natural Health Product was reviewed by the Expert Committee and added to the *ADBL* effective March 1, 2018 into a MAC grouping with other 8 mEq potassium chloride capsule formulations:

- **JAMP-POTASSIUM CHLORIDE ER** (potassium chloride) (JPC) **600 mg (8 mEq) capsule**

Highlights of Changes to Currently Listed Products

Additional indications were added for the following Drug Products effective March 1, 2018:

- **ZOLEDRONIC ACID* 4 mg/5 mL injections** (all brands) for the prevention of skeletal-related events in patients with metastatic castration-resistant prostate cancer (CRPC) with one or more bony metastases was previously reviewed by the Expert Committee and this indication is now eligible for coverage via Special Authorization.

Restricted Benefit Criteria Changes

The Restricted Benefit criteria for coverage for the following Drug Products has been revised effective March 1, 2018 to include Specialists in Hematology to the Restricted Benefit prescriber designations:

- **MEROPENEM* 500 mg & 1 gram vial injections** (all brands)
- **PIPERACILLIN/TAZOBACTAM* 2 gram/250 mg, 3 gram/375 mg & 4 gram/500 mg vial injections** (all brands)
- **PRIMAXIN*** (imipenem/cilastatin sodium) (MFC) **500 mg/500 mg vial injection**

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective March 1, 2018:

- **CANCIDAS*** (caspofungin) (MFC) **50 mg & 70 mg vial injections**
- **CASPOFUNGIN*** (caspofungin) (MDA) **50 mg & 70 mg vial injections**

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 (03/2018)

the DBL report

Issue #100, February 2018

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

100th Issue of the DBL Report

The first DBL Report was published in January 1995, and with very few exceptions there has been a DBL report published after every meeting of the Expert Committee since then. The DBL Report is intended to be a resource for health professionals and the public, providing information about new Drug Products which have been approved for listing by the Minister of Health, as well as changes in listing status and Special Authorization criteria. The DBL report also includes a summary of the volume of Drug Products reviewed by the Expert Committee and the number of Drug Products which undergo Expedited Review.

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 20 & 21, 2017. The Committee reviewed Manufacturer submissions for twenty (20) 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 fifteen (15) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, five (5) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2017, and four (4) Drug Products underwent Expedited Review for listing effective February 1, 2018.

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

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).

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

The following Drug Products were previously reviewed by pCODR (pan-Canadian Oncology Drug Review) and the Expert Committee and added to the *ADBL* via Special Authorization, for the treatment of multicentric Castleman's disease (MCD), effective January 1, 2018:

- **SYLVANT*** (siltuximab) (JAI) **100 mg/vial & 400 mg/vial injections**

Highlights of Drug Products Added

The following Line Extension Drug Product was previously reviewed by the Expert Committee and added to the *ADBL* via Special Authorization for the same indications as the Cimzia 200 mg/mL prefilled syringe, effective January 1, 2018:

- **CIMZIA*** (certolizumab pegol) (UCB) **200 mg/mL auto-injector pen**

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 December 1, 2017:

- **AURO-FLECAINIDE** (flecainide acetate) (AUR) **50 mg & 100 mg tablets**
- **MINT-ITRACONAZOLE** (itraconazole) (MPI) **100 mg capsule**

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective February 1, 2018*:*

- **APO-PHENYTOIN** (phenytoin sodium) (APX) **100 mg capsule**
- **MINT-CLONIDINE** (clonidine hydrochloride) (MPI) **0.1 mg & 0.2 mg tablets**
- **ODAN-BENZYDAMINE** (benzydamine hydrochloride) (ODN) **1.5 mg/mL oral rinse solution**
- **JAMP-HYDRALAZINE** (hydralazine hydrochloride) (JPC) **10 mg, 25 mg & 50 mg tablets**

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective February 1, 2018:

- **MEROPENEM*** (meropenem) (STM) **1 gram/vial injection**
- **MERREM*** (meropenem) (AZC) **500 mg and 1 gram per vial injections**
- **PRIMAXIN*** (imipenem/cilastatin sodium) (MFC) **500 mg/500 mg per 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 (02/2018)

the DBL report

Issue #99, November 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)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC (Chair)
Fiona Clement, PhD (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD (Vice-Chair)
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD

ALBERTA HEALTH LIAISONS:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 21, 2017. The Committee reviewed Manufacturer submissions for twenty-two (22) 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 four (4) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-three (23) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2017, and one (1) Drug Product underwent Expedited Review for listing on the *ADBL* effective November 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 the Expert Committee and added to the *ADBL* via Special Authorization for adjunctive therapy to levodopa for the treatment of patients with advanced stage Parkinson's disease, effective October 1, 2017:

- **NEUPRO*** (rotigotine) (UCB) **2 mg/24 hour, 4 mg/24 hour, 6 mg/24 hour & 8 mg/24 hour transdermal patches**

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

- **BASAGLAR** (insulin glargine) (LIL) **100 unit/mL injection cartridge & Kwikpen**

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 (11/2017)

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Step Therapy/ Special Authorization for the treatment of Type 2 diabetes (with criteria), effective October 1, 2017:

- **XIGDUO*** (dapagliflozin propanediol monohydrate/ metformin hydrochloride) (AZC) **5 mg/850 mg & 5 mg/1000 mg tablets**

Highlights of Line Extension Drug Products Added

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

- **JADENU*** (deferasirox) (NOV) **90 mg, 180 mg & 360 mg tablets**

Highlights of Expedited Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* via Restricted Benefit has resulted in the creation of a New IC Grouping, effective October 1, 2017:

- **APO-TENOFOVIR*** (tenofovir disoproxil fumarate) (APX) **300 mg tablet**
- **AURO-TENOFOVIR*** (tenofovir disoproxil fumarate) (AUR) **300 mg tablet**
- **MYLAN-TENOFOVIR*** (tenofovir disoproxil fumarate) (MYP) **300 mg tablet**
- **TEVA-TENOFOVIR*** (tenofovir disoproxil fumarate) (TEV) **300 mg tablet**

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Entry IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective November 1, 2017*:*

- **APO-DOXYLAMINE/B6** (doxylamine succinate/ pyridoxine HCl) (APX) **10 mg/10 mg SR tablet**
- **PMS-DOXYLAMINE-PYRIDOXINE** (doxylamine succinate/ pyridoxine HCl) (PMS) **10 mg/10 mg SR tablet**

Addition of the following Entry IC Drug Product to the *ADBL* via Special Authorization has resulted in the creation of New IC Grouping, effective November 1, 2017*:*

- **TARO-BENZOYL PEROXIDE/ CLINDAMYCIN*** (clindamycin phosphate/ benzoyl peroxide) (TAR) **5%/1% topical gel kit**

Highlights of Other Drug Products Added

The following Drug Product was reviewed as a Resubmission, and has been added to the *ADBL* effective November 1, 2017:

- **APO-TRAVOPROST Z** (travoprost) (APX) **0.004% ophthalmic solution**

Highlights of Changes to Currently Listed Products

Additional indications were added for the following Drug Product effective October 1, 2017:

- **HUMIRA*** (adalimumab) (ABV) **40 mg/0.8 mL injection syringe** for Ulcerative Colitis was reviewed by CDR and the Expert Committee and this indication is now eligible for coverage via Special Authorization.

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 (11/2017)

the DBL report

Issue #98, September 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)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC (Chair)
Saibal Nandy, MBBS, MRCPsych, FRCPC (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Fiona Clement, PhD
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Jeremy Slobodan, BSP

ALBERTA HEALTH LIAISONS:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 20, 2017. The Committee reviewed Manufacturer submissions for twenty (20) 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 fifty-two (52) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, sixteen (16) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2017, and four (4) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* as a Restricted Benefit, effective August 1, 2017:

- **EYLEA*** (aflibercept) (BAI) **2 mg/vial injection**

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization, effective September 1, 2017:

- **BRENZYS*** (etanercept) (SSB) **50 mg/mL auto-injector syringe and injection syringe**
- **ENTRESTO*** (sacubitril/valsartan) (NOV) **24.3 mg/25.7 mg, 48.6 mg/51.4 mg & 97.2 mg/102.8 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).*

ABC 81171 (09/2017)

Highlights of Drug Products Added

The following Non-Interchangeable Old Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective September 1, 2017:

- **M-ESLON IR** (morphine sulfate) (ETP) **5 mg, 10 mg, 20 mg & 30 mg capsules**

Highlights of Expedited Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective September 1, 2017*:*

- **CASPOFUNGIN*** (caspofungin) (MDA) **50 mg & 70 mg injections** listed via Restricted Benefit/SA
- **DEFERASIROX*** (various brands: APX, TAR, TEV) **125 mg, 250 mg, & 500 mg dispersible tablets for oral suspension** listed via Step Therapy/SA

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 September 1, 2017*:*

- **MINT-INDOMETHACIN** (indomethacin) (MPI) **25 mg & 50 mg capsules**

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective September 1, 2017, for the indication of chronic renal failure:

- **ARANESP*** (darbepoetin) (AMG) **10 mcg /0.4 mL & 20 mcg /0.5 mL injection syringes, 100 mcg /mL, 200 mcg/ mL & 500 mcg/mL injections, 10 mcg/0.4 mL, 20 mcg /0.5 mL, 30 mcg /0.3 mL, 40 mcg/0.4 mL, 50 mcg /0.5 mL, 60 mcg/ 0.3 mL, 80 mcg/0.4 mL, 100 mcg/ 0.5 mL, 130 mcg/0.65 mL, 150 mcg/0.3 mL, 200 mcg/0.4 mL, 300 mcg/0.6 mL, 500 mcg/1.0 mL singleject prefilled injection syringes**
- **EPREX*** (epoetin alfa) (JAI) **1,000 unit/0.5 mL, 2,000 unit/0.5 mL, 3,000 unit/0.3 mL, 4,000 unit/0.4 mL, 5,000 unit/0.5 mL, 6,000 unit/0.6 mL, 8,000 unit/0.8 mL, 10,000 unit/mL & 20,000 unit/0.5 mL injection syringes**

Restricted Benefit Criteria Changes

The Restricted Benefit criteria for coverage for the following Drug Product has been revised effective August 1, 2017 due to the addition of Eylea:

- **LUCENTIS*** (ranibizumab) (NOV) **2.3 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 (09/2017)

the DBL report

Issue #97, July 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)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC (Chair)
Saibal Nandy, MBBS, MRCPsych, FRCPC (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Fiona Clement, PhD
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Jeremy Slobodan, BSP

ALBERTA HEALTH LIAISONS:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 15 & 16, 2017. The Committee reviewed Manufacturer submissions for twenty-four (24) 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-three (23) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 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 the Expert Committee and added to the *ADBL* via Special Authorization, effective July 1, 2017:

- **ENTYVIO*** (vedolizumab) (TAK) **300 mg/vial injection**
- **FERRIPROX*** (deferiprone) (APP) **1000 mg tablet & 100 mg/mL oral solution**
- **PLEGRIDY*** (peginterferon beta-1a) (BIO) **63 mcg/94 mcg starter pack & 125 mcg pre-filled syringes/pens**

In keeping with recommendations from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **CORTIMENT** (budesonide) (FEI) **9 mg delayed and extended release tablet**
- **FENTORA** (fentanyl) (TMP) **100 mcg, 200 mcg, 400 mcg, 600 mcg & 800 mcg buccal/sublingual effervescent 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).*

ABC 81171 (07/2017)

Highlights of Devices Added

The following Device was added as a Restricted Benefit to the *ADBL* effective July 1, 2017 after a Full review by the Expert Committee:

- **AEROCHAMBER PLUS FLOW-VU CHAMBER*** (anti-static valved holding chamber/mask) (TMI) **with adult small mask**

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective July 1, 2017*:*

- **OLMESARTAN** (olmesartan medoxomil) (APH, APX, AUR, JPC and SDZ) **20 mg & 40 mg tablets**
- **OLMESARTAN/HCTZ** (olmesartan medoxomil/hydrochlorothiazide) (APH and APX) **20 mg/12.5 mg, 40 mg/12.5 mg & 40 mg/25 mg tablets**

Highlights of Non-Interchangeable Old Drug Products Added

The following Non-Interchangeable Old Drug Product has been added to the *ADBL* effective July 1, 2017:

- **LIDODAN** (lidocaine hydrochloride) (ODN) **2% topical jelly**

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 (07/2017)

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)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC (Chair)
Saibal Nandy, MBBS, MRCPsych, FRCPC (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
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Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Jeremy Slobodan, BSP

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Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

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**

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 (05/2017)

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**

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 (05/2017)

the DBL report

Issue #95, February 2017

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Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 24 & 25, 2016. The Committee reviewed Manufacturer submissions for thirty-one (31) 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 one hundred and eleven (111) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, four (4) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2016, and eleven (11) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 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 Product was reviewed by CDR and added to the *ADBL* via Special Authorization effective December 1, 2016:

- **INFLECTRA*** (infliximab) (CHH) **100 mg/vial injection** for the indications of Moderate to Severely Active Crohn's and Fistulizing Crohn's Disease and Ulcerative Colitis

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* as Regular Benefits, effective February 1, 2017:

- **ARNUITY ELLIPTA** (fluticasone furoate) (GSK) **100 mcg/dose & 200 mcg/dose powder for inhalation**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* via Step Therapy/Special Authorization effective February 1, 2017:

- **BREO ELLIPTA*** (fluticasone furoate/vilanterol trifenatate) (GSK) **200 mcg/25 mcg powder for inhalation**

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 (02/2017)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective December 1, 2016*:*

- **VISTITAN** (bimatoprost) (SDZ) **0.03% ophthalmic solution**

Vistitan is a pharmaceutical alternative which has been designated as interchangeable with Lumigan RC 0.01%. When Lumigan RC 0.01% was initially listed on the *ADBL*, based on evidence submitted by the Manufacturer, the Expert Committee on Drug Evaluation and Therapeutics considered it interchangeable with the original Lumigan 0.03% for purposes of the *ADBL*. Lumigan 0.03% was discontinued in 2013 and subsequently removed from the *ADBL.* Vistitan 0.03% has provided data demonstrating interchangeability with Lumigan 0.03%, thus is considered interchangeable with Lumigan RC 0.01% for purposes of the *ADBL*.

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

- **CEFAZOLIN** (cefazolin) (STM) **10 G/vial injection**
- **MYLAN-VERAPAMIL SR** (verapamil hydrochloride) (MYP) **240 mg sustained-release tablet**
- **SANDOZ PREDNISOLONE ACETATE** (prednisolone acetate) (SDZ) **1% ophthalmic suspension**

Highlights of Other Products Added

The following Non-Interchangeable Old Drug Product was added to the *ADBL* as a non-interchangeable Regular Benefit effective February 1, 2017:

- **JAMP-FOLIC ACID** (folic acid) (JPC) **5 mg tablet**

The following Natural Health Product was also reviewed by the Expert Committee and added to the *ADBL* as a non-interchangeable Regular Benefit effective February 1, 2017:

- **JAMP-K EFFERVESCENT** (potassium bicarbonate) (JPC) **975 mg (25 mEq) tablet**

Changes in Listing Status

The Expert Committee conducted a review of inhalers used in the treatment of Chronic Obstructive Pulmonary Disease (COPD) and asthma, in order to align their coverage status. As a result of the review, the Committee recommended changes to the listing status of all fixed-dose combination inhalers. Effective February 1, 2017, the listing status of the following products will be changed from Regular Benefit to Step Therapy/Special Authorization:

- **ADVAIR*** (salmeterol xinafoate/fluticasone propionate) (GSK) **125 mcg & 250 mcg metered dose aerosols and 100 mcg, 250 mcg & 500 mcg diskus powder for inhalation**
- **SYMBICORT TURBUHALER*** (budesonide/formoterol fumarate dihydrate) (AZC) **100 & 200 metered inhalation powder**

In addition, effective February 1, 2017, the listing status of the following products will be revised from Special Authorization to Step Therapy/Special Authorization:

- **ANORO ELLIPTA*** (umeclidinium bromide/ vilanterol trifenatate) (GSK) **62.5 mcg/25 mcg inhalation powder**
- **BREO ELLIPTA*** (fluticasone furoate/vilanterol trifenatate) (GSK) **100 mcg/25 mcg powder for inhalation**
- **DUAKLIR GENUAIR*** (aclidinium bromide/ formoterol fumarate dihydrate) (AZC) **400 mcg/12 mcg inhalation powder**
- **INSPIOLTO RESPIMAT*** (tiotropium bromide monohydrate/ olodaterol hydrochloride) (BOE) **2.5 mcg/actuation inhalation solution**
- **ULTIBRO BREEZHALER*** (indacaterol maleate/ glycopyrronium bromide) (NOV) **110 mcg/50 mcg inhalation capsule**

The listing status of select anti-infective medications was reviewed by the Expert Committee. As a result of their deliberations, certain anti-infectives will be made available to Specialists in Infectious Diseases as Restricted Benefits, and will continue to be available through the Special Authorization process for all other prescribers. The following products will be changed from Special Authorization to Restricted Benefit/Special Authorization effective February 1, 2017:

- **AMPICILLIN* 250 mg & 500 mg capsules** (all brands)
- **AZITHROMYCIN* 600 mg tablet** (all brands)
- **CANCIDAS*** (caspofungin) (MFC) **50 mg & 70 mg injection**
- **CEFADROXIL* 500 mg capsule** (all brands)
- **CEFOXITIN* 1 gram & 2 gram vials for injection** (all brands)
- **DIFLUCAN*** (fluconazole) (PFI) **10 mg/mL oral suspension**
- **INVANZ*** (ertapenem) (MFC) **1 gram vial injection**
- **LINEZOLID* 600 mg tablet** (all brands)
- **MEROPENEM* 500 mg & 1 gram vials for injection** (all brands)
- **MYCOBUTIN*** (rifabutin) (PFI) **150 mg capsule**
- **PIPERACILLIN/TAZOBACTAM* 2 gram/250 mg, 3 gram/375 mg & 4 gram/500 mg vials for injection** (all brands)
- **PRIMAXIN*** (imipenem/cilastatin) (MFC) **500 mg/500 mg vial for injection**
- **SPORANOX*** (itraconazole) (JAI) **10 mg/mL oral solution**
- **VANCOMYCIN* 125 mg & 250 mg capsules** (all brands)
- **VORICONAZOLE* 50 mg & 200 mg tablets, 40 mg/mL oral suspension & 200 mg/vial injection** (all brands)

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 (02/2017)

Changes in Listing Status, cont.

Effective February 1, 2017, the status of all brands of clopidogrel currently listed on the *ADBL* will change from a Limited Restricted Benefit/Special Authorization to a Regular Benefit.

Special Authorization Criteria Change

Due to the limited availability of the Insulin Tolerance Test (ITT) in some regions of Alberta, the Special Authorization Criteria of the following Drug Products have been revised to allow the use of an alternative, the glucagon stimulation test, effective February 1, 2017:

- **GENOTROPIN*** (somatropin) (PFI) **Miniquick 0.6 mg, 0.8 mg, 1 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg & 2 mg injection syringes, and Goquick 5.3 mg & 12 mg pen injection syringes**
- **HUMATROPE*** (somatropin) (LIL) **6 mg & 12 mg injections**
- **OMNITROPE*** (somatropin r-dna origin) (SDZ) **5 mg/1.5 mL & 10 mg/1.5 mL injection cartridges**
- **SAIZEN*** (somatropin r-dna origin) (SRO) **3.3 mg, 5 mg & 8.8 mg injections and 6 mg, 12 mg & 20 mg cartridges**

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).*

the ADBL report

Issue #94, November 2016

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Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 22, 2016. The Committee reviewed Manufacturer submissions for thirty-six (36) 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-nine (29) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, eight (8) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2016, and one (1) Drug Product underwent Expedited Review for listing on the *ADBL* effective November 1, 2016.

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 the Expert Committee and added to the *ADBL* via Special Authorization effective November 1, 2016:

- **ESBRIET*** (pirfenidone) (HLR) **267 mg capsule**
- **OFEV*** (nintedanib esilate) (BOE) **100 mg & 150 mg capsules**

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 November 1, 2016*:*

- **JAMP-BEZAFIBRATE** (bezafibrate) (JPC) **400 mg sustained-release tablet**

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 (11/2016)

The following IC Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective November 1, 2016:

- **MYLAN-VERAPAMIL SR** (verapamil hydrochloride) (MYP) **180 mg sustained-release tablet**
- **SANDOZ CIPROFLOXACIN** (ciprofloxacin hydrochloride) (SDZ) **0.3% ophthalmic solution**

The following IC Drug Product was reviewed by the Expert Committee and added to the *ADBL* as a Restricted Benefit effective November 1, 2016:

- **SANDOZ MOMETASONE** (mometasone furoate) (SDZ) **50 mcg/dose aqueous nasal spray**

Highlights of Other Products Added

The following Infant Formula was added to the *ADBL* via Special Authorization effective November 1, 2016:

- **PURAMINO A+*** (infant formula) (MJO) **powder**

The following Natural Health Products were reviewed by the Expert Committee and added to the *ADBL* effective November 1, 2016*:*

- **DERMAFLEX HC** (hydrocortisone acetate/urea) (PAL) **1% cream & topical lotion**

Maximum Allowable Cost (MAC) New Category

On October 1, 2016, Alberta government sponsored plans introduced Maximum Allowable Cost (MAC) pricing for eligible proton pump inhibitors (PPI), with the MAC price based on the lowest cost PPI. This change was made based on the evidence and advice of expert bodies from across Canada. According to work done by the Canadian Agency for Drug and Technologies in Health, all medications for acid reflux conditions are considered therapeutically similar and equally effective. Choosing Wisely Canada, in partnership with the Canadian Medical Association, has patient information regarding the use of PPIs available online at

http://www.choosingwiselycanada.org/wp-content/uploads/2014/09/GERD-EN-web.pdf

There is a four month transition which will allow patients currently using a PPI that is not the MAC product to have their prescription changed to the MAC product, if appropriate. Starting in February 2017, coverage will be provided only to the level of the lowest cost medication for the category.

The following IC groupings* are affected*:*

Lansoprazole (various brands) **15 mg delayed-release capsule**	*MAC pricing for products in these IC groupings will be applied February 1, 2017 based on the LCA Price for Rabeprazole Sodium 1 X 10 mg enteric-coated tablet.*
Omeprazole (various brands) **10 mg capsule/sustained-release tablet**	
Rabeprazole sodium (various brands) **10 mg enteric-coated tablet**	
Lansoprazole (various brands) **30 mg delayed-release capsule**	*MAC pricing for products in these IC groupings will be applied February 1, 2017 based on the LCA Price for Pantoprazole Magnesium 1 X 40 mg enteric-coated tablet.*
Omeprazole (various brands) **20 mg capsule/sustained-release tablet**	
Pantoprazole magnesium (various brands) **40 mg enteric-coated tablet**	
Pantoprazole sodium (various brands) **40 mg enteric-coated tablet**	
Rabeprazole sodium (various brands) **20 mg enteric-coated tablet**	

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 (11/2016)

the DBL report

Issue #93, September 2016

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In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 21, 2016. The Committee reviewed Manufacturer submissions for forty-four (44) 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 three (3) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, four (4) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2016, and six (6) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 1, 2016.

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 the Expert Committee and added to the *ADBL* via Special Authorization effective August 1, 2016:

- **COSENTYX*** (secukinumab) (NOV) **150 mg/mL injection syringe**
- **XELJANZ*** (tofacitinib citrate) (PFI) **5 mg tablet**

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization effective September 1, 2016:

- **LEMTRADA*** (alemtuzumab) (GZM) **12 mg/1.2 mL injection**
- **ZAXINE*** (rifaximin) (SLX) **550 mg tablet**

In keeping with recommendations from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **FORXIGA** (dapagliflozin propanediol monohydrate) (AZC) **5 mg & 10 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).*

ABC 81171 (09/2016)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *Palliative Care Drug Benefit Supplement* has resulted in the creation of New IC Groupings, effective September 1, 2016*:*

- **BUPIVACAINE** (bupivicaine hydrochloride) (STM) **2.5 mg/mL & 5 mg/mL injections**

The following IC Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective September 1, 2016:

- **ACT BUPROPION XL** (bupropion hydrochloride) (APH) **150 mg & 300 mg extended-release tablets**
- **AURO-BETAHISTINE**(betahistine dihydrochloride) (AUR) **16 mg tablet**
- **NAT-GRANISETRON** (granisetron hydrochloride) (NTP) **1 mg tablet**
- **VAN-RAMIPRIL** (ramipril) (VAN) **1.25 mg, 2.5 mg, 5 mg & 10 mg capsules**

Highlights of Other Products Added

The following Drug Product was added to the *ADBL* as a Regular Benefit effective September 1, 2016:

- **AURO-BETAHISTINE**(betahistine dihydrochloride) (AUR) **8 mg tablet**

The following Natural Health Product was reviewed by the Expert Committee and added to the *ADBL* September 1, 2016*:*

- **JAMP-SODIUM PHOSPHATE** (sodium acid phosphate/sodium bicarbonate/potassium bicarbonate) (JPC) **500 mg/469 mg/123 mg effervescent tablet**

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 (09/2016)

the DBL report

Issue #92, July 2016

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In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 16 & 17, 2016. 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 seventy-four (74) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-three (23) Drug Products underwent Expedited Review for listing on the *ADBL* effective June 1, 2016, and thirty (30) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 1, 2016.

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 the Expert Committee and added to the *ADBL* via Step Therapy/Special Authorization (SA) effective June 1, 2016:

- **JARDIANCE*** (empagliflozin) (BOE) **10 mg & 25 mg tablets**

In keeping with recommendations from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **JINARC** (tolvaptan/tolvaptan) (OTS) **45 mg/15 mg, 60 mg/30 mg & 90 mg/30 mg combination packs**

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 (07/2016)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective July 1, 2016*:*

- **DULOXETINE** (duloxetine hydrochloride) (APX, AUR, JPC, MAR, MPI, PMS, RAN, SDZ, SIV, and TEV) **30 mg & 60 mg delayed-release capsules**
- **LUPIN-ESTRADIOL** (estradiol-17ß) (LPC) **0.5 mg, 1 mg & 2 mg tablets**

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Product has been revised effective June 1, 2016:

- **NEUPOGEN*** (filgrastim) (AMG) **0.3 mg/mL 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 (07/2016)

the DBL report

Issue #91, May 2016

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC (Chair)
Saibal Nandy, MBBS, MRCPsych, FRCPC (Vice-Chair)
Caitlin A. Clarke, BScPharm, PharmD
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Jeremy Slobodan, BSP

ALBERTA HEALTH LIAISONS:
Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 17, 2016. The Committee reviewed Manufacturer submissions for thirty-eight (38) 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 fourteen (14) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty (30) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 1, 2016.

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 Product was review by CDR and the Expert Committee and added to the *ADBL* via Special Authorization (SA) for the indications of Ankylosing Spondylitis, Plaque Psoriasis, Psoriatic Arthritis and Rheumatoid Arthritis effective April 1, 2016:

- **INFLECTRA*** (infliximab) (CHH) **100 mg/vial injection**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective May 1, 2016:

- **SPIRIVA RESPIMAT** (tiotropium bromide monohydrate) (BOE) **2.5 mcg actuation inhalation solution**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* via SA effective May 1, 2016:

- **INSPIOLTO RESPIMAT*** (tiotropium bromide monohydrate/olodaterol hydrochloride) (BOE) **2.5 mcg/2.5 mcg actuation inhalation solution**

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 (05/2016)

Highlights of Non-Interchangeable Old Drug Products Added

The following Non-Interchangeable Old Drug Product has been added to the *Palliative Coverage Drug Benefit Supplement (PCDBS)* effective May 1, 2016:

- **EMOLAX** (polyethylene glycol 3350) (JPC) **1 g/g oral powder**

Highlights of Line Extension Drug Products Reviewed for the ADBL

The following Drug Product was added to the *ADBL* as a Regular Benefit effective May 1, 2016:

- **MINT-CITALOPRAM** (citalopram hydrobromide) (MPI) **10 mg tablet**

The following Drug Product was reviewed but **NOT** added as it did not offer a cost or therapeutic advantage:

- **PLAN B** (levonorgestrel) (PAL) **1.5 mg tablet**

Highlights of Other Products Reviewed but Not Added

- **ANTI-STATIC COMPACT SPACE CHAMBER PLUS** (aerosol holding chamber/mask) (MPI) **WITH MOUTHPIECE, and SMALL/MEDIUM/ LARGE MASKS** were reviewed but not added as they fail to offer a cost or therapeutic advantage.

Highlights of Interchangeable Drug Products Reviewed

The following Drug Product was reviewed by the Expert Committee as a Resubmission and was added to the *ADBL* effective May 1, 2016*:*

- **AZATHIOPRINE** (azathioprine) (SNS) **50 mg tablet**

The following Drug Product was reviewed by the Expert Committee and added via Optional Special Authorization effective May 1, 2016*:*

- **APO-MOXIFLOXACIN*** (moxifloxacin HCL) (APX) **400 mg tablet**

Highlights of Other Products Added

The following Product was reviewed by the Expert Committee and added to the *ADBL* via SA effective May 1, 2016*:*

- **NEOCATE WITH DHA & ARA*** (NUN) **oral powder infant formula**

Please note that the coverage criteria for this product on the *Human Services Drug Benefit Supplement (HSDBS)* will remain unchanged.

Highlights of New Interchangeable (IC) Groupings

Addition of the following Drug Products to the *ADBL* has resulted in the creating of a New IC Grouping, effective May 1, 2016*:*

- **TEVA-TOBRAMYCIN** (tobramycin sulfate) (TEV) **60 mg/mL inhalation solution**
- **TOBRAMYCIN** (tobramycin sulfate) (SDZ) **60 mg/mL inhalation solution**

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Products have been revised effective May 1, 2016:

- **JAMP-VANCOMYCIN*** (vancomycin HCL) (JPC) **125 mg & 250 mg capsules**
- **RITUXAN*** (rituximab) (HLR) **10 mg/mL injection**
- **VANCOCIN*** (vancomycin HCL) (MLI) **125 mg & 250 mg capsules**
- **VANCOMYCIN HYDROCHLORIDE*** (vancomycin HCL) (FKC) **125 mg & 250 mg capsules**

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 (05/2016)

the ADBL report

Issue #90, March 1, 2016

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC
Saibal Nandy, MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP

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Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

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Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 21, 2016. 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 twenty-six (26) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-nine (39) Drug Products underwent Expedited Review for listing on the *ADBL* effective March 1, 2016.

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 by CDR

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization effective March 1, 2016:

- **ACTEMRA*** (tocilizumab) (HLR) **162 mg/0.9 mL injection syringe** for the indication of Rheumatoid Arthritis
- **CIMZIA*** (certolizumab pegol) (UCB) **200 mg/mL injection syringe** for the indications of Rheumatoid Arthritis, Psoriatic Arthritis and Ankylosing Spondylitis
- **DIFICID*** (fidaxomicin) (MFC) **200 mg film-coated tablet**

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 (03/2016)

Highlights of Devices Added

The following Devices were added as Restricted Benefits to the *ADBL* effective March 1, 2016 after a Full review by the Expert Committee:

- **INSPIRACHAMBER*** (anti-static valved holding chamber) (LPC) **with mouthpiece, small mask/soothermask & medium mask/soothermask**

Highlights of Line Extension Drug Products Reviewed for the ADBL

The following Drug Product was added as a regular benefit to the *ADBL* effective March 1, 2016:

- **MYLAN-VALACYCLOVIR** (valacyclovir) (MYP) **1000 mg caplet**

Highlights of Other Drug Products Reviewed but Not Added

The following Drug Products were reviewed by the Expert Committee and have not been added to the *ADBL*:

- **JANUMET XR** (sitagliptin phosphate monohydrate/metformin hydrochloride) (MFC) **50 mg/500 mg, 50 mg/1000 mg & 100 mg/1000 mg extended-release tablets**
- **FORXIGA** (dapagliflozin propanediol monohydrate) (AZC) **5 mg & 10 mg tablets**

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:

- **ROSIVER** (ivermectin) (GAL) **1% topical cream**

In keeping with recommendations from the CDR, the following Drug Product has not been added to the *ADBL:*

- **ELELYSO** (taliglucerase alfa) (PFI) **200 unit/vial injection**

Highlights of Interchangeable Drug Products Reviewed

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective March 1, 2016:

- **AURO-VALACYCLOVIR** (valacyclovir) (AUR) **500 mg tablet**

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* via Optional Special Authorization effective March 1, 2016:

- **TEVA-MOXIFLOXACIN*** (moxifloxacin hydrochloride) (TEV) **400 mg tablet**

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* via Special Authorization effective March 1, 2016. This Drug Product will be interchangeable with Clindoxyl topical gel:

- **TARO-CLINDAMYCIN/BENZOYL PEROXIDE*** (clindamycin phosphate/ benzoyl peroxide) (TAR) **1%/5% topical gel**

Highlights of Natural Health Products Added

The following Natural Health Product has been added to the *ADBL* effective March 1, 2016:

- **JAMP-HYDROCORTISONE** (hydrocortisone) (JPC) **1% topical lotion**

Change in Listing Status

Current pricing and listing status was reviewed and the Expert Committee recommended that the benefit listing status of the following Drug Products be changed from Special Authorization to Regular benefits:

- **DUTASTERIDE** 0.5 mg capsules (all brands)
- **FINASTERIDE** 5 mg tablets (all brands)

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 (03/2016)

the DBL report

Issue #89, February 1, 2016

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC
Saibal Nandy, MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP

ALBERTA HEALTH LIAISONS:
Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 26, 2015. The Committee reviewed Manufacturer submissions for nineteen (19) 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 eight (8) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, twenty-seven (27) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2015, and twenty-seven (27) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 1, 2016.

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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective December 1, 2015:

- **SIMBRINZA** (brinzolamide/brimonidine tartrate) (ALC) **1%/0.2% ophthalmic suspension**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* as a Restricted Benefit effective January 1, 2016:

- **FIBRISTAL*** (ulipristal acetate) (ASC) **5 mg tablet**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization effective January 1, 2016:

- **FIRAZYR*** (icatibant acetate) (SOT) **10 mg/mL (3 mL) injection syringe**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective February 1, 2016:

- **INCRUSE ELLIPTA** (umeclidinium bromide) (GSK) **62.5 mcg inhalation powder**

The following Drug Product was reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization effective February 1, 2016:

- **DUAKLIR GENUAIR*** (aclidinium bromide/formoterol dihydrate) (AZC) **400 mcg/12 mcg inhalation powder**

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 (02/2016)

Highlights of Line Extension Drug Products Reviewed for the ADBL

The following Drug Product was added as a Regular Benefit to the *ADBL* effective December 1, 2015:

- **LODALIS** (colesevelam hydrochloride) (VCL) **3.75 gram/dose oral powder packet**

The following Drug Product was added to the *ADBL* via Special Authorization effective December 1, 2015:

- **IBAVYR*** (ribavirin) (PPH) **200 mg tablet**

The following Drug Product was added to the *ADBL* as a Regular Benefit effective February 1, 2016:

- **HUMALOG** (insulin lispro) (LIL) **200 unit/mL injection Kwikpen**

Highlights of Other Products Reviewed but Not Added

The following Drug Products were reviewed by the Expert Committee and have not been added to the *ADBL* because they do not offer a therapeutic advantage:

- **BUTRANS 5, BUTRANS 10 & BUTRANS 20** (buprenorphine) (PUR) **5 mcg/hr, 10 mcg/hr & 20 mcg/hr transdermal patches**.

In keeping with recommendations from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **CONSTELLA** (linaclotide) (FLC) **145 mcg & 290 mcg capsules**

Highlights of Interchangeable Drug Products Reviewed

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective February 1, 2016*:*

- **CO VALACYCLOVIR** (valacyclovir) (APH) **500 mg tablet (caplet)**
- **PMS-VALACYCLOVIR** (valacyclovir) (PMS) **1000 mg caplet**

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* via Step Therapy/Special Authorization effective February 1, 2016*:*

- **SANDOZ SOLIFENACIN*** (solifenacin succinate) (SDZ) **5 mg & 10 mg tablets**

Special Authorization Criteria Changes

Due to the addition of Aptiom, a new antiepileptic drug, the Special Authorization criteria for coverage for the following Drug Products have been revised effective December 1, 2015:

- **FYCOMPA*** (perampanel) (EIS) **2 mg, 4 mg, 6 mg, 8 mg, 10 mg & 12 mg tablets**
- **VIMPAT*** (lacosamide) (UCB) **50 mg, 100 mg, 150 mg & 200 mg tablets**

The Special Authorization criteria for coverage for the following Drug Products have been revised effective January 1, 2016:

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

The Special Authorization criteria for coverage for the following Drug Product have been revised for a number of reasons effective February 1, 2016:

- **PROLIA*** (denosumab) (AMG) **60 mg/mL injection syringe**

The SA criteria have been updated to include the indication of Osteoporosis in Men. The SA criteria were also modified to provide greater clarity with regard to esophageal abnormalities, and to allow for denosumab to be used for patients in whom bisphosphonates are contraindicated due to severe renal impairment.

The Special Authorization criteria for coverage for the following Drug Products have also been revised to clarify esophageal abnormalities, effective February 1, 2016:

- **ACLASTA*** (zoledronic acid) (NOV) **5 mg/100 mL injection**
- **TARO-ZOLEDRONIC ACID*** (zoledronic acid) (TAR) **5 mg/100 mL injection**
- **ZOLEDRONIC ACID*** (zoledronic acid) (TEV) **5 mg/100 mL injection**
- **ZOLEDRONIC ACID*** (zoledronic acid) (DRL) **5 mg/100 mL injection**

ROBS Review of Growth Hormone Products

As part of the Review of Benefit Status (ROBS) process, comprehensive clinical reviews of growth hormone products were undertaken. Following discussion and consultation with stakeholders, and examination of all information available, the Expert Committee recommended that the Special Authorization criteria for somatropin Drug Products should not be changed, and should remain as currently listed.

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 (02/2016)

the ADBL report

Issue #88, November 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Saibal Nandy, MBBS, MRCPsych, FRCPC (Vice-chair)
Jeffrey A. Johnson, BSP, MSc, PhD
Scott Klarenbach, MD, MSc (Health Econ), FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP

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Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 22, 2015. The Committee reviewed Manufacturer submissions for forty-eight (48) 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 twelve (12) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-two (32) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2015, and five (5) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 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

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* via Step Therapy/Special Authorization effective October 1, 2015:

- **INVOKANA*** (canagliflozin) (JAI) **100 mg & 300 mg tablets**

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via Special Authorization (SA) effective October 1, 2015:

- **DIACOMIT*** (stiripentol) (BCF) **250 mg & 500 mg capsules and 250 mg & 500 mg oral powder packets**

The following Drug Products were reviewed by CDR and the Expert Committee and added to the *ADBL* via SA effective November 1, 2015:

- **APTIOM*** (eslicarbazepine acetate) (SUN) **200 mg, 400 mg, 600 mg & 800 mg tablets**
- **MODERIBA*** (ribavirin) (ABV) **200 mg, 400 mg & 600 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).*

ABC 81171 (11/2015)

Highlights of Non-Interchangeable Old Drug Products Added

The following Non-Interchangeable Old Drug Product has been added to the *ADBL* effective November 1, 2015:

- **JAMP-NYSTATIN** (nystatin) (JPC) **100,000 unit/mL oral suspension**

Highlights of Line Extension Drug Products Reviewed for the ADBL

The following Drug Product was added to the *ADBL* as a Restricted Benefit effective November 1, 2015:

- **ASMANEX TWISTHALER** (mometasone furoate) (MFC) **100 mcg/dose metered inhalation powder**

The following Drug Products were added as Regular Benefits effective November 1, 2015:

- **FRAGMIN** (dalteparin sodium) (PFI) **3,500 IU/0.28 mL injection**
- **APO-VALACYCLOVIR** (valacyclovir) (APX) **1000 mg caplet**

The following Drug Products were reviewed but **NOT** added as they did not offer a therapeutic advantage:

- **TOUJEO SOLOSTAR** (insulin glargine) (SAV) **300 unit/mL injection**
- **VYVANSE** (lisdexamfetamine dimesylate) (SHB) **10 mg capsule**

Highlights of Other Products Reviewed but Not Added

- **TARGIN** (oxycodone HCL/ naloxone HCL) (PUR) **5 mg/2.5 mg, 10 mg/5 mg, 20 mg/10 mg & 40 mg/20 mg extended-release tablets** were reviewed but not added as they fail to offer a therapeutic advantage.

In keeping with recommendations from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **OTEZLA & OTEZLA STARTER PACK** (apremilast) (CLG) **30 mg & 10 mg/20 mg/30 mg tablets**
- **DYMISTA** (fluticasone propionate/ azelastine hydrochloride) (MDP) **50 mcg/137 mcg metered dose nasal spray**

Highlights of Interchangeable Drug Products Reviewed

The following Drug Products were reviewed by the Expert Committee and added to the *ADBL* effective November 1, 2015*:*

- **APO-DEXTROAMPHETAMINE** (dextroamphetamine sulfate) (APX) **5 mg tablet**
- **APO-VALACYCLOVIR** (valacyclovir) (APX) **500 mg caplet**
- **METHOTREXATE (PRESERVED)** (methotrexate sodium) (SDZ) **25 mg/mL injection USP**
- **MOVISSE** (norethindrone) (FMP) **0.35 mg tablet**
- **MYLAN-GLICLAZIDE MR** (gliclazide) (MYP) **30 mg sustained-release tablet**
- **MYLAN-VALACYCLOVIR** (valacyclovir) (MYP) **500 mg caplet**
- **PMS-VALACYCLOVIR** (valacyclovir) (PMS) **500 mg caplet**
- **VAN-GABAPENTIN** (gabapentin) (VAN) **100 mg, 300 mg & 400 mg capsules**

The following Drug Products were reviewed by the Expert Committee and added via Restricted Benefit/ Special Authorization effective November 1, 2015*:*

- **MINT-RIZATRIPTAN ODT** (rizatriptan benzoate) (MPI) **5 mg & 10 mg orally disintegrating tablets**

Highlights of Product Listing Changes

The following Drug Products were reviewed by the Expert Committee, and in order to enable improved patient access, these products were changed from Special Authorization to Regular Benefits on the *ADBL* effective November 1, 2015*:*

- **Valganciclovir HCL** (VALCYTE, Teva and Apotex brands) **450 mg tablets,** and **Valganciclovir HCL** (VALCYTE brand) **50 mg/mL oral suspension**

Special Authorization Criteria Changes

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

- **TYSABRI*** (natalizumab) (BIO) **20 mg/mL (15 mL) injection**
- **ELIQUIS*** (apixaban) (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).*

ABC 81171 (11/2015)

the DBL report

Issue #87, September 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
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Scott Klarenbach, MD, MSc (Health Econ), FRCPC
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Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 9, 2015. The Committee reviewed Manufacturer submissions for fifty (50) 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-nine (29) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, seventeen (17) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2015 and twenty-seven (27) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 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

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* via Special Authorization (SA) effective September 1, 2015:

- **ABILIFY MAINTENA*** (aripiprazole) (OTS) **300 mg/vial & 400 mg/vial injections**
- **BANZEL*** (rufinamide) (EIS) **100 mg, 200 mg & 400 mg tablets**
- **INSPRA*** (eplerenone) (PFI) **25 mg & 50 mg tablets**
- **ULTIBRO BREEZHALER*** (indacaterol maleate/ glycopyrronium bromide) (NOV) **110 mcg/50 mcg inhalation capsule**

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

- **HOLKIRA PAK*** (ombitasvir/ paritaprevir/ ritonavir/ dasabuvir sodium monohydrate) (ABV) **12.5 mg/75 mg/50 mg/250 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).*

ABC 81171 (09/2015)

The following Drug Products were reviewed by CDR and the Expert Committee and were added to the *ADBL* via Step Therapy / Special Authorization effective September 1, 2015:

- **MYRBETRIQ*** (mirabegron) (ASP) **25 mg & 50 mg extended-release tablets**

Highlights of Other Products Reviewed but Not Added

- **COMBIVENT RESPIMAT** (ipratropium bromide/salbutamol) (BOE) **20 mcg/100 mcg inhalation solution** re-submission was reviewed as a Line Extension to Combivent nebules but was not added as this Drug Product fails to offer a therapeutic advantage.

In keeping with recommendations from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **AFINITOR** (everolimus) (NOV) **2.5 mg, 5 mg & 10 mg tablets**
- **JUXTAPID** (lomitapide mesylate) (AEP) **5 mg, 10 mg & 20 mg capsules**

Highlights of Interchangeable Drug Products Added

The following Drug Product was reviewed by the Expert Committee and added to the *ADBL* effective September 1, 2015*:*

- **TEVA-PROGESTERONE with peanut oil**** (progesterone) (TEV) **100 mg capsule**

****Note:** Due to the high prevalence of peanut allergies within the population, Alberta Health has chosen to highlight the fact that Teva-Progesterone 100mg Capsule (DIN 02439913) contains peanut oil while the brand name drug product, Prometrium 100 mg Capsule (DIN 02166704) does not. Please note that the Expert Committee does not regularly review possible allergens within drug products listed on the *ADBL* and it remains the responsibility of the prescribing physician and dispensing pharmacist to review all patient allergies.

The following Drug Product was reviewed by the Expert Committee and added to the *Palliative Coverage Drug Benefit Supplement* effective September 1, 2015*:*

- **RELAXA** (PEG 3350) (RED) **oral powder**

Special Authorization Criteria Changes

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

- **GILENYA*** (fingolimod HCL) (NOV) **0.5 mg capsule**
- **IBAVYR*** (ribavirin) (PPH) **400 mg & 600 mg tablets**
- **TYSABRI*** (natalizumab) (BIO) **20 mg/mL (15 mL) 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 (09/2015)

the DBL report

Issue #86, July 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Saibal Nandy, MBBS, MRCPsych, FRCPC (Vice-chair)
Jeffrey A. Johnson, BSP, MSc, PhD
Scott Klarenbach, MD, MSc (Health Econ), FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP

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Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 12 & 13, 2015. The Committee reviewed Manufacturer submissions for seventy-three (73) 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, eight (8) Drug Products underwent Expedited Review for listing on the *ADBL* effective June 1, 2015 and seven (7) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 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

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

The following Drug Products were reviewed by CDR and the Expert Committee and were added to the *ADBL* via Special Authorization (SA) effective June 1, 2015:

- **ANORO ELLIPTA*** (umeclidinium bromide/vilanterol trifenatate) (GSK) **62.5 mcg/25 mcg metered inhalation powder**
- **BREO ELLIPTA*** (fluticasone furoate/vilanterol trifenatate) (GSK) **100 mcg/25 mcg metered inhalation powder**

The following Drug Product was reviewed by CDR and the Expert Committee and was added to the *ADBL* via SA effective July 1, 2015:

- **CUBICIN*** (daptomycin) (CUB) **500 mg/vial injection**

The following Drug Products were reviewed by the CDR and the Expert Committee and were not added to the *ADBL*:

- **REVOLADE** (eltrombopag olamine) (GSK) **25 mg & 50 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).*

ABC 81171 (07/2015)

In keeping with the recommendation from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **SIGNIFOR** (pasireotide diaspartate) (NOV) **0.3 mg/mL, 0.6 mg/mL & 0.9 mg/mL injections**
- **VIMIZIM** (elosulfase alfa) (BMI) **5 mg/5 mL (single-use) vial injection**

Highlights of Products Not Added

- **COLCHICINE** (colchicine) (EUP) **0.6 mg tablet** was reviewed as a Resubmission. This Drug Product was not recommended for addition to the *ADBL* as there was insufficient information upon which to base an interchangeability designation.
- **TIMOLOL MALEATE-EX** (timolol maleate) (ALC) **0.25% & 0.5% ophthalmic solutions** were reviewed under the Interchangeable Drug Products submission category. As no new information was provided in the current submission to warrant a change to their previous recommendation, the Expert Committee upheld their prior recommendation to not add these Drug Products to the *ADBL*.
- **VIDEXTRA** (vitamin D3) (ORI) **10,000 unit tablet** was reviewed under the Non-Interchangeable Old Drug Products submission category. The Expert Committee advised that this Drug Product does not offer a therapeutic advantage over the alternative over-the-counter vitamin D3 Drug Products. Accordingly, this Drug Product was not recommended for addition to the *ADBL*.

Highlights of Non-Interchangeable Old Drug Products Added

The following Non-Interchangeable Old Drug Product has been added to the *ADBL* effective July 1, 2015:

- **METADOL-D** (methadone hydrochloride) (PAL) **1 mg/mL oral solution**

Highlights of Line Extension Drug Products Reviewed for Addition to the ADBL

The following Drug Product was added to the *ADBL* effective July 1, 2015 after a Full review by the Expert Committee:

- **METADOL-D CONCENTRATE** (methadone hydrochloride) (PAL) **10 mg/mL oral liquid**

Highlights of Interchangeable Drug Products Added

Due to recent changes to the front section of the *ADBL*, there are now published criteria specific to the use of Canadian Non-Innovator Reference Products (CNIRPs). As of April 1, 2015, the Expert Committee is able to consider demonstration of bioequivalence with a CNIRP as evidence of interchangeability. Each of the following Drug Products were reviewed as Resubmissions by the Expert Committee and were added to the *ADBL* effective July 1, 2015*:*

- **MAR-DOMPERIDONE** (domperidone maleate) (MAR) **10 mg tablet**
- **MYLAN-BISOPROLOL** (bisoprolol fumarate) (MYP) **5 mg & 10 mg tablets**

Highlights of Drug Products De-Listed from the ADBL

The following Drug Product was de-listed and removed from the *ADBL* effective July 1, 2015:

- **Synacthen Depot** (cosyntropin zinc hydroxide complex) (QST) **1 mg/mL injection**

Special Authorization Criteria Changes

The criteria for coverage via Special Authorization for the following Drug Product have been revised effective June 1, 2015 to enable improved patient access:

- **XOLAIR*** (omalizumab) (NOV) **150 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 (07/2015)

the DBL report

Issue #85, May 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Saibal Nandy, MBBS, MRCPsych, FRCPC (Vice-chair)
Jeffrey A. Johnson, BSP, MSc, PhD
Scott Klarenbach, MD, MSc (Health Econ), FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP

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Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

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Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 12, 2015. 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 twenty-eight (28) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, nineteen (19) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 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

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

The following Drug Products were reviewed by CDR and the Expert Committee and were added effective May 1, 2015:

- **ACTEMRA*** (tocilizumab) (HLR) **80 mg/4 mL & 200 mg/10 mL vial injections** via Special Authorization for the new indication of polyarticular Juvenile Idiopathic Arthritis (pJIA)

In keeping with the recommendation from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **KAZANO** (alogliptin benzoate/metformin hydrochloride) (TAK) **12.5 mg/500 mg, 12.5 mg/850 mg & 12.5 mg/1000 mg tablets**
- **NESINA** (alogliptin benzoate) (TAK) **6.25 mg, 12.5 mg & 25 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).*

ABC 81171 (05/2015)

Highlights of Line Extension Drug Products Added to the ADBL

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

- **INNOHEP** (tinzaparin sodium) (LEO) **8,000 IU, 12,000 IU & 16,000 IU injection syringes**
- **LEVEMIR FLEXTOUCH** (insulin detemir) (NNA) **100 unit/mL injection**
- **PREMARIN** (conjugated estrogens) (PFI) **0.3 mg, 0.625 mg & 1.25 mg sustained-release tablets** as a single-source product as the old formulation Premarin products are discontinued.

Highlights of Natural Health Products (NHPs) Not Added

The following Natural Health Product has not been added to the *ADBL* as it fails to demonstrate a therapeutic advantage:

- **PHARMA-K20** (potassium chloride) (PMS) **20 mEq sustained release tablet**

Special Authorization Criteria Changes

The criteria for coverage via Special Authorization for the following Drug Products have been revised:

- **RISPERDAL CONSTA*** (risperidone) (JAI) **25 mg, 37.5 mg & 50 mg per vial injections**
- **INVEGA SUSTENNA*** (paliperidone palmitate) (JAI) **50 mg, 75 mg, 100 mg & 150 mg injection syringes**

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 (05/2015)

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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
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Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

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).*

ABC 81171 (04/2015)

the ADBL report

Issue #83, February 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Saibal Nandy, MBBS, MRCPsych, FRCPC (Vice-chair)
Jeffrey A. Johnson, BSP, MSc, PhD
Scott Klarenbach, MD, MSc (Health Econ), FRCPC
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Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 25 & 26, 2014. The Committee reviewed Manufacturer submissions for twenty-nine (29) 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 (20) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, sixteen (16) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2014, and forty-seven (47) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 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

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 December 1, 2014 via Special Authorization:

- **AUBAGIO*** (teriflunomide) (GZM) **14 mg tablet**

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

- **GALEXOS*** (simeprevir sodium) (JAI) **150 mg capsule**

In keeping with the recommendation from the CDR and the Expert Committee the following Drug Products have been added effective December 1, 2014 via Step Therapy/Special Authorization:

- **JENTADUETO*** (linagliptin/ metformin hydrochloride) (BOE) **2.5 mg/500 mg, 2.5 mg/850 mg & 2.5 mg/1000 mg tablets**

The following Drug Product has been reviewed by CDR and the Expert Committee, and the listing of this Drug Product has been deferred at this time:

- **BREO ELLIPTA** (fluticasone furoate/ vilanterol trifenatate) (GSK) **100 mcg/25 mcg powder for inhalation**

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 (02/2015)

Highlights of Drug Products Added

- **PONSTAN** (mefenamic acid) (ERF) **250 mg capsule** was added effective February 1, 2015 as a single-source product. This Drug Product will not be designated as interchangeable with the currently listed Mefenamic Acid (AAP) 250 mg capsule.

Highlights of Line Extension Drug Products Reviewed for Addition to the ADBL

The following Drug Product was added to the *ADBL* effective February 1, 2015 after a Full review by the Expert Committee:

- **TEVA-CITALOPRAM** (citalopram hydrobromide) (TEV) **10 mg tablet**

The following Drug Products were reviewed by the Expert Committee and have been deferred at this time:

- **LATUDA** (lurasidone hydrochloride) (SUN) **20 mg & 60 mg tablets**

The following Drug Products were NOT added to the *ADBL* after a Full Review by the Expert Committee:

- **COMBIVENT RESPIMAT** (ipratropium bromide/salbutamol) (BOE) **20 mcg/100 mcg inhalation solution** was reviewed as a Line Extension to Combivent nebules but was not added as this Drug Product fails to offer a therapeutic advantage.
- **LUXIQ** (betamethasone valerate) (GSK) **0.12% topical foam** was reviewed as a Line Extension to Prevex 0.1% topical occlusive cream and not added as it fails to offer a cost advantage.

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 February 1, 2015:

- **APO-CLARITHROMYCIN XL** (clarithromycin) (APX) **500 mg extended-release tablet**

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective February 1, 2015:

- **CELECOXIB*** (celecoxib) (APX, APH, GMD, JPC, MAR, MPI, MYP, PMS, RAN, SDZ, and TEV) **100 mg & 200 mg capsules**
- **AURO-CEFIXIME** (cefixime) (AUR) **400 mg tablet**

Highlights of Interchangeable Drug Products Not Added

As there are currently no published criteria in the *ADBL* specific to use of Canadian Non-Innovator Reference Products (CNIRPs), the Expert Committee was unable to consider demonstration of bioequivalence with a CNIRP as evidence of interchangeability. Therefore, each of the following Drug Products will not be added to the *ADBL:*

- **JAMP-METHOTREXATE (UNPRESERVED)** (methotrexate) (JPC) **25 mg/mL injection**
- **JAMP-VANCOMYCIN** (vancomycin hydrochloride) (JPC) **500 mg/vial, 1 gram/vial & 10 gram/vial injections**

Highlights of Non-Interchangeable Old Drug Products (NICOD) Not Added

The following Old Drug Product has not been added to the *Palliative Care DBS* as it fails to demonstrate a therapeutic advantage:

- **BISACODYL** (bisacodyl) (JPC) **10 mg rectal suppository**

Special Authorization Criteria Changes

The criteria for coverage via Special Authorization for the following Drug Products have been revised to better reflect current practice:

- **APO-VALGANCICLOVIR*** (valganciclovir hydrochloride) (APX) **450 mg tablet**
- **VALCYTE*** (valganciclovir hydrochloride) (HLR) **450 mg tablet**
- **VALCYTE*** (valganciclovir hydrochloride) (HLR) **50 mg/mL oral suspension**
- **RITUXAN*** (rituximab) (HLR) **10 mg/mL injection**

Changes in Benefit Status due to product discontinuation

Vertex Pharmaceuticals (Canada) Inc. has made the decision to discontinue the sale and distribution of this Drug Product as of January 1, 2015:

- **INCIVEK** (telaprevir) (VER) **375 mg tablet**

Special Authorization criteria will remain part of the *ADBL* to ensure that all patients who initiated therapy prior to January 1, 2015 can finish their course of treatment by March 31, 2015. No new patients will be approved to initiate Incivek therapy at this time.

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 (02/2015)

the DBL report

Issue #82, November 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy, MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP

ALBERTA HEALTH LIAISON:
Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 25, 2014. The Committee reviewed Manufacturer submissions for twenty-five (25) 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 fifty (50) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, seventeen (17) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2014, and thirty (30) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 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 Interchangeable (IC) Drug Products Added

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

- **Ezetimibe*** (ACT, MYLAN, RAN, SANDOZ and TEVA brands) **10 mg tablets**
- **Escitalopram** (APO, AURO, CO, Sanis, MYLAN, PMS, RAN and TEVA brands) **10 mg & 20 mg tablets**

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

- **PENICILLIN G SODIUM** (penicillin G sodium) (PPC) **1,000,000 unit/vial, 5,000,000 unit/vial & 10,000,000 unit/vial injections**

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 (11/2014)

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

The following Drug Products were added to the *ADBL* effective October 1, 2014:

- **LATUDA** (lurasidone HCL) (SUN) **40 mg, 80 mg & 120 mg tablets**
- **LODALIS** (colesevelam HCL) (VCL) **625 mg tablet**

In keeping with CDR recommendations, the following Drug Product was added to the *ADBL* as of November 1, 2014:

- **TUDORZA GENUAIR** (aclidinium bromide) (ALM) **400 mcg /dose inhalation powder**.

The following Drug Products have been reviewed by CDR and the Expert Committee, and the listing of these drug products have been deferred pending a Product Listing Agreement (PLA) at this time:

- **AUBAGIO** (teriflunomide) (GZS) **14 mg tablet**
- **GALEXOS** (simeprevir sodium) (JAI) **150 mg capsule**
- **IBAVYR** (ribavirin) (PPH) **400 mg & 600 mg tablets**
- **KOMBOGLYZE** (saxagliptin HCL/ metformin HCL) (AZC) **2.5 mg/500 mg, 2.5 mg/850 mg & 2.5 mg/1000 mg tablets**
- **SIMPONI I.V.** (golimumab) (JAI) **50 mg/4 mL vial injection**
- **SOVALDI** (sofosbuvir) (GIL) **400 mg tablet**

Highlights of Changes to Currently Listed Products

Additional indications for Special Authorization were added for the following Drug Products effective October 1, 2014:

- **REMICADE*** (infliximab) (JAI) **100 mg/vial injection** for Ulcerative Colitis was reviewed by the Expert Committee, in consultation with Alberta gastroenterologists, and this indication is now eligible for coverage via Special Authorization.
- **HUMIRA*** (adalimumab) (ABV) **40 mg/syringe injection** for pediatric Juvenile Idiopathic Arthritis was reviewed by the Expert Committee and this indication is now eligible for coverage via Special Authorization.

Criteria for coverage via Special Authorization were revised for the following Drug Products effective October 1, 2014:

- **PROLIA*** (denosumab) (AMG) **60 mg/mL injection syringe**
- **Zoledronic Acid*** (NOVARTIS, DR. REDDY'S LABORATORIES, TARO and TEVA brands) **5 mg/100 mL injection**

A clinical review of the benefit status of rifabutin was undertaken in response to Specialist feedback. The Expert Committee gave due consideration to the information, and as a result, Special Authorization criteria for coverage have been revised for the following Drug Product effective November 1, 2014:

- **MYCOBUTIN*** (rifabutin) (PFI) **150 mg capsule**

After assessment by the Expert Committee and consultation with pediatric Specialists, the listing status of Chloral Hydrate is changed from an open benefit to a Restricted Benefit, effective November 1, 2014, for patients less than 18 years of age:

- **PMS-CHLORAL HYDRATE*** (chloral hydrate) (PMS) **100 MG/ML oral syrup**

Criteria for coverage via Special Authorization have also been revised for the following Drug Products effective November 1, 2014:

- **SOLIRIS*** (eculizumab) (API) **300 mg/vial injection**
- **GILENYA*** (fingolimod HCL) (NOV) **0.5 mg capsule**
- **TYSABRI*** (eculizimab) (BIO) **20 mg/mL injection**

Highlights of Interchangeable Drug Products Not Added

As there are currently no published criteria in the *ADBL* specific to use of Canadian Non-Innovator Reference Products (CNIRPs), the Expert Committee was unable to consider demonstration of bioequivalence with a CNIRP as evidence of interchangeability. Therefore, each of the following Drug Products will not be added to the *ADBL:*

- **CYANOCOBALAMIN** (cyanocobalamin) (MYP) **1000 mcg/mL injection**
- **MAR-AMITRIPTYLINE** (amitriptyline) (MAR) **10 mg, 25 mg, 50 mg & 75 mg tablets**
- **METHOTREXATE** (methotrexate sodium) (MYP) **25 mg/mL injection (unpreserved)**

The Expert Committee advised that insufficient information was provided to support bioequivalence of the following Products with the Canadian Reference Products. As a result, these Drug Products will not be added to the *ADBL:*

- **DOXYCIN** (doxycycline hyclate) (RIV) **100 mg capsule and tablet**

Highlights of Other Changes to the ADBL

The following Drug Products were added to the *ADBL* as Restricted Benefits effective October 1, 2014 for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) for patients 6 years of age and older:

- **BIPHENTIN*** (methylphenidate HCL) (PUR) **10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg, 60 mg & 80 mg controlled-release capsules**

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).*

the ADBL report

Issue #81, September 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy, MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH LIAISON:
Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, M.A.
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD
Darcia Wasarab-Rolland, BSc (Pharm)

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 24, 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 thirteen (13) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, thirty-four (34) Drug Products underwent Expedited Review for listing on the *ADBL* effective August 1, 2014, and twelve (12) Drug Products underwent Expedited Review for listing on the *ADBL* effective September 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 Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendation from the CDR, the following Drug Products have NOT been added to the *ADBL*:

- **INSPRA** (eplerenone) (PFI) **25 mg and 50 mg tablets** for NYHA class II systolic chronic heart failure. Although this Drug Product demonstrated benefit for the population studied, the Expert Committee agreed with the CDR recommendation of not listing at the submitted price.
- **NEUPRO** (rotigotine) (UCB) **2 mg/24 hour, 4 mg/24 hour, 6 mg/24 hour and 8 mg/24 hour transdermal patches.** CDR recommended that rotigotine not be listed for the treatment of idiopathic Parkinson disease (PD).

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 (09/2014)

Highlights of Entry 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 September 1, 2014:

- **ACT DUTASTERIDE*** (dutasteride) (APH) **0.5 mg capsule**
- **APO-DUTASTERIDE*** (dutasteride) (APX) **0.5 mg capsule**
- **PMS-DUTASTERIDE*** (dutasteride) (PMS) **0.5 mg capsule**
- **SANDOZ DUTASTERIDE*** (dutasteride) (SDZ) **0.5 mg capsule**
- **TEVA-DUTASTERIDE*** (dutasteride) (TEV) **0.5 mg capsule**
- **VPI-BACLOFEN INTRATHECAL** (baclofen) (VPI) **0.05 mg/mL, 0.5 mg/mL and 2 mg/mL injections**

Highlights of Non-Interchangeable Old Drug Products Not Added

The Following Old Drug Products have not been added to the *ADBL*:

- **CELESTODERM-V** (betamethasone valerate) (VLP) **0.05% and 0.1% topical creams, and 0.05% and 0.1% topical ointments.** The Expert Committee reviewed a re-submission for Celestoderm-V but noted that no new information had been provided in support of the Manufacturer's wish to resubmit as a Multisource Drug Product. Therefore, the Expert Committee recommended that Celestoderm-V not be added to the *ADBL* as these Drug Products fail to offer a therapeutic advantage.

Highlights of Line Extension Drug Products Reviewed by the Expert Committee

The following Drug Products were added to the *ADBL*, effective September 1, 2014 after a Full Review by the Expert Committee:

- **ACUVAIL** (ketorolac tromethamine) (ALL) **0.45% ophthalmic solution** was submitted and reviewed as a Line Extension to the currently listed Acular 0.5% ophthalmic solution. The Expert Committee recommended this Drug Product be listed on the *ADBL* as it offers a therapeutic advantage.
- **VALCYTE*** (valganciclovir) (HLR) **50 mg/mL oral suspension** was submitted and reviewed as a Line Extension to the currently listed 450 mg tablet. The Expert Committee recommended this Drug Product be listed on the *ADBL* via Special Authorization with the same criteria as the valganciclovir tablets as it offers a therapeutic advantage.

The following Drug Product was NOT added to the *ADBL* after a Full Review by the Expert Committee:

- **TECFIDERA** (dimethyl fumarate) (BIO) **240 mg delayed-release capsule** was submitted and reviewed as a Line Extension to the Tecfidera 120 mg* delayed-release capsule which is currently listed via Special Authorization. The Expert Committee recommended that Tecfidera 240 mg capsule not be listed as this Drug Product fails to offer a cost or therapeutic advantage.

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).*

the DBL report

Issue #80, July 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy, MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

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Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm), ACPR
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 13 & 14, 2014. 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-six (26) Drug Products.

In addition, to Drug Products reviewed by the Expert Committee, twenty-two (22) Drug Products underwent Expedited Review for listing on the *ADBL* effective June 1, 2014 and seventeen (17) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 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 Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendations from the CDR, the following Drug Products have been added to the *ADBL* via Special Authorization (please refer to the current *ADBL* for a full listing of coverage criteria):

- **GENOTROPIN GoQuick* & GENOTROPIN MiniQuick*** (somatropin) (PFI) **5.3 mg & 12 mg injection pens & 0.6 mg, 0.8 mg, 1.0 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg & 2.0 mg injection syringes** for Growth Hormone Deficiency in Adults.
- **KALYDECO*** (ivacaftor) (VER) **150 mg tablet**
  Special Authorization coverage may be provided for the treatment of cystic fibrosis (CF) in patients age 6 years and older who have a G551D mutations in the Cystic Fibrosis Transmembrane conductance Regulator (CFTR) gene and who meet all other criteria included on the *ADBL*.

Highlights of Single Source Drug Products Added

Addition of the following Drug Product to the *ADBL* will be effective July 1, 2014:

- **FENTANYL CITRATE*** (fentanyl citrate) (SDZ) **50 mcg/mL 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 (07/2014)

Highlights of Entry 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 July 1, 2014:

- **APO-VORICONAZOLE*** (voriconazole) (APX) **50 mg & 200 mg tablets**
- **SANDOZ VORICONAZOLE*** (voriconazole) (SDZ) **50 mg & 200 mg tablets**

Highlights of Non-Interchangeable Old Drug Products Not Added

The Following Non-Interchangeable Old Drug Product has not been added to the *ADBL* as it failed to demonstrate a therapeutic advantage:

- **EURO-HYDROCORTISONE** (hydrocortisone) (EUR) **1% cream**

The Following Non-Interchangeable Old Drug Products have not been added to the *Palliative Care Drug Benefit Supplement (PCDBS)* as they failed to demonstrate a therapeutic advantage:

- **JAMP-BISACODYL** (bisacodyl) (JPC) **5 mg tablet**
- **JAMP-DOCUSATE SODIUM** (docusate sodium) (JPC) **50 mg/mL oral syrup**

Aranesp and Eprex Special Authorization (SA) Criteria Changes

The criteria for coverage via Special Authorization have been revised for the following Drug Products for the indication of the treatment of anemia of chronic renal failure:

- **ARANESP** (darbepoetin) **injection syringes** (all strengths)
- **EPREX** (epoetin) **injection syringes** (all strengths except the 30,000 and 40,000 unit injection syringes)

The Special Authorization criterion was modified to extend the authorization period from six (6) months to twelve (12) months to reduce the administrative burden for prescribers. Auto-renewal will still be eligible for this criterion.

Highlights of Line Extension Drug Products Added to the ADBL

The following Drug Products were added to the *ADBL*, effective July 1, 2014 after a Full Review by the Expert Committee:

- **ABBOTT-CITALOPRAM** (citalopram) (ABB) **10 mg tablet** was submitted and reviewed as a Line Extension to the currently reviewed 20 mg & 40 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic advantage.
- **MAR-CITALOPRAM** (citalopram) (MAR) **10 mg tablet** was submitted and reviewed as a Line Extension to the currently listed 20 mg & 40 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic advantage.

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).*

the DBL report

Issue #79, May 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy, MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH LIAISON:
Michele Evans, BSP, MHSc (Health Admin)
Andrea Nagle, BSc (Pharm), LLB

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm), ACPR
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 20, 2014. 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 an additional thirty-five (35) Drug Products.

In addition, to those reviewed by the Expert Committee, twenty-nine (29) Drug Products underwent Expedited Review for listing on the *ADBL* effective May 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 Line Extension Drug Products Added to the ADBL

The following Drug Product was added to the *ADBL*, effective May 1, 2014 after a Full Review by the Expert Committee:

- **RAN-ATENOLOL** (atenolol) (RAN) **25 mg tablet** was submitted and reviewed as a Line Extension to the currently listed 50 mg & 100 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic advantage.

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

In keeping with the recommendations from the CDR, the following Drug Products have been added to the *ADBL* (please refer to the current *ADBL* for a full listing of coverage criteria):

- **FYCOMPA*** (perampanel) (EIS) **2 mg, 4 mg, 6 mg, 8 mg, 10 mg & 12 mg tablets** via Special Authorization for the adjunctive therapy in patients with refractory partial-onset seizures.
- **LUCENTIS*** (ranibizumab) (NOV) **2.3 mg/vial injection** via Restricted Benefit for the new indication of macular edema secondary to retinal vein occlusion.

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 (05/2014)

Highlights of Products not Added

- **JAMP-QUININE** (quinine sulfate) (JPC) **200 mg & 300 mg capsules** were reviewed as Natural Health Products (NHPs). The Expert Committee indicated that these NHPs failed to demonstrate a therapeutic advantage. Accordingly, these products were not recommended for addition to the *ADBL*.
- **DOCUSATE SODIUM** (docusate sodium) (JPC) **100 mg capsule** was reviewed under the Non-Interchangeable Old Drug Products submission category. This Drug Product was not recommended for addition to the *Palliative Care Drug Benefit Supplement (PCDBS)* as it failed to demonstrate a therapeutic advantage.
- **THEO ER** (theophylline) (AAP) **400 mg & 600 mg sustained-release tablets** were reviewed as Resubmissions. The Expert Committee advised that no new information had been provided in support of interchangeability with the innovator that would warrant a change to their previous recommendation to not list these Drug Products. Accordingly, these products were not recommended for addition to the *ADBL* as they failed to offer a cost advantage.

Highlights of Non-Interchangeable Old Drug Products Added

The following Non-Interchangeable Old Drug Product has been added to the *PCDBS*:

- **JAMP-DOCUSATE CALCIUM** (docusate calcium) (JPC) **240 mg capsule**

Highlights of Entry Interchangeable (IC) Drug Products Added

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

- **FONDAPARINUX SODIUM** (fondaparinux sodium) (DRL) **2.5 mg/0.5 mL & 7.5 mg/0.6 mL injections**

Vimpat Special Authorization Criteria Changes

The criteria for coverage via Special Authorization have been revised for the following Drug Products to align with the Special Authorization criteria implemented for Fycompa (please refer to the current *ADBL* for a full listing of coverage criteria):

- **VIMPAT*** (lacosamide) (UCB) **50 mg, 100 mg, 150 mg & 200 mg tablets** for adjunctive therapy in patients with refractory partial-onset seizures.

Leflunomide Restricted Benefit Criteria Changes

The Restricted Benefit criteria have been revised for all brands of **Leflunomide** 10 mg & 20 mg tablet Drug Products:

Original Restricted Benefit criteria for leflunomide required all prescriptions to be written by a Specialist in Rheumatology or Internal Medicine, in order for coverage to be provided. The Expert Committee recommended that the Restricted Benefit criteria be modified to allow other prescribers to continue leflunomide for their patients after initial prescription by a Specialist in Rheumatology or Internal Medicine.

The new Restricted Benefit criteria, effective May 1, 2014, will read as follows:

This product is a benefit for the treatment of rheumatoid arthritis when the initial prescription is prescribed by a Specialist in Rheumatology or Internal Medicine.

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).*

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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
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Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm), ACPR
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

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).*

ABC 81171 (03/2014)

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).*

the ADBL report

Issue #77, February 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)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

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Michele Evans, BSP, MHSc (Health Admin)
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm), ACPR
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 26 & 27, 2013. The Committee reviewed Manufacturer submissions for fifteen (15) 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 seventy-one (71) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, seventy-one (71) Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2013 and ten (10) Drug Products underwent Expedited Review for listing on the *ADBL* effective February 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 February 1, 2014 after a Full Review by the Expert Committee:

- **VAL-VANCOMYCIN** (vancomycin hydrochloride) (VAL) **10 g/vial injection** was submitted as a line extension to the currently listed 500 mg and 1 g vials. This Drug Product has been recommended for listing for use by Home Parenteral Therapy (HPT) Programs only, as it offers a therapeutic and/or cost advantage.

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

In keeping with the recommendations from the CDR, the following Drug Product has not been added to the *ADBL:*

- **XIAFLEX** (collagenase clostridium histolyticum) (ACT) **0.9 mg/vial injection** will not be listed as it fails to provide a therapeutic or cost advantage. At the current price for a 3-injection treatment course, this Drug Product does not appear to be cost-effective compared to current treatment modalities such as percutaneous needle fasciotomy (PNF) and open partial fasciotomy (OPF).

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 (02/2014)

Highlights of Interchangeable (IC) Drug Products Added

Addition of the following Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective February 1, 2014:

- **TEVA-ALENDRONATE/ CHOLECALCIFEROL** (alendronate/ cholecalciferol) (TEV) **70 mg/5600 IU tablet**

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

- **APO-RAMIPRIL/HCTZ** (ramipril/hydrochlorothiazide) (APO) **2.5 mg/12.5 mg, 5 mg/12.5 mg, 5 mg/25 mg, 10 mg/12.5 mg & 10 mg/25 mg tablets**
- **APO-ALMOTRIPTAN** (almotriptan malate) (APO) **6.25 mg & 12.5 mg tablets***
  **Coverage criteria may apply. Please refer to the full ADBL.*

Highlights of Non-Interchangeable Old Drug Products Added

- **PMS-ACETAMINOPHEN WITH CODEINE** (acetaminophen/codeine phosphate) (PMS) **160 mg/8 mg/5 mL elixir** will be restricted to patients 12 years of age and older, in keeping with recent Health Canada recommendations that Drug Products containing codeine should not be used in children less than 12 years of age due to safety concerns.

Highlights of Deferrals

- **HUMIRA** (adalimumab) (ABB) **40 mg/0.8 mL injection syringe** for the indication of polyarticular Juvenile Idiopathic Arthritis (pJIA) has been deferred pending consultation on Special Authorization criteria with Alberta experts in the field of pJIA.

Benefit Coverage and Special Authorization (SA) Criteria Changes for Osteoporosis Medications:

In response to the discontinuation of calcitonin nasal spray from the Canadian market, and to reflect current clinical practice guidelines, the Expert Committee considered modifications to the coverage status and SA criteria of agents used to treat osteoporosis. As a result of their deliberations, the Expert Committee recommended that the benefit status of the following Drug Products be changed to an unrestricted listing:

- **ALENDRONATE SODIUM** 70 mg tablets (all brands)
- **RISEDRONATE SODIUM** 35 mg tablets (all brands)
- **ALENDRONATE/CHOLECALCIFEROL** (all brands)

In addition, the Expert Committee recommended that the criteria for SA coverage be revised for the following Drug Products:

- **ALENDRONATE SODIUM** 10 mg tablets (all brands)
- **RALOXIFENE HYDROCHLORIDE** 60 mg tablets (all brands)
- **RISEDRONATE SODIUM** 5 mg tablets (all brands)

The revised SA criteria for osteoporosis read as follows:

"For the treatment of osteoporosis in patients with a 20% or greater 10-year fracture risk who have documented intolerance to alendronate 70 mg or risedronate 35 mg.
Special authorization may be granted for 6 months."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 6 months after the last dose of denosumab 60 mg/syr injection syringe."

"Requests for other osteoporosis medications covered via special authorization will not be considered until 12 months after the last dose of zoledronic acid 0.05 mg/mL injection."

Note: The fracture risk can be determined by the World Health Organization's fracture risk assessment tool, FRAX, or the most recent (2010) version of the Canadian Association of Radiologists and Osteoporosis Canada (CAROC) table.

In order to facilitate calculation of the 10-year fracture risk, the following links are available for the FRAX tool and the CAROC table:
http://www.shef.ac.uk/FRAX/tool.jsp?country=19
http://www.osteoporosis.ca/multimedia/pdf/CAROC.pdf

ROBS Review of Beta-Blockers

As part of the Review of Benefit Status (ROBS) process, comprehensive clinical reviews of the beta-blockers were undertaken. The Expert Committee gave due consideration to the information available and recommended de-listing a number of beta-blockers from the *ADBL* as they were found to no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments, and to enable broader coverage of higher priority products. In order to minimize the impact these changes will have on patient care, health professionals will be receiving information regarding the implementation of these changes, and will have an opportunity to communicate these changes to their patients.

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).****

the ADBL report

Issue #76, November 2013

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
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Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

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Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm), ACPR
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 19, 2013. The Committee reviewed Manufacturer submissions for fifty-seven (57) 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 eight (8) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, eighteen (18) Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2013, and sixty-seven (67) Drug Products underwent Expedited Review for listing on the *ADBL* effective November 1, 2013.

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 Drug Products Added

- **MONUROL** (fosfomycin tromethamine) (TPI) **3 gram oral powder packet** is indicated in the treatment of acute uncomplicated lower urinary tract infections (acute cystitis) in women of 18 years of age and older caused by the following susceptible pathogens: *Escherichia coli*, *Enterococcus faecalis*. This Drug Product was added to the *ADBL* as evidence provided in the Manufacturer submission supported that it provides a therapeutic advantage.

Highlights of Line Extension Drug Products Added

The following Drug Product was added to the *ADBL*, effective November 1, 2013 after a Full Review by the Expert Committee:

- **CO AMLODIPINE** (amlodipine besylate) (COB) **2.5 mg tablet** was submitted and reviewed as a Line Extension to the currently listed 5 mg & 10 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic advantage.

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 (11/2013)

Highlights of Natural Health Products Added

The following Natural Health Products (NHPs) have been added to the *ADBL* and the Maximum Allowable Cost (MAC) Price Policy applies to the MAC groupings:

- **EURO-K20** (potassium chloride) (EUP) **20 mEq sustained-release tablet**
- **EURO-K 600** (potassium chloride) (EUP) **8 mEq sustained-release tablet**

Highlights of Non-Interchangeable Old Drug Products Added

The following Non-Interchangeable Drug Product has been added to the *ADBL*:

- **EURO FOLIC** (folic acid) (EUP) **5 mg tablet**

Highlights of Expedited Interchangeable Drug Products Added

Addition of the following IC Drug Products to the *ADBL* has resulted in the creation of a New IC Grouping, effective November 1, 2013:

- **ZAMINE 21** (drospirenone/ethinyl estradiol) (APX) **3 mg/0.03 mg tablets**
- **ZARAH 21 (drospirenone/ethinyl estradiol) (COB) 3 mg/0.03 mg tablets**

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

In keeping with the recommendations from the CDR, the following Drug Product has been added to the *ADBL* via Special Authorization:

- **ORENCIA** (abatacept) (BMS) **125 mg/mL injection syringe** for adults with rheumatoid arthritis. The addition of this new strength and formulation resulted in associated revisions to the existing Special Authorization criteria for coverage for the currently listed **250 mg/vial injection** formulation. Please refer to the current *ADBL* for a full listing of coverage criteria.

Also in keeping with the recommendations from the CDR, the following Drug Product has not been added to the *ADBL*:

- **BYSTOLIC** (nebivolol hydrochloride) (FLC) **2.5 mg, 5 mg, 10 mg & 20 mg tablets**

Finally, in keeping with CDR recommendations, the coverage status of the following Drug Products will be maintained (i.e., coverage will not be extended to the new indications):

- **REBIF** (interferon beta-1a) (SRO) **44 mcg/0.5 ml (12 million IU) injection syringe** for the indication of Clinically Isolated Syndrome in Multiple Sclerosis
- **SOLIRIS** (eculizumab) (API) **300 mg/vial injection** for the indication of Atypical Hemolytic Uremic Syndrome

Highlights of Interchangeable (IC) Drug Products Added

The following are Drug Products added to the *ADBL* effective November 1, 2013 in Established IC Groupings, after a Full Review by the Expert Committee:

- **MINT-RIVASTIGMINE** (rivastigmine hydrogen tartrate) (MPI) **1.5 mg, 3 mg, 4.5 mg & 6 mg capsules**
- **RAN-MONTELUKAST** (montelukast sodium) (RAN) **4 mg & 5 mg chewable tablets**

Highlights of Special Authorization (SA) Criteria Changes

PROLIA (denosumab) (AMG) **60 mg/mL injection syringe** was originally reviewed via the CDR and was listed on the *ADBL* via SA for postmenopausal osteoporosis, effective July 1, 2011. The Expert Committee considered requests from prescribers for clarification of the SA criteria, and have recommended that the criteria be revised; specifically defining oral bisphosphonate hypersensitivity and allowing coverage for patients with severe gastrointestinal intolerance. Please refer to the current *ADBL* for a full listing of coverage criteria.

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).****

the ADBL report

Issue #75, September 2013

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
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Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

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Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm), ACPR
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 25, 2013. The Committee reviewed Manufacturer submissions for fifty-two (52) 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 seven (7) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, forty-four (44) Drug Products underwent Expedited Review for listing on the *ADBL*.

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 Line Extension Drug Products Added to the ADBL

The following are Drug Products, added to the *ADBL*, effective September 1, 2013 after a Full Review by the Expert Committee:

- **ACCEL-CITALOPRAM** (citalopram hydrobromide) (ACP) **10 mg tablet** was submitted as a Line Extension to the currently listed 20 mg & 40 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic and/or cost advantage.
- **SANDOZ AMLODIPINE** (amlodipine besylate) (SDZ) **2.5 mg tablet** was submitted as a Line Extension to the currently listed 5 mg & 10 mg tablets. The Expert Committee recommended this Drug Product be listed on the *ADBL* in the applicable interchangeable grouping as it offers a therapeutic advantage.
- **CEFAZOLIN** (cefazolin sodium) (PPC) **100 G/SmartPak Bulk Package injection** was submitted as a Line Extension to the currently listed 500 mg/vial & 10 g/vial injections. This Drug Product has been recommended for listing as a Restricted Benefit for use by Home Parenteral Therapy (HPT) programs only as it offers a cost and/or therapeutic advantage.
- **STELARA** (ustekinumab) (JAI) **90 mg/1.0 mL vial or syringe injection** was submitted as a Line Extension to the currently listed 45 mg/0.5 mL syringe. The Expert Committee recommended this Drug Product be listed via Special Authorization with criteria similar to Stelara 45 mg. However the 90 mg dose is available for patients over 100 kg as it provides a therapeutic advantage.

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 (09/2013)

Highlights of Expedited Interchangeable (IC) Drug Products Added

Addition of the following IC Drug Product to the *ADBL* has resulted in the creation of a New IC Grouping, effective September 1, 2013:

- **APO-VALGANCICLOVIR** (valganciclovir hydrochloride) (APX) **450 mg tablet**

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

In keeping with the recommendations from the CDR, the following Drug Product has not been added to the *ADBL*:

- **ALOXI** (palonosetron) (EIS) **0.05 mg/mL injection**

Highlights of Drug Products Not Added

The following Drug Products have not been recommended for addition to the *ADBL*:

- **EPURIS** (isotretinoin) (CIP) **10 mg, 20 mg, 30 mg & 40 mg capsules** will not be listed on the *ADBL* as they do not provide a therapeutic advantage over currently listed products.
- **HEPARIN** (heparin sodium) (PFI) **1,000 unit/mL, 5,000 unit/mL & 10,000 unit/mL injections** will not be listed as these Drug Products fail to offer a therapeutic or cost advantage.

Highlights of Criteria Changes

The criteria for coverage via Special Authorization have been revised for the following Drug Product:

- **STELARA** (ustekinumab) (JAI) **45 mg/0.5 mL vial or syringe injection** criteria for Special Authorization were modified to indicate that patients weighing over 100 kg may receive the new 90 mg dose.

Risk of Hypoglycemia with Anti-diabetic Agents

Currently published Step Therapy/Special Authorization coverage criteria for DPP-4 inhibitor agents, JANUVIA/JANUMET (sitagliptin), ONGLYZA (saxagliptin) and TRAJENTA (linagliptin) position these Drug Products in a stepped approach after metformin, sulfonylureas, and insulin.

Inquiries from concerned health care practitioners prompted the Expert Committee to specifically discuss the relative risks of hypoglycemia with the various agents. The risk of hypoglycemia is one factor considered in the review for potential coverage of any anti-diabetic agent. It was noted that both insulins and sulfonylureas show an increased risk of hypoglycemia over DPP-4 inhibitors. However, the literatures show that severe hypoglycemic events in patients with type 2 diabetes are rare across all drug classes, including the insulins and sulfonylureas.[1] Accordingly, special authorization requests for DPP-4 inhibitor agents citing that insulin, metformin or sulfonylureas are contraindicated due to risk of hypoglycemia will not be considered.

[1] Canadian Agency for Drugs and Technologies in Health. Second-line pharmacotherapy for type 2 diabetes — Update. Ottawa: The Agency; July 2013. (CADTH optimal use report; vol.3, no. 1a).

Bloomfield HE, Greer N, Newman D, et al. Predictors and Consequences of Severe Hypoglycemia in Adults with Diabetes - A Systematic Review of the Evidence [Internet]. Washington (DC): Department of Veterans Affairs; 2012 Apr. http://www.ncbi.nlm.nih.gov/books/NBK114893/pdf/TOC.pdf

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).****

the ADBL report

Issue #74, July 2013

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EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
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Margaret Barr, BSc (Pharm)
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ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm), ACPR
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Alberta Health Expert Committee on Drug Evaluation and Therapeutics met on May 21 & 22, 2013. The Committee reviewed Manufacturer submissions for fifty-seven (57) Drug Products for potential listing, or change in listing status, on the *ADBL*. The Committee also considered information for a number of supplementary assessments of coverage status of thirteen (13) Drug Products.

In addition, twenty-four (24) generic Drug Products underwent Expedited Review for listing on the *ADBL*.

The following are highlights of recent changes to the *ADBL* effective July 3, 2013. A complete list of changes and the full *ADBL* can be found at https://www.ab.bluecross.ca/dbl/publications.html

Highlights of New Products Added

- **LIDEMOL** (fluocinonide) (VLP) **0.05% emollient cream** & **LIDEX** (flucocinonide) (VLP) **0.05% cream, gel & ointment** are indicated for topical therapy of corticosteroid responsive acute and chronic skin eruptions where an anti-inflammatory, anti-allergenic and anti-pruritic activity in the topical management is required. Each of these Drug Products was added to the *ADBL* as they provide a cost advantage.

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

In keeping with the recommendations from the CDR, the following Drug Products have not been added to the *ADBL*:

- **ALOXI** (palonosetron) (EIS) **0.5 mg tablet**
- **APPRILON** (doxycycline monohydrate) (GAL) **40 mg modified-release capsule**
- **ESBRIET** (pirfenidone) (INC) **267 mg capsule**

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 (07/2013)

Highlights of Interchangeable Drug Products Added

Addition of the following Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective July 3, 2013:

- **pms-Colchicine** (colchicine) (PMS) **0.6 mg tablet**

The following are Established IC Drug Products, added to the *ADBL*, effective July 3, 2013 after a Full Review by the Expert Committee:

- **AVIANE 21 & 28** (levonorgestrel/ethinyl estradiol) (TEV) **100 mcg/20 mcg tablets**
- **ACCEL-CITALOPRAM** (citalopram hydrobromide) (ACP) **20 mg & 40 mg tablets**
- **FREYA 21 & 28** (desogestrel/ethinyl estradiol) (MYP) **0.15 mg/0.03 mg tablets**
- **JAMP-AMLODIPINE** (amlodipine besylate) (JPC) **2.5 mg tablet**
- **MAR-MONTELUKAST** (montelukast sodium) (MAR) **4 mg & 5 mg chewable tablets and 10 mg tablet**

Highlights of Natural Health Products Added

The following Natural Health Products (NHPs) have been added to the *ADBL*:

- **MAGNESIUM-ODAN** (magnesium gluceptate) (ODN) 100 mg/mL oral solution
- **ODAN-K 20** (potassium chloride) (ODN) **20 mEq tablet**

Highlights of Line Extension Drug Products Added

The following are Drug Products, added to the *ADBL*, effective July 3, 2013 after a Full Review by the Expert Committee:

- **ESTROGEL PROPAK** (estradiol-17 beta/progesterone) (MFC) **0.06% transdermal gel/100 mg capsule**, a co-packaged line extension to ESTROGEL transdermal gel and PROMETRIUM capsules, was recommended to be listed on the *ADBL* as this Drug Product provides a cost advantage relative to Estrogel and Prometrium prescribed and dispensed separately.
- **PENTASA** (mesalazine) (FEI) **1 g extended-release tablet** was submitted as a Line Extension submission to the currently listed 500 mg extended-release tablet. The Expert Committee recommended that this Drug Product be listed on the *ADBL* as it provides a therapeutic advantage consisting of a reduced pill burden for patients.
- **XEOMIN** (clostridium botulinum neurotoxin type A (150KD)) (MPC) **50 unit/vial injection** was submitted as a Line Extension submission to the currently listed 100 unit/vial injection. The Expert Committee recommended that this Drug Product be listed on the *ADBL* as it provides a cost advantage.

Highlights of Criteria Changes

The criteria for coverage via Special Authorization have been revised for the following Drug Products:

- **CARNITOR** (levocarnitine) (PPC) **100 mg/mL oral solution, 200 mg/mL injection & 330 mg tablet**

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).****

the ADBL report

Issue #73, June 2013

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH LIAISON:
Michele Evans, BSP, MHSc (Health Admin)
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm), ACPR
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Alberta Health Expert Committee on Drug Evaluation and Therapeutics met on March 13, 2013. The Committee reviewed Manufacturer submissions for 50 Drug Products for potential listing, or change in listing status, on the *ADBL*. The Committee also considered information for a number of supplementary assessments of coverage status of 21 Drug Products.

In addition, thirty-five (35) generic Drug Products underwent Expedited Review for listing on the *ADBL*.

The following are highlights of recent changes to the *ADBL* effective June 1, 2013. A complete list of changes and the full *ADBL* can be found at https://www.ab.bluecross.ca/dbl/publications.html

Highlights of New Products Added

- **ALLERJECT** (epinephrine) (SAV) **0.3 mg/0.3 mL & 0.15 mg/0.15 mL solutions for injection,** for the emergency treatment of anaphylactic reactions, were added to the *ADBL* as they provide a therapeutic advantage.
- **DIVIGEL** (estradiol-17B) (FEI) **0.1% transdermal gel,** indicated in the treatment of moderate to severe vasomotor symptoms associated with menopause, was recommended to be added to the *ADBL* as it provides a slight cost advantage over currently listed Drug Products.
- **METHADOSE** and **METHADOSE SUGAR FREE** (methadone hydrochloride) (MAL) **10 mg/mL oral liquids** were added as they fulfill an unmet need and appear to be associated with improved safety and quality control as compared with compounded methadone preparations.

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

In keeping with the recommendations from the CDR, the following Drug Products have not been added to the *ADBL*:

- **LATUDA** (lurasidone hydrochloride) (SUN) **40 mg, 80 mg & 120 mg tablets**
- **SAMSCA** (tolvaptan) (OTS) **15 mg & 30 mg tablets**

Highlights of Established IC Drug Products Added

- **TEVA-RAMIPRIL/HCTZ** (ramipril/hydrochlorothiazide) (TEV) **2.5 mg/12.5 mg, 5 mg/12.5 mg, 10 mg/12.5 mg, 5 mg/25 mg & 10 mg/25 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).*

ABC 81171 (06/2013)

Highlights of Natural Health Products Added

The Expert Committee reviews Natural Health Product (NHP) submissions based on the submission requirements including evidence that the active moiety or moieties or Natural Health Product was previously or is currently listed on the *ADBL* and evidence from the Manufacturer to demonstrate that there is an unmet need for the submitted product.

The following NHPs have been added to the *ADBL*:

- **JAMP-K 8** (potassium chloride) (JPC) **600 mg tablet**
- **JAMP-K 20** (potassium chloride) (JPC) **1500 mg tablet**
- **JAMP MAGNESIUM GLUCONATE** (magnesium gluconate) (JPC) **500 mg tablet**
- **JAMP POTASSIUM CHLORIDE LIQUID** (potassium chloride) (JPC) **1.33 mEq/mL oral liquid**

The following NHPs have been added to the *Palliative Care Drug Benefit Supplement* (*PCDBS*)*:*

- **JAMP-SENNA** (sennosides) (JPC) **8.6 mg tablet**
- **JAMP SENNAQUIL** (sennosides) (JPC) **1.7 mg/mL liquid**
- **SENNOSIDES** (sennosides) (JPC) **8.6 mg & 12 mg tablets**

Highlights of Entry IC Drug Products Added

Addition of the following Expedited Entry IC Drug Products to the *ADBL* has resulted in the creation of New IC Groupings, effective June 1, 2013:

- **PMS-TETRABENAZINE** (tetrabenazine) (PMS) **25 mg tablet**
- **SANDOZ LATANOPROST/TIMOLOL** (latanoprost/timolol maleate) (SDZ) **0.005%/0.5% ophthalmic solution**

The following are Entry IC Drug Products, added to the *ADBL*, effective June 1, 2013 after a Full Review by the Expert Committee:

- **ONDISSOLVE ODF** (ondansetron) (TAK) **4 mg & 8 mg orally disintegrating films**

Highlights of Criteria Changes

The criteria for coverage via Special Authorization have been revised for the following Drug Products:

- **ACTEMRA** (tocilizumab) (HLR) **80 mg/4 mL, 200 mg/10 mL & 400 mg/20 mL vial injections** (Indication - Rheumatoid Arthritis)
- **ARANESP** (darbepoetin) (AMG) **10 mcg/0.4 mL & 20 mcg/0.5 mL injection syringes, 100 mcg/mL, 200 mcg/mL & 500 mcg/mL injections** (Indication – Anemia of Chronic Renal Failure)
- **EPREX** (epoetin alfa) (JAI) **1,000 unit/0.5 mL injection, 10,000 unit/mL, 2,000 unit/0.5 mL, 20,000 unit/0.5 mL, 3,000 unit/0.3 mL, 4,000/0.4 mL, 5,000 unit/0.5 mL, 6,000 unit/0.6 mL & 8,000 unit/0.8 mL injection syringes** (Indication – Anemia of Chronic Renal Failure)

The Restricted Benefit criteria have been revised for the following Drug Products:

- **ABILIFY** (aripiprazole) (BMS) **2 mg & 5 mg tablets**

Follow-up: Pre-Requisite Medications for Biologic Coverage

Special Authorization (SA) coverage criteria for biologic agents were recently reviewed for when pregnancy or fertility issues are cited as reasons for not utilizing pre-requisite medications (e.g., leflunomide, methotrexate). Please note: The requirement for a trial of pre-requisite medications will not be waived due to a patient being of child bearing age or potential.

The following statement is from Motherisk, which provides evidence-based information and guidance about the safety or risk to the developing fetus or infant, of maternal exposure to drugs, chemicals, diseases, radiation and environmental agents (www.motherisk.org):

“There is, to the best of our knowledge, no evidence that methotrexate or leflunomide should not be used in women of childbearing age, provided proper explanation of their teratogenic potential is given to the women and the importance of contraception is explained and emphasized by her treating physicians and proper contraception is practiced by her during the treatment period. It’s vital to emphasize the importance of pregnancy planning in this population in order to optimize pregnancy outcomes.”

The following, provided for interested clinicians, is for information only and is not intended to constitute medical advice.

Leflunomide and pregnancy:
Leflunomide is recommended to be discontinued and a wash out procedure performed prior to conception. One procedure involves administering cholestyramine 8 g, three times daily, for a period of 11 days, followed by two separate levels of the active metabolite, taken at least 14 days apart (*Drugs. 2011;71(15):1973-87*). Another regimen involves activated charcoal administration. The plasma levels of the active metabolite must be < 0.02 mg/L for the teratogenic risk to be considered low (sanofi-aventis Canada Inc., Arava product monograph, December 6, 2012).

Methotrexate and pregnancy:
Methotrexate is recommended to be discontinued three months prior to conception (*Drugs. 2011;71(15):1973-87*). High dose folic acid supplementation is recommended preconception and during the first trimester of pregnancy at least.

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).*

the ADBL report

Issue #72, March 2013

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH LIAISON:
Michele Evans, BSP, MHSc (Health Admin)
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Ken Hanson, BSc (Pharm)
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Alberta Health Expert Committee on Drug Evaluation and Therapeutics met on January 24, 2013. The Committee reviewed Manufacturer submissions for 60 Drug Products for potential listing, or change in listing status, on the *ADBL*. The Committee also considered information for a number of supplementary assessments of coverage status of 21 Drug Products.

In addition, seven (7) generic Drug Products underwent Expedited Review for listing on the *ADBL* effective March 1, 2013. Interchangeability of one (1) Drug Product was assessed for another government-sponsored program.

The following are highlights of recent changes to the *ADBL*. A complete list of changes and the full *ADBL* can be found at https://www.ab.bluecross.ca/dbl/publications.html

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

In keeping with the recommendations from the CDR, the following Drug Products have not been added to the *ADBL*:

- **DIFICID** (fidaxomicin) (OPL) **200 mg film-coated tablet**
- **FAMPYRA** (fampridine) (BIO) **10 mg sustained release tablet**
- **LODALIS** (colesevelam hydrochloride) (VCL) **625 mg tablet**

Highlights of Expedited Entry 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 March 1, 2013:

- **TEVA-FLUVASTATIN** (fluvastatin sodium) (TEV) **20 mg & 40 mg capsules**

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 (03/2013)

Highlights of Established IC Drug Products Added

- **APO-NARATRIPTAN** (naratriptan hydrochloride) (APX) **1 mg & 2.5 mg tablets***
- **APO-NITROGLYCERIN** (nitroglycerin) (APX) **0.4 mg/dose sublingual metered dose spray**
- **APO-RIZATRIPTAN RPD** (rizatriptan benzoate) (APX) **5 mg & 10 mg orally disintegrating tablets***
- **APO-ZOLMITRIPTAN RAPID** (zolmitriptan) (APX) **2.5 mg orally dispersible tablet***
- **MYLAN-FENTANYL MATRIX PATCH** (fentanyl) (MYP) **12 mcg/hr, 25 mcg/hr, 50 mcg/hr, 75 mcg/hr & 100 mcg/hr transdermal patches***
- **PMS-RIZATRIPTAN RDT** (rizatriptan benzoate) (PMS) **5 mg & 10 mg orally disintegrating tablets***
- **TEVA-CLARITHROMYCIN** (clarithromycin) (TEV) **250 mg & 500 mg tablets**

**Coverage criteria may apply. Please refer to the full ADBL.*

Highlights of Other Additions to the ADBL

The following Drug Product was added to the *ADBL*, effective January 1, 2013:

- **NOVORAPID FLEXTOUCH** (insulin aspart) (NNA) **100 unit/mL injection**

Coverage of Controlled Release Oxycodone Drug Products

At their most recent meeting, the Committee continued to review the listing status of **OXYNEO** (oxycodone hydrochloride) (PUR) **10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, & 80 mg controlled release tablets**, pursuant to a resubmission from the Manufacturer. The Committee recommended the interchangeability designation between **OXYNEO** and **OXYCONTIN** (oxycodone hydrochloride) (PUR) be removed as available evidence supports that the introduction onto the market of the **OXYNEO** formulation has resulted in the reduction in abuse of long-acting oxycodone prescription medication.

Further to this, the Committee recommended that **OXYCONTIN** Drug Products be de-listed from the *ADBL* as they no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatment of the disease entity for which **OXYCONTIN** is indicated. Assessment of therapeutic advantage may include consideration of clinical efficacy, risk/benefit ratio, toxicity, compliance, clinical outcomes, Health Canada advisories, population health issues, and any factor which affects the therapeutic value of the product, class or category.

Finally, the Committee considered interchangeable submissions for **APO-OXYCODONE CR** (oxycodone hydrochloride) (APX), **CO OXYCODONE CR** (oxycodone hydrochloride) (COB), and **PMS-OXYCODONE CR** (oxycodone hydrochloride) (PMS). However, these Drug Products were not recommended for addition to the *ADBL* as they do not offer a therapeutic advantage.

Based upon these recommendations, the following products are currently the only oxycodone controlled release tablets listed on the *ADBL*:

- **OXYNEO** (oxycodone hydrochloride) (PUR) **10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg, & 80 mg controlled release 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).****

the ADBL report

Issue #71, February 2013

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH LIAISON:
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Ken Hanson, BSc (Pharm)
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 27 & 28, 2012. The Committee reviewed Manufacturer submissions for 54 Drug Products for potential listing, or change in listing status, on the *ADBL*.

In addition to these Drug Products, 49 generic Drug Products underwent Expedited Review for listing on the *ADBL* effective December 1, 2012, and 28 generic Drug Products underwent Expedited Review for listing effective February 1, 2013.

The following are highlights of recent changes to the *ADBL*. A complete list of changes and the full *ADBL* can be found at

https://www.ab.bluecross.ca/dbl/publications.html

Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendations from the CDR, the following Drug Products have been added to the *ADBL* (please refer to the current *ADBL* for a full listing of coverage criteria):

- **TOVIAZ** (fesoterodine fumarate) (PFI) **4 mg & 8 mg extended-release tablets** are indicated for the treatment of patients with overactive bladder with symptoms of urinary frequency, urgency, or urge incontinence, or any combination of these symptoms. The Expert Committee recommended these Drug Products for listing on the *ADBL*, via Step therapy/Special Authorization, as they offer a cost advantage.
- **ASMANEX TWISTHALER** (mometasone furoate) (MFC) **200 mcg/dose & 400 mcg/dose breath-acuated dry powder inhalers** was reviewed as a resubmission and is indicated for the prophylactic management of steroid-responsive bronchial asthma in patients 12 years of age and older. The Expert Committee recommended these Drug Products for listing on the *ADBL*, as they offer a cost and/or therapeutic advantage.
- **SAPRHIS** (asenapine maleate) (LBC) **5 mg & 10 mg sublingual tablets** was reviewed as a resubmission for the indication of Bipolar I Disorder. The Expert Committee recommended these Drug Products for listing on the *ADBL*, via Special Authorization, as they offer a therapeutic advantage.

In keeping with the recommendations from the CDR, the following Drug Product has not been added to the *ADBL*:

- **MOZOBIL** (plerixafor) (GZM) **20 mg/mL 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).*

Highlights of Products Added to the ADBL

The Expert Committee recommended that the following Drug Products be added to the *ADBL*, effective February 1, 2013:

- **GD-AMLODIPINE** (amlodipine besylate) (GMD) **2.5 mg tablet**
- **JAMP-ATENOLOL** (atenolol) (JPC) **25 mg tablet**
- **JAMP-CITALOPRAM** (citalopram hydrobromide) (JPC) **10 mg tablet**

Highlights of Entry IC Products Added

The following are Entry IC Drug Products, added to the ADBL, effective February 1, 2013 after a Full Review by the Expert Committee:

- **ACCEL-CLARITHROMYCIN** (clarithromycin) (ACP) **25 mg/mL & 50 mg/mL oral suspensions**
- **APO-LAMIVUDINE HBV** (lamivudine) (APX) **100 mg tablet** as a restricted benefit

Highlights of Established IC Products Added

- **APO-RIZATRIPTAN** (rizatriptan benzoate) (APX) **10 mg tablet** as a restricted benefit
- **JAMPZINC-HC** (hydrocortisone acetate/zinc sulfate monohydrate) (JPC) **0.5%/0.5% rectal ointment**
- **MAR-GABAPENTIN** (gabapentin) (MAR) **100 mg, 300 mg & 400 mg capsules**

Highlights of Expedited Entry IC Products Added

The following are Entry IC Drug Products, added to the ADBL, effective February 1, 2013:

- **APO-CANDESARTAN/HCTZ** (candesartan cilexetil/ hydrochlorothiazide) (APX) **32 mg/12.5 mg & 32 mg/25 mg tablets**
- **APO-ENTECAVIR** (entecavir) (APX) **0.5 mg tablet** as a restricted benefit

Motherisk Guidance: Use of Pre-Requisite Medications Prior to Biologic Coverage

The Expert Committee reviewed the administration of coverage criteria for biologic agents when pregnancy or fertility issues are cited as reasons for not utilizing pre-requisite medications, particularly leflunomide and methotrexate. The Committee indicated that the fact that a patient may be of child bearing age or potential does not merit the practice of waiving the use of pre-requisite medications for biologics. Please see below for a response from The Motherisk Program:

“There is, to the best of our knowledge, no evidence that methotrexate or leflunomide should not be used in women of childbearing age, provided proper explanation of their teratogenic potential is given to the women and the importance of contraception is explained and emphasized by her treating physicians and proper contraception is practiced by her during the treatment period. It’s vital to emphasize the importance of pregnancy planning in this population in order to optimize pregnancy outcomes.”

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).****

the DBL report

Issue #70, November 2012

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 20, 2012. The Committee reviewed Manufacturer submissions for 76 Drug Products for potential listing, or change in listing status, on the *ADBL*.

In addition to these Drug Products, 32 generic Drug Products underwent Expedited Review for listing on the *ADBL* effective October 1, 2012, and 16 generic Drug Products underwent Expedited Review for listing effective November 1, 2012.

The following are highlights of recent changes to the *ADBL*. A complete list of changes and the full *ADBL* can be found at

https://www.ab.bluecross.ca/dbl/publications.html

Highlights of Products Added to the ADBL

- **OPTICHAMBER DIAMOND** (aerosol holding chamber) (RNA) **with small, medium & large masks and chamber only** were submitted as Line Extensions to the currently listed OPTICHAMBER ADVANTAGE II aerosol holding chamber and masks with the Manufacturer indicating their intention of phasing out the currently listed OPTICHAMBER devices in the future. The Expert Committee recommended **OPTICHAMBER DIAMOND** be listed on the *ADBL* via Restricted Benefits as each of these products offers a cost advantage. Please refer to the current *ADBL* for a full listing of coverage criteria.
- **LAX-A-DAY** (polyethylene glycol 3350) (PPH) **powder for solution**, a laxative, will be listed on the *Palliative Care Drug Benefit Supplement (PCDBS)* effective November 1, 2012. Alberta Health sponsors *Palliative Care Drug Coverage*, which is offered through Alberta Blue Cross to any Albertan who has been diagnosed as being palliative and whose physician or nurse practitioner has applied on their behalf.
- **ROVAMYCINE-250** (spiramycin) (ODN) **750,000 unit** & **ROVAMYCINE-500 1,500,000 unit capsules** are indicated for the treatment of infections of the respiratory tract, buccal cavity, skin and soft tissues due to susceptible organisms. The Expert Committee recommended these Drug Products for listing on the *ADBL*, following consultation with Alberta specialists in infectious diseases.
- **SANDOZ FLUOROMETHOLONE** (fluorometholone) (SDZ) **0.1% ophthalmic solution** is indicated for steroid responsive inflammation of palpebral and bulbar conjunctiva, cornea and anterior segment of globe. The Expert Committee recommended this Drug Product for listing on the *ADBL* as it offers a therapeutic advantage.

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 (11/2012)

Highlights of Entry IC Products Added

The following are Entry IC Drug Products, added to the ADBL, effective November 1, 2012 after a Full Review by the Expert Committee:

- **CLOXACILLIN FOR INJECTION** (cloxacillin sodium) (STM) **0.5 g/vial, 1 g/vial & 2 g/vial powders for injection**
- **VANCOMYCIN HYDROCHLORIDE** (vancomycin hydrochloride) (PPC) **125 mg & 250 mg capsules**

Highlights of Expedited Entry IC Products Added

The following are Entry IC Drug Products, added to the ADBL, effective November 1, 2012:

- **CO CANDESARTAN/HCT** (candesartan cilexetil/ hydrochlorothiazide) (COB) **16 mg/12.5 mg tablet**
- **pms CANDESARTAN/HCTZ** (candesartan cilexetil/ hydrochlorothiazide) (PMS) **16 mg/12.5 mg tablet**
- **MYLAN-CANDESARTAN/HCTZ** (candesartan cilexetil/ hydrochlorothiazide) (MYP) **16 mg/12.5 mg tablet**
- **SANDOZ CANDESARTAN PLUS** (candesartan cilexetil/ hydrochlorothiazide) (SDZ) **16 mg/12.5 mg tablet**

Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendations from the CDR, the following Drug Products have been added to the *ADBL* (please refer to the current *ADBL* for a full listing of coverage criteria):

- **ACTEMRA** (tocilizumab) (HLR) **80 mg/4 mL, 200 mg/10 mL** & **400 mg/20 mL vial injections** was reviewed for the new indication of active systemic juvenile idiopathic arthritis (sJIA). The Expert Committee recommended each of these Drug Products for listing on the *ADBL*, via Special Authorization, as they offer a therapeutic advantage.
- **INCIVEK** (telepravir) (VER) **375 mg tablet** is indicated for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment naïve or who have previously been treated with interferon-based treatment, including prior null responders, partial responders, and relapsers. This Drug Product was recommended for listing on the *ADBL*, via Special Authorization, as it offers a therapeutic advantage.
- **RITUXAN** (rituximab) (HLR) **10 mg/mL injection** was reviewed for the new indications of granulomatosis with polyangiitis (GPA) and microscopic polyangiitis (MPA). The Expert Committee recommended this Drug Product for listing on the *ADBL*, via Special Authorization, as it offers a therapeutic advantage.
- **VISANNE** (dienogest) (BAI) **2 mg tablet** was reviewed for treatment of pelvic pain associated with endometriosis. The Expert Committee recommended this Drug Product for listing on the *ADBL*, via Special Authorization, as it offers cost and/or therapeutic advantage.

In keeping with the recommendations from the CDR, the following Drug Products have not been added to the *ADBL*:

- **BYETTA** (exenatide) (LIL) **5 mcg/dose (1.2 mL) & 10 mcg/dose (2.4 mL) injection syringes**
- **RESOTRAN** (prucalopride succinate) (JAI) **1 mg & 2 mg film coated tablets**

Changes in SA Criteria for Clopidogrel

The Expert Committee completed a review of anti-platelet agents for secondary prevention of ischemic stroke. The Expert Committee agreed that the available evidence supported removing the requirement for a trial of dipyramidole plus ASA before patients could be provided coverage on the *ADBL* for **CLOPIDOGREL 75 mg tablet**. Accordingly, the Special Authorization criteria pertaining to this indication have been revised to:

"For the prevention of ischemic events (cerebrovascular (e.g. stroke, TIA) or noncerebrovascular) in patients who have experienced an ischemic event while on ASA, or who have a contraindication to ASA. Special authorization for this criterion may be granted for 6 months."

In addition, auto-renewal is available for patients approved for coverage under these criteria. Please refer to the *ADBL* for a complete listing of coverage criteria and **CLOPIDOGREL** Drug Products affected.

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).****

the DBL report

Issue #69, September 2012

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

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Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

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Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 19, 2012. The Committee reviewed Manufacturer submissions for 34 Drug Products for potential listing, or change in listing status, on the *AHWDBL*.

In addition to these Drug Products, 32 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective September 1, 2012.

The following are highlights of recent changes to the *AHWDBL*. A complete list of changes and the full *AHWDBL* can be found at

https://www.ab.bluecross.ca/dbl/publications.html

Highlights of Products Added to the AHWDBL

- **VFEND** (voriconazole) (PFI) **40 mg/mL oral suspension** was submitted as a Line Extension to the existing **50 mg & 200 mg tablets**. The Expert Committee recommended **VFEND** oral suspension be listed on the *AHWDBL* via Special Authorization as it offers a therapeutic advantage for patients who require an alternative formulation to tablets. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

- **ELIQUIS** (apixaban) (BMS) **2.5 mg tablet** was initially reviewed via the CDR process. **ELIQUIS** is indicated for the prevention of venous thromboembolic events (VTE) in adult patients who have undergone elective knee or hip replacement surgery. In keeping with the recommendations from the CDR, this Drug Product has been added to the *AHWDBL* with a listing via Restricted Benefit. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (09/2012)

Highlights of IC Products Added

The following are established IC Groupings Drug Product, added to the AHWDBL, effective September 1, 2012:

- **JAMP-RIZATRIPTAN** (rizatriptan benzoate) (JPC)
  5 mg & 10 mg tablets

- **MYLAN-ZOLMITRIPTAN ODT** (zolmitriptan) (MYP)
  2.5 mg orally disintegrating tablet

Highlights of Products Not Added

- **MYLAN-BISOPROLOL** (bisoprolol fumarate) (MYP)
  5 mg & 10 mg tablets were not recommended to be added to the *AHWDBL* as the Manufacturer failed to provide sufficient evidence of interchangeability with an Innovator Drug Product.

Highlights of Changes to the Multiple Sclerosis (MS) Drug Coverage

On September 1, 2012, the MS Drug Product **GILENYA** (fingolimod hydrochloride) **0.5 mg capsule** was added as a Special Authorization benefit to the *AHWDBL*. In addition, changes were made to Section 2 of the *AHWDBL*: Multiple Sclerosis (MS) Drug Coverage, and the coverage criteria for MS drugs. Please refer to the September *AHWDBL* update (https://www.ab.bluecross.ca/dbl/pdfs/ahw_september.pdf) for details on the changes.

Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendations from the CDR, the following Drug Products have not been added to the *AHWDBL*:

- **BENLYSTA** (belimumab) (GKC) **120 mg/vial & 400 mg/vial injections**
- **EFFIENT** (prasugrel hydrochloride) (BMS) **10 mg tablet**
- **GELNIQUE** (oxybutynin chloride) (WAT) **100 mg/g topical gel**
- **OZURDEX** (dexamethasone) (ALL) **0.7 mg intravitreal implant**
- **SAPHRIS** (asenapine maleate) (BAI) **5 mg & 10 mg sublingual tablets (for the treatment of schizophrenia)**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

the DBL report

Issue #68, August 2012

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 23 and 24, 2012. The Committee reviewed Manufacturer submissions for 43 Drug Products for potential listing or change in listing status on the *AHWDBL*.

The following are highlights of recent changes to the *AHWDBL*. A complete list of changes and the full *AHWDBL* can be found at https://www.ab.bluecross.ca/dbl/publications.html.

Expanded Funding to Cover Diabetes Self-management Supplies

On February 16, 2012 the Alberta Government announced expanded funding for Albertans with insulin-treated diabetes. As part of the diabetic supply initiative the following products will be funded: syringes, pen needles, lancets, blood glucose and urine testing strips. The criteria for this Restricted Benefit is as follows: "This product is a benefit for patients with diabetes who are currently and regularly using insulin. Eligible individuals will have coverage to a maximum of $600 per person each benefit year for eligible diabetic supplies purchased from a licensed pharmacy."Please refer to the current *AHWDBL* for a full listing of coverage criteria.

Highlights of Products Added to the AHWDBL

pms-Valacyclovir (valacyclovir hydrochloride) (PMS) **1000 mg caplet. pms-Valacyclovir** was submitted as line-extension to the existing **500 mg** strength. The Expert Committee recommended addition to the AHWDBL as it offers a therapeutic advantage by decreasing pill burden, as well as a cost advantage by providing savings over the use of two 500 mg caplets.

In addition, the following Interchangeable Drug Products were recommended for addition to the *AHWDBL* effective August 1, 2012:

- **Apo-Zolmitriptan** (zolmitriptan) (APX) **2.5 mg tablet**
- **Mar-Rizatriptan** (rizatriptan benzoate) (MAR) **5 mg & 10 mg tablets**

A complete list of changes, as well as the full AHWBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (08/2012)

the DBL report

Issue #67, May 2012

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 15, 2012. The Committee reviewed Manufacturer submissions for 52 Drug Products for potential listing or change in listing status on the *AHWDBL*.

In addition to these Drug Products, 119 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective May 1, 2012.

The following are highlights of recent changes to the *AHWDBL*. A complete list of changes and the full *AHWDBL* can be found at https://www.ab.bluecross.ca/dbl/publications.html.

Products Originally Reviewed via the Common Drug Review (CDR)

In keeping with the recommendations from the CDR, the following Drug Products have not been added to the *AHWDBL*:

- **ONSOLIS** (fentanyl) (MED) **200 mcg, 400 mcg, 600 mcg, 800 mcg & 1200 mcg buccal soluble films**

- **TARGIN** (oxycodone HCL/ naloxone HCL) (PUR) **10 mg/ 5 mg, 20 mg/10 mg & 40 mg/ 20 mg extended release tablets**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (05/2012)

Other Products Added to the AHW DBL

TRAJENTA (linagliptin) (BOE) **5 mg tablet** was reviewed via the CDR process. **TRAJENTA** is indicated in adult patients with type 2 diabetes mellitus (T2DM) to improve glycaemic control. In keeping with the recommendations from the CDR, this Drug Product has been added to the *AHWDBL* with a listing via Step Therapy/Special Authorization. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

JANUVIA (sitagliptin phosphate monohydrate) (MFC) **100 mg tablet** and **JANUMET** (sitagliptin phosphate monohydrate/ metformin HCl) (MFC) **50 mg/ 500 mg, 50 mg/ 850 mg and 50 mg/100 mg tablets** were reviewed via the CDR process. **JANUVIA** and **JANUMET** are indicated in adult patients with type 2 diabetes mellitus (T2DM) to improve glycaemic control. In keeping with the recommendations from the CDR, these Drug Products have been added to the *AHWDBL* with a listing via Step Therapy/Special Authorization. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

PRADAX (dabigatran etexilate) (BOE) **110 mg and 150 mg capsule** were reviewed via the CDR process. **PRADAX** will be available to at-risk patients with non-valvular atrial fibrillation for the prevention of stroke and systemic embolism. Further, anticoagulation must be inadequate following a reasonable trial on warfarin or warfarin is contraindicated or not possible due to inability to regularly monitor the patient's INR. These Drug Products have been added to the AHWDBL with a listing via Step Therapy/Special Authorization. Please refer to the AHWDBL for a full listing of coverage criteria.

Highlights of New Interchangeable (IC) Groupings

The recent additions of the following Drug Products to the *AHWDBL* have resulted in the creation of New IC Groupings, effective May 1, 2012:

- **ENTACAPONE 200 mg tablet**
  - **APO-ENTACAPONE** (APX)
  - **TEVA-ENTACAPONE** (TEV)
- **LOSARTAN POTASSIUM 25 mg, 50 mg & 100 mg tablets**
  - **APO-LOSARTAN** (APX)
  - **CO LOSARTAN** (COB)
  - **MYLAN-LOSARTAN** (MYP)
  - **PMS-LOSARTAN** (PMS)
  - **SANDOZ LOSARTAN** (SDZ)
  - **TEVA-LOSARTAN** (TEV)
- **LOSARTAN POTASSIUM/ HYDROCHLOROTHIAZIDE 50 mg/12.5 mg, 100 mg/12.5 mg & 100/25 mg tablets**
  - **APO-LOSARTAN/HCTZ** (APX)
  - **MYLAN-LOSARTAN HCTZ** (MYP)
  - **SANDOZ LOSARTAN HCT** (SDZ)
  - **SANDOZ LOSARTAN HCT DS** (SDZ) **(100 mg/25 mg tablet only)**
  - **TEVA-LOSARTAN HCT** (TEV)
- **NABILONE 0.5 mg & 1 mg capsules**
  - **PMS-NABILONE** (PMS)
  - **RAN-NABILONE** (RAN)
- **RIZATRIPTAN BENZOATE 5 mg & 10 mg orally disintegrating tablets**
  - **CO RIZATRIPTAN ODT** (COB)
  - **MYLAN-RIZATRIPTAN ODT** (MYP)
  - **SANDOZ RIZATRIPTAN ODT** (SDZ)
- **ROSUVASTATIN CALCIUM 5 mg, 10 mg, 20 mg & 40 mg tablets**
  - **APO-ROSUVASTATIN** (APX)
  - **CO ROSUVASTATIN** (COB)
  - **MYLAN-ROSUVASTATIN** (MYP)
  - **PMS-ROSUVASTATIN** (PMS)
  - **RAN-ROSUVASTATIN** (RAN)
  - **SANDOZ ROSUVASTATIN** (SDZ)
  - **TEVA-ROSUVASTATIN** (TEV)
- **TELMISARTAN 40 mg & 80 mg tablets**
  - **MYLAN-TELMISARTAN** (MYP)
  - **SANDOZ TELMISARTAN** (SDZ)
  - **TEVA-TELMISARTAN** (TEV)
- **TELMISARTAN/HYDROCHLOROTHIAZIDE 80 mg/12.5 mg & 80 mg/25 mg tablets**
  - **MYLAN-TELMISARTAN HCTZ** (MYP)
  - **TEVA-TELMISARTAN HCTZ** (TEV)

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #66, March 2012

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey A. Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl A. Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly B. Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 26, 2012. The Committee reviewed Manufacturer submissions for 43 Drug Products for potential listing or change in listing status on the *AHWDBL*.

In addition to these Drug Products, 82 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective February 1, 2012, and another 33 generic Drug Products underwent Expedited Review for listing effective March 1, 2012.

The following are highlights of recent changes to the *AHWDBL*. A complete list of changes and the full *AHWDBL* can be found at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of New Products Added

- **OXYNEO** (oxycodone hydrochloride) (PUR) **10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg & 80 mg extended-release tablets** are a new formulation of sustained-release oxycodone, consisting of a matrix with hydrogelling properties (i.e., particles or whole tablets become highly viscous (gel-like) in water). The tablets have also been hardened, by a unique process, to reduce the risk of being broken, crushed or chewed. **OXYNEO** tablets were reviewed as line extensions to the currently listed OXYCONTIN Drug Products, which the Manufacturer intends to replace with **OXYNEO**. The Expert Committee recommended adding **OXYNEO** to the *AHWDBL*, as line extension Drug Products to, and in interchangeable groupings with, OXYCONTIN Drug Products. **OXYNEO** offers a therapeutic advantage in replacing a Drug Product that will be withdrawn from the market.
- **TWYNSTA** (telmisartan/amlodipine besylate) (BOE) **40 mg/5 mg, 40 mg/10 mg, 80 mg/5 mg & 80 mg/10 mg tablets** are new combination Drug Products indicated for the treatment of mild to moderate hypertension. **TWYNSTA** was originally reviewed via the Common Drug Review (CDR). The Expert Committee recommended that **TWYNSTA** be added to the *AHWDBL* as it offers a cost advantage over presently accepted therapies.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (03/2012)

Highlights of New Interchangeable (IC) Groupings

The recent additions of the following Drug Products to the *AHWDBL* has resulted in the creation of New IC Groupings, effective March 1, 2012:

- **APO-CLOPIDOGREL** (clopidogrel bisulfate) (APX) **75 mg tablet**
- **CO CANDESARTAN** (candesartan cilexetil) (COB) **32 mg tablet**
- **CO CLOPIDOGREL** (clopidogrel bisulfate) (COB) **75 mg tablet**
- **MYLAN-CLOPIDOGREL** (clopidogrel bisulfate) (MYP) **75 mg tablet**
- **PMS-CLOPIDOGREL** (clopidogrel bisulfate) (PMS) **75 mg tablet**
- **PMS-RISPERIDONE ODT** (risperidone) (PMS) **3 mg & 4 mg orally disintegrating tablets**
- **SANDOZ CLOPIDOGREL** (clopidogrel bisulfate) (SDZ) **75 mg tablet**
- **TEVA-CLOPIDOGREL** (clopidogrel bisulfate) (TEV) **75 mg tablet**

Highlights of Benefit Coverage and Criteria Changes

- **CHAMPIX** (varenicline tartrate) (PFI) **0.5 mg & 1 mg tablets** and **0.5 mg/1 mg tablet starter pack** were reviewed, following receipt of a resubmission from the Manufacturer requesting consideration be given to revising the benefit status. **CHAMPIX** was initially listed on the *AHWDBL*, as a Restricted Benefit (RB), effective June 15, 2011. The original RB criteria required that a patient provide proof of enrolment in an eligible tobacco-cessation program in order to receive coverage of **CHAMPIX**. The Expert Committee recommended changes to the RB criteria to further facilitate access to this smoking cessation therapy. The revised RB criteria allow for initial coverage up to a total of 12 weeks, without requiring proof of enrolment in a tobacco-cessation program. In addition, the Expert Committee recommended **CHAMPIX** be made available via Special Authorization to provide supplementary coverage beyond the initial RB allowance, to a maximum of 24 weeks per year. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

Additional Products Originally Reviewed via the Common Drug Review (CDR)

- **XGEVA** (denosumab) (AMG) **120 mg/vial injection** received a CDR recommendation for listing for a specific indication, in jurisdictions where zoledronic acid is listed for the same indication. Zoledronic acid is not currently listed on the *AHWDBL* for the reviewed indication. Therefore, in keeping with the CDR recommendation, **XGEVA** has not been recommended for addition to the *AHWDBL*.

Also in keeping with the recommendations from the CDR, the following Drug Products have not been added to the *AHWDBL*:

- **ABSTRAL** (fentanyl) (PAL) **100 mcg, 200 mcg, 300 mcg, 400 mcg, 600 mcg & 800 mcg sublingual tablets**
- **REVOLADE** (eltrombopag olamine) (GSK) **25 mg & 50 mg tablets**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #65, February 2012

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Jeffrey Johnson, BSP, MSc, PhD
Saibal Nandy MBBS, MRCPsych, FRCPC
Glen J. Pearson, BScPhm, PharmD, FCSHP
Cheryl Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 22, 2011. The Committee reviewed Manufacturer submissions for 30 Drug Products.

In addition to Drug Products reviewed by the Expert Committee, 71 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective December 1, 2011. The following are highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of New Interchangeable (IC) Groupings

Addition of the following Drug Products to the *AHWDBL* has resulted in the creation of New IC Groupings, effective December 1, 2011:

- **APO-MONTELUKAST** (montelukast sodium) (APX) **10 mg tablet**
- **PMS-MONTELUKAST** (montelukast sodium) (PMS) **4 mg and 5 mg chewable tablets and 10 mg tablet**
- **SANDOZ MONTELUKAST**(montelukast sodium) (SDZ) **4 mg and 5 mg chewable tablets, 4 mg granules and 10 mg tablet,**
- **TEVA-MONTELUKAST FC** (montelukast sodium) (TEV) **4 mg and 5 mg chewable tablets and 10 mg tablet**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (11/2011)

Highlights of IC Products Added

Submissions for the following Drug Products did not meet the requirements for the Interchangeable Expedited Review process. Accordingly, these Drug Products were forwarded to the Expert Committee for a Full Review, and have subsequently been recommended for addition to the *AHWDBL* in interchangeable groupings, effective February 1, 2012:

- **MAR-CITALOPRAM** (citalopram hydrobromide) (MAR) **20 mg and 40 mg tablets**
- **MAR-ONDANSETRON** (ondansetron hydrochloride) (MAR) **4 mg and 8 mg tablets**
- **TARO-CARBAMAZEPINE** (carbamazepine) (TAR) **100 mg/5 mL suspension**

Highlights of Additional Products Added

The following Drug Product has been recommended for addition to the *AHWDBL*:

- **TOBI PODHALER** (tobramycin) (NOV) **28 mg inhalation capsule**
- **BENZTROPINE OMEGA** (benztropine mesylate) (OMG) **1 mg/mL injection**

Highlights of Products Not Added

The following Drug Products have not been recommended for addition to the *AHWDBL*:

- **JAMP-FOLIC ACID** (folic acid) (JPC) **5 mg tablet** was not recommended to be added as the Manufacturer failed to provide sufficient evidence of interchangeability with an innovator Drug Product.
- **LITHMAX** (lithium carbonate) (AAP) **300 mg sustained-release tablet** was reviewed as a resubmission. **LITHMAX** (lithium carbonate) **300 mg** was not recommended for addition as the Manufacturer failed to provide sufficient evidence of interchangeability with the innovator Drug Product.

The following Drug Products have not been recommended for addition to the *AHWDBL* following review by the Common Drug Review (CDR) process:

- **BUTRANS** (buprenorphine) (PUR) **5 mcg/hr and 10 mcg/hr and 20 mcg/hr transdermal patch**
- **DAXAS** (roflumilast) (NYC) **500 mcg tablet**
- **NUCYNTA CR** (tapentadol HCl) (JAI) **50 mg, 100 mg, 150 mg, 200 mg and 250 mg extended-release tablet**
- **RESTASIS** (cyclosporine) (ALL) **0.05% oph emulsion**
- **VICTOZA** (liraglutide) (NNA) **6 mg/ml pen injection syringe**
- **ZENHALE** (formoterol fumarate dihydrate/ mometasone furoate) (MFC) **50 mcg/5 mcg/dose metered dose aerosol**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #64, November 2011

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Margaret Barr, BSc (Pharm)
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Cheryl Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 22, 2011. The Committee reviewed Manufacturer submissions for 21 Drug Products.

In addition to Drug Products reviewed by the Expert Committee, 13 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective October 1, 2011, and another 68 generic Drug Products underwent Expedited Review for listing effective November 1, 2011. The following are highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Product Originally Reviewed via the Common Drug Review (CDR)

CAYSTON (aztreonam) (GIL) **75 mg/vial lyophilized powder for inhalation solution**. The Expert Committee recommended that this Drug Product be listed via Step Therapy/Special Authorization for the treatment of chronic pulmonary *Pseudomonas aeruginosa* infections when used as cyclic treatment (28-day cycles) in patients 6 years of age and older with moderate to severe cystic fibrosis and deteriorating clinical condition despite treatment with inhaled tobramycin.

Highlights of New Interchangeable (IC) Groupings

Addition of the following Drug Product to the *AHWDBL* has resulted in the creation of a New IC Grouping, effective October 1, 2011:

- **APO-LATANOPROST** (latanoprost) (APX) **0.005% ophthalmic solution**

Addition of the following Drug Product to the *AHWDBL* has resulted in the creation of a New IC Grouping, effective November 1, 2011:

- **TARO-MOMETASONE** (mometasone furoate) (TAR) **0.1% topical cream**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (11/2011)

Highlights of Products Not Added

The following Drug Products have not been recommended for addition to the *AHWDBL*:

- **ACTONEL DR** (risedronate sodium) (WCC) **35 mg tablet** was not recommended for addition to the *AHWDBL* as the Manufacturer failed to provide sufficient evidence of cost and/or therapeutic advantage.
- **APO-TIMOP GEL** (timolol maleate) (APX) **0.5% ophthalmic long acting gellan solution** was reviewed as a resubmission. **APO-TIMOP GEL 0.5%** was not recommended to be added as the Manufacturer failed to provide sufficient evidence of interchangeability with the innovator Drug Product.

Highlights of New Products Added

Submissions for the following Drug Products did not meet the requirements for the Interchangeable Expedited Review process. Accordingly, these Drug Products were forwarded to the Expert Committee for a Full Review, and have subsequently been recommended for addition to the *AHWDBL* in interchangeable groupings, effective November 1, 2011:

- **APO-DICLO SR** (diclofenac sodium) (APX) **75 mg & 100 mg sustained release tablets**
- **CARVEDILOL** (carvedilol) (SNS) **3.125 mg, 6.25 mg, 12.5 mg & 25 mg tablets**
- **TEVA-LACTULOSE** (lactulose) (TEV) **667 mg/mL oral syrup**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #63, Sept 2011

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Margaret Barr, BSc (Pharm)
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Cheryl Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on July 21, 2011. The Committee reviewed Manufacturer submissions for 28 Drug Products. The Committee also considered information for a number of supplementary assessments of the coverage status of 19 Drug Products.

In addition to Drug Products reviewed by the Expert Committee, 10 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective August 1, 2011, and another 11 generic Drug Products underwent Expedited Review for listing effective September 1, 2011. The following are highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Products Originally Reviewed via the Common Drug Review (CDR)

Invega Sustenna 50 mg/0.5 mL, 75 mg/0.75 mL, 100 mg/mL and 150 mg/1.5 mL suspensions for injection (paliperidone palmitate) (JAI) were reviewed via the CDR process. These Drug Products have been added to the *AHWDBL* with a listing via special authorization as they offer a cost advantage for the management of the manifestations of schizophrenia in patients who demonstrate a pattern of significant non-compliance that compromises therapeutic success. In addition, to maintain consistancy, the special authorization criteria for **Risperdal Consta** were updated. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

Vimpat 50 mg, 100 mg, 150 mg and 200 mg tablets (lacosamide) (UCB) were reviewed via the CDR process. In keeping with the recommendations from the CDR, these Drug Products have been added to the *AHWDBL* with a listing via special authorization. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (9/2011)

Highlights of Special Authorization (SA) Criteria Changes

In their July 21, 2011 meeting, the Expert Committee on Drug Evaluation and Therapeutics discussed a request to clarify the special authorization criteria for biologic agents in the treatment of plaque psoriasis. The Expert Committee confirmed that it was their intent that patients try either cyclosporine or methotrexate prior to utilizing a biologic agent. Accordingly, the Expert Committee recommended that the following criterion be included within the special authorization criteria for coverage of all biologics used in the treatment of plaque psoriasis: "Patients who have a contraindication to either cyclosporine or methotrexate will be required to complete an adequate trial of the other pre-requisite medication prior to potential coverage being considered."

Highlights of New Products Added

The following Drug Products have been recommended for addition to the *AHWDBL*:

- **Hydromorph Contin 4.5 mg and 9 mg controlled-release capsules** (hydromorphone HCl) (PUR)
- **RAN-Metformin 850 mg tablet** (metformin HCl) (RAN)
- **pms-Clarithromycin 250 mg tablet** (clarithromycin) (PMS)
- **pms-Rivastigmine 1.5 mg, 3 mg and 4.5 mg capsules** (rivastigmine hydrogen tartrate) (PMS)

Highlights of New Interchangeable (IC) Groupings

Addition of the following Drug Products to the *AHWDBL* has resulted in the creation of New IC Groupings, effective September 1, 2011:

- **Mylan-Zolmitriptan 2.5 mg tablet** (zolmitriptan) (MYP)
- **pms-Zolmitriptan 2.5 mg tablet** (zolmitriptan) (PMS)
- **pms-Zolmitriptan ODT 2.5 mg orally dispersible tablet** (zolmitriptan) (PMS)
- **Sandoz Zolmitriptan 2.5 mg tablet** (zolmitriptan) (SDZ)
- **Sandoz Zolmitriptan ODT 2.5 mg orally dispersible tablet** (zolmitriptan) (SDZ)
- **Teva-Zolmitriptan 2.5 mg tablet** (zolmitriptan) (TEV)
- **Teva-Zolmitriptan OD 2.5 mg orally dispersible tablet** (zolmitriptan) (TEV)

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A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #62, July 2011

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Margaret Barr, BSc (Pharm)
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Cheryl Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 17 and 18, 2011. The Committee reviewed Manufacturer submissions for 11 Drug Products. The Committee also considered information for a number of supplementary assessments of the coverage status of 43 Drug Products.

In addition to Drug Products reviewed by the Expert Committee, 12 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective June 1, 2011, and another 6 generic Drug Products underwent Expedited Review for listing effective July 1, 2011. The following are highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Products Originally Reviewed via the Common Drug Review (CDR)

ULORIC 80 MG TABLET (febuxostat) (TAK) was reviewed via the CDR process. In keeping with the recommendations from the CDR, this product has been added to the *AHWDBL* with a listing via special authorization as it offers a therapeutic advantage for select patients who are unable to take allopurinol and who cannot tolerate or experience a lack of response to other presently accepted therapies. The special authorization criteria for this Drug Product will read: "For patients with symptomatic gout who have documented hypersensitivity or severe intolerance to allopurinol, AND intolerance or lack of response to sulfinpyrazone AND probenecid. Special authorization may be granted for 6 months." This product is eligible for auto-renewal.

ACTEMRA 80 MG/4 ML, 200 MG/10 ML & 400 MG/20 ML INTRAVENOUS SOLUTIONS (tocilizumab) (HLR) was reviewed via the CDR process. In keeping with the recommendations from the CDR, this product has been added to the *AHWDBL* with a listing via special authorization. Please refer to the current *AHWDBL* for a full listing of coverage criteria.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (7/2011)

Products Not Added

LITHMAX 300 MG SUSTAINED RELEASE TABLET (lithium carbonate) (AAP) The Expert Committee recommended that Lithmax 300 mg sustained-release tablet not be added to the *AHWDBL* as it failed to satisfy the published requirements of Critical Dose Drug Products.

RAN-CLARITHROMYCIN 500 MG TABLET (clarithromycin) (RAN) The Expert Committee recommended that RAN-Clarithromycin 500 mg tablet not be added to the *AHWDBL* as it failed to satisfy the published requirements of Non-Linear Drug Products. For Non-Linear Drug Products, it is required they meet all criteria in the Non-Linear Drug Product Appendix to the Interchangeable Drug Products - Additional Criteria in the *AHWDBL* (i.e., the bioavailability of at least the highest dose be studied and that all requirements be met in the fasted and fed state, except where it has been demonstrated that food does not modify bioavailability at doses within the range of strengths to be marketed).

Highlights of New Interchangeable (IC) Groupings

Addition of the following products to the *AHWDBL* has resulted in the creation of New IC Groupings, effective July 1, 2011:

- **APO-CANDESARTAN** (APO) and **SANDOZ CANDESARTAN** (SDZ) (candesartan) **8 MG & 16 MG TABLETS**

Osteoporosis

In their May 17 and 18 meetings, the Expert Committee on Drug Evaluation and Therapeutics discussed osteoporosis therapy in association with a Review of Benefit Status (ROBS) of bisphosphonates in the treatment of osteoporosis, as well as consideration of special authorization criteria for Prolia (denosumab).

ROBS Review: The ROBS review was undertaken to examine the place of bisphosphonates in osteoporosis therapy and if any changes in the present listing status of these agents should be proposed. The ROBS Sub-Committee considered recent literature, as well as several new Canadian and International Guidelines. Following discussion, the Expert Committee on Drug Evaluation and Therapeutics recommended that the listing status and criteria for each of the bisphosphonates should remain unchanged.

PROLIA 60 MG/ML SOLUTION FOR INJECTION (denosumab) (AMG) was reviewed via the CDR process. In keeping with the recommendations from the CDR, this product has been added to the *AHWDBL* with a listing via special authorization as it offers a therapeutic advantage for select high risk patients who are unable to take bisphosphonates due to hypersensitivity or to abnormalities of the esophagus that cannot be corrected. The special authorization criteria for this Drug Product will read: "For the treatment of postmenopausal osteoporosis in women for whom oral bisphosphonates are contraindicated due to hypersensitivity or an endoscopically or radiographically confirmed untreatable abnormality of the esophagus which delays esophageal emptying (e.g., stricture or achalasia), AND who have at least two of the following:
- Age greater than or equal to 75 years
- A prior fragility fracture
- A bone mineral density (BMD) T-score of less than or equal to -2.5

Special authorization may be granted for 12 months.

Patients will be limited to receiving one dose of denosumab per prescription at their pharmacy.

Coverage cannot be provided for two or more osteoporosis medications (alendronate, calcitonin, denosumab, etidronate, raloxifene, risedronate) when these medications are intended for use as combination therapy."

This product is eligible for auto-renewal.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #61, May 2011

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Margaret Barr, BSc (Pharm)
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Cheryl Sadowski, BSc (Pharm), PharmD, FCSHP
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISONS:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on March 16, 2011. The Committee reviewed Manufacturer submissions for 4 Drug Products. The Committee also considered information for a number of supplementary assessments of the coverage status of 13 Drug Products.

In addition to Drug Products reviewed by the Expert Committee, 29 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective April 1, 2011, and another 31 generic Drug Products underwent Expedited Review for listing effective May 1, 2011.

The following are highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of New Products Added

■ **PMS-QUETIAPINE** (quetiapine fumarate) (PMS) **50 mg tablet** has been added to the *AHWDBL* as a line extension to other currently listed strengths. The Expert Committee indicated that **PMS-QUETIAPINE 50 mg tablet** provides a therapeutic advantage of not having to split an unscored 100 mg tablet and a decreased pill burden for patients who would otherwise require two 25 mg tablets for a 50 mg dose. In addition, **PMS-QUETIAPINE 50 mg** provides a cost advantage, based on savings over two 25 mg tablets.

Review of Benefit Status (ROBS) Process

(A version of this article originally appeared in Issue # 36, July 2005)

The Review of Benefit Status (ROBS) is a process by which the current *AHWDBL* Drug Products may be reviewed for continued value and appropriateness. In addition, Alberta Health and Wellness and/or the Expert Committee on Drug Evaluation and Therapeutics may at any time recommend that the benefit status of an individual product, class or category of Drug Products on the *AHWDBL* be reviewed.

Continued on next page…

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (5/2011)

ROBS Process

…Continued from previous page

Developed in response to feedback from the Auditor General of Alberta, the ROBS process serves to assess the continued value of Drug Products after they have been added to the *AHWDBL*, thereby assisting with the sustainability of the government-sponsored drug programs.

As with the review of any Drug Product by the Committee, recommendations are made by considering the potential benefit to all patients covered by the government-sponsored drug programs. Following a ROBS review, the listing status of a product may remain unchanged, or could be revised or discontinued if one or more of the ROBS criteria, published in Section 1 of the *AHWDBL*, are met. If a change in benefit status is deemed to be warranted, Manufacturers of the affected Drug Products are notified and provided with an opportunity to make a submission to the Committee prior to a final recommendation being made. Other stakeholders, such as prescribers, are also often consulted for input before a final recommendation is issued. The Expert Committee is the advisory committee to the Minister of Health and Wellness on matters pertaining to the coverage of Drug Products on the *AHWDBL*.

Highlights of New Interchangeable (IC) Groupings

Addition of the following products to the *AHWDBL* has resulted in the creation of New IC Groupings, effective April 1, 2011:

- **RAN-VALSARTAN** (valsartan) (RAN) **80 mg & 160 mg tablets**
- **SANDOZ VALSARTAN** (SDZ) & **TEVA-VALSARTAN** (TEV) (valsartan) **80 mg, 160 mg & 320 mg tablets**
- **SANDOZ VALSARTAN HCT** (SDZ) & **TEVA-VALSARTAN/HCTZ** (TEV) (valsartan/hydrochlorothiazide) **80 mg/12.5 mg, 160 mg/12.5 mg, 160 mg/25 mg, 320 mg/12.5 mg & 320 mg/25 mg tablets**

Addition of the following products to the *AHWDBL* has resulted in the creation of New IC Groupings, effective May 1, 2011:

- **PMS-IRBESARTAN** (PMS), **RATIO-IRBESARTAN** (RPH), **SANDOZ IRBESARTAN** (SDZ) & **TEVA-IRBESARTAN** (TEV) (irbesartan) **75 mg, 150 mg & 300 mg tablets**
- **PMS-IRBESARTAN-HCTZ** (PMS), **RATIO-IRBESARTAN HCTZ** (RPH), **SANDOZ IRBESARTAN HCT** (SDZ) & **TEVA-IRBESARTAN/HCTZ** (TEV) (irbesartan/hydrochlorothiazide) **150/12.5 mg, 300/12.5 mg & 300/25 mg tablets**
- **PMS-RAMIPRIL-HCTZ** (ramipril/hydrochlorothiazide) (PMS) **2.5mg/12.5 mg, 5 mg/12.5 mg & 5 mg/25 mg tablets**

Products Originally Reviewed via the Common Drug Review (CDR)

■ **FINACEA** (azelaic acid) (BAI) **15% topical gel** was reviewed via the CDR process. In keeping with the recommendations from the CDR, this product has been added to the *AHWDBL* as a Regular Benefit.

■ In keeping with recommendations from the CDR, the following products have not been added to the *AHWDBL*:

- **EFFIENT** (prasugrel hydrochloride) (LIL) **10 mg tablet**
- **ILARIS** (canakinumab) (NOV) **150 mg/vial powder for solution**
- **KUVAN** (sapropterin dihydrochloride) (BMI) **100 mg tablet**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #60, March 2011

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on January 27, 2011. The Committee reviewed manufacturer submissions for 24 Drug Products. The Committee also considered information for a number of supplementary assessments that resulted in changes to Special Authorization criteria for coverage of 53 Drug Products.

In addition to Drug Products reviewed by the Expert Committee, one resubmission based on the *AHWDBL* Price Policy was received and considered. As well, 17 generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective March 1, 2011.

The following articles provide highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of New Products Added

■ The following Line Extension products (i.e., new strengths and formulations or reformulations of Drug Products that are currently listed or are under consideration for listing) have been recommended for addition to the *AHWDBL*:

- **APO-VALACYCLOVIR** (valacyclovir) (APO) **1000 mg caplet**
- **DIAMICRON MR** (gliclazide) (SEV) **60 mg sustained release tablet**
- **SAIZEN** (somatropin r-DNA origin) (SRO) **6 mg (5.83 mg/mL), 12 mg (8 mg/mL) & 20 mg (8 mg/mL) solution for injection in cartridges**

Highlights of New IC Groupings

■ **SANDOZ TAMSULOSIN CR** (tamsulosin hydrochloride) (SDZ) **0.4 mg extended release tablet** has been added to the *AHWDBL*, creating a New Interchangeable (IC) Grouping with FLOMAX CR (BOE) 0.4 mg.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (3/2011)

Alzheimer's Disease SA Drug Products

The Special Authorization (SA) criteria for these products have been revised to incorporate the use of the InterRAI-Cognitive Performance Scale as an alternative assessment tool, allowing use of *either* the MMSE or the InterRAI-Cognitive Performance Scale for the purposes of administering the SA criteria. The InterRAI-Cognitive Performance Scale is one component of InterRAI Home Care (InterRAI-HC), a comprehensive instrument that has been designed to collect information on a broad range of physical, mental, and social abilities. InterRAI Home Care has been adopted and is in use by Home Care in the majority of Alberta. The requirement for an initial 12 week authorization has also been removed. The following products are affected:

■**ARICEPT** (donepezil hydrochloride) (PFI) **5 mg & 10 mg tablets**

■**RIVASTIGMINE HYDROGEN TARTRATE 1.5 mg, 3 mg, 4.5 mg & 6 mg capsules, [and 2 mg/mL oral solution** EXELON brand only**]**

- **APO-RIVASTIGMINE** (APO)
- **EXELON** (NOV)
- **MYLAN-RIVASTIGMINE** (MYP)
- **NOVO-RIVASTIGMINE** (TEV)
- **PMS-RIVASTIGMINE** (PMS) (6 mg strength only)
- **RATIO-RIVASTIGMINE** (RPH)
- **SANDOZ RIVASTIGMINE** (SDZ)

■**GALANTAMINE HYDROBROMIDE 8 mg, 16 mg & 24 mg extended-release capsules**

- **MYLAN-GALANTAMINE ER** (MYP)
- **PAT-GALANTAMINE ER** (PAT)
- **REMINYL ER** (JAI)

Please refer to the current *AHWDBL* for a full listing of the current SA criteria for these Drug Products.

Highlights of Special Authorization (SA) Criteria Changes

■ **RITUXAN (rituximab) (HLR) 10 mg/mL injection** – The manufacturer provided a resubmission requesting specific changes to the Special Authorization (SA) criteria for coverage. The Expert Committee considered the information provided in the resubmission and recommended the requirement for an initial DAS28 score of greater than or equal to 5.1 be removed from the SA criteria. The Expert Committee directed that patients now be required to improve by a minimum of 1.2 on the DAS28 score following the initial course of therapy only, and thereafter would need to achieve a post-treatment DAS28 score at least 1.2 points better than the score prior to the initial course of therapy (i.e., baseline). Please refer to the current *AHWDBL* for a full listing of the current SA criteria for **RITUXAN**.

■ **OCTREOTIDE ACETATE** and **LANREOTIDE ACETATE** – Currently listed via Special Authorization (SA), these products were recommended to have the SA and auto-renewal periods increased to 12 months. Affected products include:

- **OCTREOTIDE** (octreotide acetate) (TEV) **100 mcg/mL, 200 mcg/mL & 500 mcg/mL injections**
- **OCTREOTIDE ACETATE OMEGA** (octreotide acetate) (OMG) **50 mcg/mL, 100 mcg/mL, 200 mcg/mL & 500 mcg/mL injections**
- **SANDOSTATIN** (octreotide acetate) (NOV) **50 mcg/mL, 100 mcg/mL, 200 mcg/mL & 500 mcg/mL injections**
- **SANDOSTATIN LAR** (octreotide acetate) (NOV) **10 mg/vial, 20 mg/vial & 30 mg/vial injections**
- **SOMATULINE AUTOGEL** (lanreotide acetate) (TCI) **60 mg/syringe, 90 mg/syringe & 120 mg/syringe injection syringes**

Please refer to the current *AHWDBL* for a full listing of the current SA criteria.

Did You Know…?

The Interactive Drug Benefit List (iDBL) is a great tool for searching the Drug Benefit List publications. Special features allow you to:

- Quickly and easily re-sort your search results.
- Obtain quick information about the date certain products became benefits.
- Find complete pricing and interchangeability information.
- Find product specific special authorization coverage criteria.

Access the iDBL at ***https://www.ab.bluecross.ca/dbl/publications.html***.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #59, February 2011

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

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Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on November 23, 2010. The Committee considered information regarding 52 Drug Products, including manufacturer submissions and various supplementary assessments.

Fifteen generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective December 1, 2010. An additional 36 Drug Products met criteria for Expedited Review for listing, effective February 1, 2011.

The following articles provide highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of New Products Added

■ **Extavia** (interferon beta-1b) 0.3 mg/vial powder for solution (NOV) has been recommended for addition to the *AHWDBL* in an interchangeable grouping with Betaseron, which is currently listed with Special Authorization criteria in the MS Drug Program. The Expert Committee considered correspondence from Novartis and Bayer Schering indicating that Extavia is manufactured under the identical master formula, manufacturing and quality control specifications as Betaseron.

■ The following products have been added to the *AHWDBL* in Interchangeable (IC) Groupings:

- **Gen-Clozapine** (clozapine) 50 mg & 200 mg tablets (MYP)
- **Mylan-Mirtazapine** (mirtazapine) 15 mg tablet (MYP)
- **Apo-Enalapril Maleate/Hydrochlorothiazide** (enalapril maleate/hydrochlorothiazide) 5 mg/12.5 mg & 10 mg/25 mg tablets (APX)

Special Authorization Criteria Change

■ **Exjade (deferasirox**) (NOV) **125 mg, 250 mg & 500 mg Tablets** – following discussions with prescribing physicians, the Expert Committee recommended that Exjade be eligible for coverage via the step therapy/special authorization process. For patients who require iron chelation therapy but who have an inadequate response to a sufficient trial (i.e. a minimum of 6 months) of deferoxamine, or for whom deferoxamine is contraindicated, special authorization may be granted for 24 months. For more detail of the changes please refer to the current *AHWDBL* for explanations of coverage.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (02/2011)

the DBL report

Issue #58, November 2010

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on September 23, 2010. The Committee considered information regarding 17 Drug Products, including manufacturer submissions and various supplementary assessments.

Seventeen generic Drug Products underwent Expedited Review for listing on the *AHWDBL* effective October 1, 2010. An additional two generic Drug Products met criteria for Expedited Review for listing, effective November 1, 2010.

The following articles provide highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of New Products Added

■ **GLUCAGEN & GLUCAGEN HYPOKIT** (glucagon, rDNA origin) (NNA) **1 mg/vial injections** have been added to the *AHWDBL* as regular benefits. The addition of each of these Drug Products offers a therapeutic advantage in providing an alternative source for glucagon, as well as potential cost savings due to a lower price relative to the currently listed Drug Product, GLUCAGON (LIL).

■ **SANTYL** (collagenase) (HPC) **250 u/g topical ointment** has been added to the *AHWDBL* as a regular benefit. It has a potential therapeutic advantage as a relatively rapid and selective treatment, which is useful in the homecare setting. In addition, **SANTYL** provides a potential cost advantage when considering the total cost of alternative treatment methods.

■ The following products have been added to the *AHWDBL* in Interchangeable (IC) Groupings:

- **AMOXICILLIN** (amoxicillin) (SNS) **250 mg chewable tablet**
- **MINT-TOPIRAMATE** (topiramate) (MPI) **25 mg, 100 mg & 200 mg tablets**
- **GD-ATORVASTATIN** (atorvastatin calcium) (GMD) **10 mg, 20 mg, 40 mg & 80 tablets**

Special Authorization Criteria Change

■ **VALCYTE** (valaganciclovir hydrochloride) (HLR) **450 mg tablet** – The results of the IMPACT study (Humar, et al.) were considered. It was concluded that the risks of a longer duration of **VALCYTE** therapy may be outweighed by the potential prevention of CMV disease in kidney transplant patients. Accordingly, the coverage period has been extended for the prevention of post-transplant CMV disease in kidney transplant patients at risk. Special authorization may now be granted for 200 days.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (11/2010)

the DBL report

Issue #57, September 2010

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on Thursday, July 29, 2010. At the meeting the Committee considered information regarding 84 Drug Products. This included review of manufacturer submissions as well as various supplementary assessments following examination of correspondence and issues raised by a range of stakeholders. An additional 51 Drug Products underwent expedited review for listing on the *AHWDBL* effective September 1, 2010. The recommendations of the Expert Committee and the listing decisions taken by Alberta Health and Wellness will result in the addition of 110 Drug Products, increasing available therapies for plan members, and providing potential cost savings of $1.8 million over the next year.

The following articles provide highlights of recent changes to the *AHWDBL* and other topics of general interest. A complete list of changes, as well as the full *AHWDBL* may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

Highlights of Products Added

■ **UROMAX** (oxybutynin chloride) (PUR) **10 mg & 15 mg extended-release tablets** have been added to the *AHWDBL* via Step Therapy/Special Authorization. **UROMAX** may provide a therapeutic advantage over immediate release oxybutynin in reduction of nocturnal incontinence. It is less expensive than other currently listed alternatives to immediate release oxybutynin.

■ **VAGIFEM LD** (estradiol-17B) (NNA) **10 mcg vaginal tablet** has been added to the *AHWDBL* as an unrestricted benefit. It offers similar therapeutic benefits to currently listed Drug Products with a potential advantage of a lower dose of estrogen.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (9/2010)

Special Authorization Criteria Changes

■ **EXJADE** (deferasirox) (NOV) **125 mg, 250 mg & 500 mg tablets** – Revisions to the Special Authorization (SA) criteria have been accepted following a recent review of coverage. The revisions clarify one of the contraindications to use of Desferal (deferoxamine) that will qualify patients for coverage with Exjade, and add an educational note.

■ **TYSABRI** (natalizumab) (BIO) **20 mg/mL injection** - Following a year of experience with administration of Tysabri coverage via the *AHWDBL*, and in light of feedback and suggestions from a number of Alberta Neurologists, the criteria for coverage of Tysabri have been revised and clarified. These changes are intended to simplify the criteria and enhance patient care.

Changes in Benefit Status

■ **XEOMIN** (clostridium botulinum neurotoxin type A (150kD), free from complexing proteins) (MPC) **100 unit/vial injection** has been moved from Special Authorization to Regular Benefit status, **effective September 1, 2010**.

■ **FLUCONAZOLE** (fluconazole) (various manufacturers) **150 mg capsules** have changed from prescription to non-prescription status. Accordingly, **effective October 31, 2010**, these Drug Products will no longer be benefits on the *AHWDBL* and will not be considered for coverage by Special Authorization.

New IC Groupings

■ **MYLAN-CLARITHROMYCIN** (clarithromycin) (MYP) **250 mg tablet** has been added to the *AHWDBL*, creating a New Interchangeable (IC) Grouping with BIAXIN BID (ABB) 250 mg.

■ **MYLAN-NIFEDIPINE** (nifedipine) (MYP) **30 mg extended-release tablet** has been added to the *AHWDBL*, creating a New IC Grouping with ADALAT XL (BAI) 30 mg.

Products Originally Reviewed via the Common Drug Review (CDR)

■ **ORENCIA** (abatacept) (BMS) **250 mg/vial injection** was reviewed via the CDR process. In keeping with the recommendation from the Canadian Expert Drug Advisory Committee (CEDAC), the SA criteria of this product have been revised to indicate patients are eligible for coverage of ORENCIA without having failed treatment with one or more anti-tumor necrosis factor (anti-TNF) therapies.

■ The following products, reviewed via the CDR process, received recommendations not to list from CEDAC. Accordingly, these products will not be listed on the *AHWDBL*:

- **CIMZIA** (certolizumab pegol) (UCB) **200 mg/mL subcutaneous solution**
- **JURNISTA** (hydromorphone hydrochloride) (JOI) **4 mg, 8 mg, 16 mg & 32 mg extended release tablets**
- **LOTEMAX** (loteprednol etabonate) (BSH) **0.5% ophthalmic suspension**
- **MULTAQ** (dronedarone hydrochloride) (SAV) **400 mg tablet**
- **NPLATE** (romiplostim) (AMG) **250 mcg/0.5 mL & 500 mcg/1 mL vial injection**
- **ONGLYZA** (saxagliptin hydrochloride) (BMS) **5 mg tablet**

Product Not Added

■ **NIASPAN FCT** (niacin) (SPC) **500 mg, 750 mg & 1000 mg extended-release tablets** were not recommended for addition to the *AHWDBL*. The Expert Committee noted that there is no available outcomes data for this Drug Product. The Expert Committee also indicated that the Drug Product submission provided little evidence to support an advantage versus over-the-counter (OTC) niacin products regarding flushing, a common side effect with niacin preparations. Accordingly, the Expert Committee determined that there is no demonstrated therapeutic advantage of this Drug Product over currently listed Drug Products. Further, other niacin products are available OTC and are not listed on the *AHWDBL*. There is no cost advantage to listing this Drug Product.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBLreport

Issue #56, July 2010

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of recent changes to the AHWDBL and other topics of general interest

Highlights of Products Added

■ **ARIXTRA** (fondaparinux sodium) (GSK) **7.5 mg/0.6 mL injection syringe**, a synthetic antithrombotic agent, is a line extension to the currently listed 2.5 mg/0.5 mL injection syringe. This product was added to the *AHWDBL* as it provides a therapeutic advantage and a potential cost advantage.

■ **EDECRIN** (ethacrynic acid) (ATP) **25 mg tablet** will be added to the *AHWDBL* as an unrestricted benefit. The product monograph indicates it is especially useful in patients unresponsive to the commonly used diuretics.

■ **EMEND** (aprepitant) (MFC) **80 mg capsule** will be added as a Restricted Benefit to be prescribed by Directors of Alberta Health Services – Cancer Care "Cancer Centres" (or their designates). Previously, only the **EMEND TRI-PACK**, which contained one 125 mg capsule and two 80 mg capsules, was listed.

■ **LUMIGAN RC** (bimatoprost) (ALL) **0.01% ophthalmic solution** will be listed as interchangeable with the original LUMIGAN 0.03%, as these products were shown to be therapeutically equivalent and can be considered pharmaceutical alternatives within the context of interchangeability.

■ **PMS-HYDROCHLOROTHIAZIDE** (hydrochlorothiazide) (PMS) **12.5 mg tablet** is being added to the *AHWDBL* in order to provide access, to avoid tablet splitting, to enhance patient safety and to reduce potential product wastage.

■ **STALEVO** (levodopa/carbidopa/entacapone) (NOV) **75 mg/18.75 mg/200 mg & 125 mg/31.25 mg/200 mg tablets** are intermediate strengths to currently listed STALEVO products, and will provide a therapeutic advantage by allowing more flexibility in dosing.

■ The following aerosol holding chambers for use with metered dose aerosol inhalers will also be added to the *AHWDBL* as Restricted Benefits:

- **AEROCHAMBER PLUS FLOW-VU** (aerosol holding chamber) (TMI) **with mouthpiece, with small mask, with medium mask and with large mask**
- **OPTICHAMBER ADVANTAGE II** (aerosol holding chamber) (ACM) **chamber only, with small mask, with medium mask and with large mask**

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).*

ABC 81171 (7/2010)

Highlights of New IC Groupings

■ As part of the Expedited Review process for interchangeable (IC) products, updates to the *AHWDBL* are now posted on a monthly basis (when applicable). Of note, the following products will be listed in a New IC Grouping with LIPITOR (atorvastatin calcium) (PFI) 10 mg, 20 mg, 40 mg & 80 mg tablets, **effective July 1, 2010**:

- **APO-ATORVASTATIN** (APX)
- **ATORVASTATIN** (RPH)
- **ATORVASTATIN** (SNS)
- **CO ATORVASTATIN** (COB)
- **NOVO-ATORVASTATIN** (TEV)
- **PMS-ATORVASTATIN** (PMS)
- **RAN-ATORVASTATIN** (RAN)
- **RATIO-ATORVASTATIN** (RPH)
- **SANDOZ ATORVASTATIN** (SDZ)

■ The following products were deemed interchangeable with respective strengths of the innovator, AMERGE (naratriptan hydrochloride) (GSK), and will be listed in a New IC Grouping as Restricted Benefits/ Special Authorization benefits:

- **NOVO-NARATRIPTAN** (naratriptan hydrochloride) (TEV) **1 mg & 2.5 mg tablets**
- **SANDOZ NARATRIPTAN** (naratriptan hydrochloride) (SDZ) **2.5 mg tablet**

Products Originally Reviewed via the Common Drug Review (CDR)

■ **AZARGA** (brinzolamide/timolol maleate) (ALC) **1%/0.5% ophthalmic suspension** was reviewed via the CDR process. In keeping with the recommendation from the Canadian Expert Drug Advisory Committee (CEDAC), this product will be listed in a similar manner as other carbonic anhydrase inhibitor/beta blocker combination products. Accordingly, this product will be granted an unrestricted listing on the *AHWDBL*.

■ **SIMPONI** (golimumab) (SCH) **50 mg/0.5 mL injection syringe & autoinjector** received positive recommendations for listing for the indications of ankylosing spondylitis (AS), psoriatic arthritis (PsA) and rheumatoid arthritis (RA). Accordingly, this product will be listed via Special Authorization. *In keeping with the CEDAC recommendation, this product will be limited to 12 doses per 12 month period.*

■ **XEOMIN** (botulinum neurotoxin type A, free from complexing proteins) (MPC) **100 U/vial injection** received positive recommendations for listing for the indications of blepharospasm and cervical dystonia (spasmodic torticollis). Accordingly, this product will be listed via Special Authorization.

■ The following products, reviewed via the CDR process, received recommendations not to list from CEDAC. Accordingly, these products will not be listed on the *AHWDBL*:

- **ABILIFY** (aripiprazole) (BMS) **2 mg, 5 mg, 10 mg, 15 mg, 20 mg & 30 mg tablets**
- **FORTEO** (teriparatide) (LIL) **250 mcg/mL injection**
- **SOLIRIS** (eculizumab) (API) **10 mg/mL vial for intravenous infusion**
- **VYVANSE** (lisdexamfetamine dimesylate) (SHB) **30 mg & 50 mg capsules**

Highlights of Products Not Added

■ The following products will not be added as data has not been provided to demonstrate interchangeability with the *Canadian innovator product*:

- **MYLAN-CARVEDILOL** (carvedilol) (MYP) **3.125 mg, 6.25 mg, 12.5 mg & 25 mg tablets**
- **NOVO-SALBUTAMOL HFA** (salbutamol) (TEV) **100 mcg/dose metered dose aerosol inhaler**

According to current published criteria for interchangeability, multisource drug products seeking a listing designation as interchangeable may be eligible for listing if "the drug product has been granted a Notice of Compliance by Health Canada that includes a declaration of bioequivalence with a Canadian brand/innovator reference product that is listed (or at the sole discretion of Alberta Health and Wellness and/or the Minister, has been previously listed) on the *Alberta Health and Wellness Drug Benefit List*."

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, including a listing of coverage criteria (where applicable).****

the DBL report

Issue #55, April 2010

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:

James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:

Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of recent changes to the AHWDBL and other topics of general interest

Highlights of New Products Added

■ **ATACAND PLUS** (candesartan cilexetil/hydrochlorothiazide) (AZC) **32 mg/12.5 mg & 32 mg/25 mg tablets** are angiotensin receptor blocker and diuretic combination products indicated for the treatment of essential hypertension. These line extensions to currently listed ATACAND and **ATACAND PLUS** products were added to the *AHWDBL* for providing a therapeutic and/or cost advantage.

■ **COVERSYL PLUS HD** (perindopril erbumine/indapamide hemihydrate) (SEV) **8 mg/2.5 tablet**, a combination angiotensin converting enzyme inhibitor and diuretic, is a line extension to currently listed COVERSYL and COVERSYL PLUS products. This product provides a therapeutic and/or cost advantage and has been added to the *AHWDBL* accordingly.

■ **PHL-AMLODIPINE** (amlodipine besylate) (PHH) **2.5 mg tablet** and **PMS-AMLODIPINE** (amlodipine besylate) (PMS) **2.5 mg tablet** are line extensions to **PHL-AMLODIPINE** and **PMS-AMLODIPINE** 5 mg & 10 mg tablets, respectively. This lower strength is supported in the dosage recommendations of the product monograph, for use in children and patients with reduced liver function. In addition, this strength was seen as a useful tool for dosage titration. Accordingly, the Committee recommended these products be added to the *AHWDBL*.

■ **VESICARE** (solifenacin succinate) (ASP) **5 mg & 10 mg tablets** have been added to the *AHWDBL* via step therapy/special authorization. This product, originally reviewed via the CDR, is indicated for treatment of overactive bladder, and will be available for patients who are intolerant to oxybutynin.

Change to Botox Unit of Issue

Please be aware that the Unit of Issue for the **BOTOX** (botulinum toxin type A) (ALL) vial injection (DIN 01981501) has changed from vial to UNIT. **BOTOX** is available in 100 unit and 200 unit vials.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.

****Please refer to the current AHWDBL for explanations of coverage, full coverage details of products and listing of coverage criteria (where applicable).****

ABC 81171 (4/2010)

Highlights of Coverage Criteria Changes

■ Changes to criteria for coverage were made for the following products:

- **ARANESP** (darbepoetin) (AMG) and **EPREX** (epoetin alfa) (JOI) for the indication of anemia of chronic renal failure
- **EXJADE** (deferasirox) (NOV)
- **EZETROL** (ezetimibe) (MFC)
- **HUMIRA** (adalimumab) (ABB) for the indication of Crohn's Disease

■ Criteria were also revised for the following biologic agents regarding the treatment of Rheumatoid Arthritis:

- **ENBREL** (etanercept) (AMG)
- **HUMIRA** (adalimumab) (ABB)
- **KINERET** (anakinra) (BVM)
- **ORENCIA** (abatacept) (BMS)
- **REMICADE** (infliximab) (SCH)
- **RITUXAN** (rituximab) (HLR)

For full details regarding SA criteria changes please refer to the current *AHWDBL*.

Reinstatement of Premarin Tablets

■ **PREMARIN** (conjugated estrogens) (WAY) **0.3 mg, 0.625 mg & 1.25 mg tablets** had previously been removed from the *AHWDBL* due to a significant increase in price (with claims to be honored until March 31, 2010). Subsequent to notification in January 2010 of a substantial price decrease, these products will be reinstated on the *AHWDBL*, as regular benefits.

Orencia for Juvenile Idiopathic Arthritis

■ **ORENCIA** (abatacept) (BMS) **250 mg/vial (base) injection** was originally reviewed via the CDR process for the new indication of **Juvenile Idiopathic Arthritis (JIA)**. The Canadian Expert Drug Advisory Committee (CEDAC) recommended **ORENCIA** be listed for JIA in children who are intolerant to, or have not had an adequate response to ENBREL (etanercept). Following consultation regarding coverage criteria with Alberta rheumatologists, including pediatric specialists, the Expert Committee has recommended this product be listed via special authorization. Stemming from the discussion of **ORENCIA**, the criteria for ENBREL in Juvenile Rheumatoid Arthritis have also been revised.

ROBS Reviews of Insulins and Oral Anti-Diabetic Agents

As part of the Review of Benefit Status (ROBS) process, comprehensive clinical reviews of insulin and oral anti-diabetic agents were undertaken. The Expert Committee gave due consideration to the information available and recommended the following changes to the listing of specific products:

■ **APO-CHLORPROPAMIDE** (chlorpropamide) (APX) **100 mg & 250 mg tablets** and **APO-TOLBUTAMIDE** (tolbutamide) (APX) **500 mg tablet** were recommended to be de-listed from the *AHWDBL* as they were found to no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments, as well as to enable broader coverage of higher priority products.

■ **HUMALOG MIX25** (insulin lispro/insulin lispro protamine) (LIL) **25%/75% (100 U/mL)** was also recommended to be de-listed from the *AHWDBL* as it was found to no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments, as well as to enable broader coverage of higher priority products. In 2007, **HUMALOG MIX50** (insulin lispro/ insulin lispro protamine) (LIL) **50%/50% (100 U/mL)** was not added to the *AHWDBL* as it was noted that the clinical data did not demonstrate a clear therapeutic advantage for this product over other currently listed alternatives.

■ **PIOGLITAZONE HYDROCHLORIDE 15 mg, 30 mg & 45 mg tablets** (APX, COB, MYP, NOP, PMS, RPH, SDZ, TAK) and **AVANDIA** (rosiglitazone maleate) (GSK) **2 mg, 4 mg & 8 mg tablets** were recommended to move from regular benefits to step therapy/special authorization. Coverage will be available where patients do not respond to an adequate trial of, or are intolerant or have a contraindication to metformin. **AVANDAMET** (rosiglitazone maleate/metformin hydrochloride) (GSK) **1 mg/500 mg, 2 mg/500 mg, 2 mg/1000 mg, 4 mg/500 mg & 4 mg/1000 mg tablets** were also recommended to move to a step therapy/ special authorization listing for patients not responding to an adequate trial of metformin alone.

Patients currently receiving coverage for the affected products will continue to receive coverage.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, full coverage details of products and listing of coverage criteria (where applicable).*

Fucithalmic De-Listed

■ **FUCITHALMIC (UNPRESERVED)** (fusidic acid) (LEO) **1% ophthalmic gel** has received no claims since being added to the *AHWDBL* in April 2006. Following a comprehensive review by the Expert Committee, and due consideration of a response from the manufacturer, this product was recommended to be de-listed from the *AHWDBL*.

Highlights of Interchangeable Products Added

■ The following are first-entry generic products deemed interchangeable with the respective innovator products, and recommended for addition to the *AHWDBL* in interchangeable groupings:

- **APO-GLICLAZIDE MR** (gliclazide) (APX) **30 mg tablet**, for DIAMICRON MR
- **CO OLANZAPINE ODT** (olanzapine) (COB), **PMS-OLANZAPINE** (olanzapine) (PMS) and **SANDOZ OLANZAPINE** (olanzapine) (SDZ) **5 mg & 10 mg orally disintegrating tablets**, for ZYPREXA ZYDIS
- **SANDOZ RIVASTIGMINE** (rivastigmine hydrogen tartrate) (SDZ) **1.5 mg, 3 mg, 4.5 mg & 6 mg capsules**, for EXELON, added to the *AHWDBL* via special authorization in an interchangeable grouping, effective November 15, 2009.

Highlights of Products Not Added

■ **DURAGESIC MAT** (fentanyl) (JOI) **25 mcg/hr, 50 mcg/hr, 75 mcg/hr & 100 mcg/hr transdermal patches** are a newer matrix formulation intended to eventually replace the original reservoir patches. This product is priced at parity with the currently listed DURAGESIC reservoir formulation; however, a number of generic products are listed in an interchangeable grouping with DURAGESIC. It was felt information provided in the product submission failed to support a therapeutic advantage of **DURAGESIC MAT** over currently listed alternatives, and with LCA pricing applied to the grouping, it does not provide a cost advantage. Accordingly, this product was not added to the *AHWDBL*.

■ **LUMIGAN** (bimatoprost) (ALL) **0.01% ophthalmic solution** was reviewed as a line extension to the currently listed LUMIGAN 0.03%. The Committee indicated that this product failed to demonstrate a therapeutic or cost advantage. Accordingly, it was not recommended for addition to the *AHWDBL*. Further, concern was expressed over the concentration of benzalkonium chloride in **LUMIGAN 0.01%**.

■ **NORLEVO** (levonorgestrel) (BAI) **0.75 mg tablet** – The Expert Committee reviewed the manufacturer's submission and concluded that this product failed to provide a therapeutic or cost advantage over existing therapy. Accordingly, this product was not recommended for addition to the *AHWDBL*.

■ **PMS-OLANZAPINE ODT** (olanzapine) (PMS) **15 mg orally disintegrating tablet** was reviewed as a line-extension to the other strengths of **PMS-OLANZAPINE ODT**, as the 15 mg strength of the innovator ZYPREXA ZYDIS has not been listed on the *AHWDBL*. **PMS-OLANZAPINE ODT 15 mg** was not recommended for addition as it was not found to provide a therapeutic or cost advantage.

■ **RENAGEL** (sevelamer hydrochloride) (GZM) **800 mg tablet** was reviewed subsequent to a resubmission by the manufacturer. As part of their review, the Committee requested information via the Health Technology Inquiry Service (HTIS) provided by the Canadian Agency for Drugs and Technologies in Health (CADTH). Due consideration was given to all available information; however, the Committee concluded that no new information had been provided that would warrant a change in the original recommendation, not to add this product to the *AHWDBL*.

■ **APO-CLARITHROMYCIN** (clarithromycin) (APX) **250 mg & 500 mg tablets** – A resubmission for this product was reviewed; however, it was concluded that the information provided to date was insufficient to deem **APO-CLARITHROMYCIN 250 mg & 500 mg tablets** interchangeable with the innovator under the submission requirements published at the time of review.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
Please refer to the current AHWDBL for explanations of coverage, full coverage details of products and listing of coverage criteria (where applicable).*

■ **MINT-TOPIRAMATE** (topiramate) (MPI) **25 mg, 100 mg & 200 mg tablets** – Upon reviewing a resubmission for this product, the Committee concluded that the bioequivalence data provided utilizing a non-Canadian reference product was insufficient to allow the designation of **MINT-TOPIRAMATE** as interchangeable with other currently listed topiramate products.

■ **APO-RIVASTIGMINE** (rivastigmine) (APX), **MYLAN-RIVASTIGMINE** (rivastigmine) (MYP), **NOVO-RIVASTIGMINE** (rivastigmine) (NOP), **PMS-RIVASTIGMINE** (rivastigmine) (PMS) and **RATIO-RIVASTIGMINE** (rivastigmine) (RPH) **1.5 mg, 3 mg & 4.5 mg capsules** were unable to be deemed interchangeable with the innovator, EXELON 1.5 mg, 3 mg & 4.5 mg capsules, as the bioavailability data provided in the manufacturer's product submissions failed to meet submission requirements in effect at the time of review. Please note, the **6 mg** strengths of these generic products were added to the *AHWDBL* in an interchangeable grouping, as information was available to allow a determination of interchangeability with the innovator, EXELON 6 mg capsule.

■ The following products, reviewed via the CDR process, received recommendations not to list from the Canadian Expert Drug Advisory Committee (CEDAC):

- **DUODOPA** (levodopa/carbidopa) (SLO) **20 mg/mL/5 mg/mL intraintestinal gel**
- **FORTEO** (teriparatide) (LIL) **250 mcg/mL injection**
- **INSPRA** (eplerenone) (PFI) **25 mg & 50 mg tablets**
- **LEVEMIR PENFILL** (insulin detemir) (NNA) **100 U/mL cartridge injection**
- **LYRICA** (pregabalin) (PFI) **25 mg, 50 mg, 75 mg, 150 mg & 300 mg capsules**
- **PRISTIQ** (desvenlafaxine succinate) (WAY) **50 mg & 100 mg extended release tablets**

■ In addition, **COPAXONE** (glatiramir acetate) (TMP) **20 mg/ mg injection syringe** was reviewed for the indication of Clinically Isolated Syndrome via the CDR process and received a recommendation not to list for this indication.

For further information on the CDR review and CEDAC recommendations for these products please visit http://www.cadth.ca/index.php/en/cdr.

Updated Price Policy

As a component of Phase 2 of the Alberta Pharmaceutical Strategy (APS), an announcement was made in October 2009 that the price for **new** generic drugs would be reduced to 45% of the brand price. In addition, starting in April 2010, the price for generic drugs in established interchangeable groupings will be reduced to 56% of the brand price. Accordingly, an updated pricing policy for products listed on, or considered for addition to, the *AHWDBL* was published on February 12, 2010. To view the Price Policy, please visit https://www.ab.bluecross.ca/dbl/pdfs/ahwdbl_sec1_prpol.pdf.

Expedited Review for Interchangeable Products & Revised Submission Requirements

Further, related to the key component concerning timely drug approval in Phase 1 of the APS, an Expedited Review Process has been introduced for select interchangeable products. As a result, the product Submission Requirements have also been reviewed and updated. Further details on the submission and review process for all products, including interchangeable products, may be found at https://www.ab.bluecross.ca/dbl/pdfs/ahwdbl_sec1_drug.pdf.

A complete list of changes, as well as the full AHWDBL may be accessed at https://www.ab.bluecross.ca/dbl/publications.html.
****Please refer to the current AHWDBL for explanations of coverage, full coverage details of products and listing of coverage criteria (where applicable).****

the DBL report

Issue #54, October 2009

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:

James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:

Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (10/2009)

Highlights of Products Added

Please refer to the current AHWDBL for explanations of coverage, full coverage details of products and listing of coverage criteria (where applicable).*

■ **CYMBALTA** (duloxetine hydrochloride) (LIL) **30 mg & 60 mg delayed release capsules** were recommended for addition to the *AHWDBL* via Special Authorization (SA) for the management of neuropathic pain associated with diabetic peripheral neuropathy.

■ **ENABLEX** (darifenacin hydrobromide) (NOV) **7.5 mg & 15 mg extended release tablets** were originally reviewed via the Common Drug Review (CDR), with a recommendation of coverage for patients who cannot tolerate or have insufficient response to an adequate trial of immediate-release oxybutynin (e.g. in a similar manner as drug plans list tolterodine). Accordingly, **ENABLEX** was recommended for addition to the *AHWDBL* via Step Therapy/SA.

■ **FOSAVANCE** (alendronate sodium/cholecalciferol) (MFC) **70 mg/5,600 U tablet** is a new combination drug product that was originally reviewed via the CDR, and was recommended for listing similar to generic alendronate. The Expert Committee agreed with the CDR recommendation. Accordingly, **FOSAVANCE** will be added to the *AHWDBL* via SA with criteria consistent with currently listed alendronate products.

■ **OLMETEC** (olmesartan medoxomil) (JOI) **20 mg & 40 mg tablets** and **OLMETEC PLUS** (olmesartan medoxomil/ hydrochlorothiazide) (JOI) **20 mg/12.5 mg, 40 mg/12.5 mg & 40 mg/25 mg tablets** are indicated for the treatment of mild to moderate essential hypertension. These products received a positive recommendation for listing in a manner similar to other angiotensin II receptor blockers (ARBs) and ARB/hydrochlorothiazide combination products following review through the CDR. Expert Committee members recognized that clinically, these products provide similar benefits to other currently listed alternatives. However, it was noted that the daily cost of treatment with **OLMETEC & OLMETEC PLUS** is less than or similar to the cost of others in the same class, providing a cost advantage. Accordingly, these products will be added to the *AHWDBL* as unrestricted benefits.

Highlights of Products Added

- **RISPERDAL CONSTA** (risperidone) (JOI) **25 mg/vial, 37.5 mg/vial & 50 mg/vial injectable prolonged release suspension** uses a patented microsphere technology to produce a long-acting injectable formulation. This product was previously reviewed but not recommend for listing, as it failed to provide a therapeutic and/or cost advantage. In the recent manufacturer resubmission, among other information, evidence was provided to show a significant reduction in hospitalizations. Upon further discussion, the Committee recommended that **RISPERDAL CONSTA** be made available via SA on the *AHWDBL*.

- **STELARA** (ustekinumab) (JOI) **45 mg/0.5 mL injection**, a biologic agent indicated for the treatment of plaque psoriasis, was originally reviewed via the CDR. The Expert Committee discussed this product and recommended it be made available via SA on the *AHWDBL*.

De-Listing of Premarin Tablets

- **PREMARIN** (conjugated estrogens) (WAY) **0.3 mg, 0.625 mg & 1.25 mg tablets** recently experienced a significant price increase. As a result, these products have been found to no longer possess a cost advantage. Accordingly, a recommendation has been made for these products to be removed from the *AHWDBL*, **effective October 1, 2009**. However, claims will be honored until March 31, 2010. Please refer to the current *AHWDBL* for a listing of reimbursed alternatives.

Highlights of Interchangeable Products Added

- **AMLODIPINE 5 mg & 10 mg tablets** (APX, COB, GPM, NOP, PMS, RPH & SDZ) are first-entry products that have been found interchangeable with the innovator, NORVASC. These products were added to the *AHWDBL*, **effective August 15, 2009**, in an interchangeable grouping. The addition of these products has the potential to save over $14 million to the government-sponsored drug programs in the first year of listing.

- **LEVOFLOXACIN 250 mg & 500 mg tablets** (APX, COB, GPM, NOP, PMS, SDZ) and **750 mg tablet** (APX, COB, NOP, PMS, SDZ) were added to the *AHWDBL*, **effective August 1, 2009**, in an interchangeable grouping with the innovator, LEVAQUIN, available via Optional Special Authorization (OSA). The addition of the interchangeable **LEVOFLOXACIN** products has the potential to save the government-sponsored drug programs over $400,000 in the first year of listing.

Special Authorization Criteria Change For Avodart & Proscar

Subsequent to correspondence received by the Expert Committee, a review of Special Authorization (SA) criteria for products used in the treatment of benign prostatic hyperplasia (BPH) listed on the *AHWDBL*, was undertaken. The Expert Committee gave due consideration to the information available and recommended that the SA criteria for **AVODART** (dutasteride) (GSK) **0.5 mg capsule** and **PROSCAR** (finasteride) (MFC) **5 mg tablet** be revised. Please be advised that with these changes, these products are no longer available as Restricted Benefits. Refer to the current *AHWDBL* for a full listing of criteria.

the DBL report

Issue #53, July 2009

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (07/2009)

Highlights of Products Added

■ **MICARDIS PLUS** (telmisartan/hydrochlorothiazide) (BOE) **80 mg/25 mg tablet** is a line extension to the currently listed **MICARDIS PLUS** 80 mg/12.5 mg tablet and MICARDIS 40 mg & 80 mg tablets. Indicated for patients whose blood pressure is not adequately controlled by the 80 mg/12.5 mg strength or patients stabilized on the individual agents given separately, the **80 mg/25 mg tablet** was deemed to provide a therapeutic advantage. Accordingly, it was recommended for addition to the *AHWDBL*.

■ **XAMIOL** (calcipotriol/betamethasone dipropionate) (LEO) **50 mcg/g/0.5 mg/g topical gel** is a line extension to the currently listed DOVOBET topical ointment. This product was found to provide a therapeutic advantage as it is indicated to be applied only once daily. Therefore, **XAMIOL** was recommended to be added to the *AHWDBL*.

■ **TYSABRI** (natalizumab) (BIO) **20 mg/mL (15 mL vial) injection** is a new drug product that was originally reviewed via the Common Drug Review. It is indicated for the treatment of Relapsing Remitting Multiple Sclerosis (RRMS), and is generally recommended in patients who have had an inadequate response to, or are unable to tolerate, other MS therapies. **TYSABRI** will be eligible for reimbursement under the Multiple Sclerosis (MS) Drug Coverage Program, with specified criteria for coverage. Please refer to Section 2 of the current *AHWDBL* for further information on the MS Drug Coverage Program, including coverage criteria and available products.

Highlights of Products Not Added

■ **ACTONEL** (risedronate sodium) (PGA) **150 mg tablet** is a line extension to the currently available **ACTONEL** products, which are listed via Special Authorization. The Expert Committee reviewed the information included in the manufacturer's product submission; however, it was concluded that the data provided failed to demonstrate an advantage over currently available therapies. **ACTONEL 150 mg tablet** was not recommended for addition to the *AHWDBL*.

■ **YAZ** (drospirenone/ethinyl estradiol) (BAI) **3 mg/0.020 mg tablet** is indicated as an oral contraceptive and for use as acne therapy. The Committee gave due consideration to the information provided in the product submission; however, this product did not appear to offer a therapeutic or cost advantage over currently available therapies. Accordingly, the Committee did not recommend this product be added to the *AHWDBL*.

Highlights of Interchangeable Products

■ **APO-LEVOCARB CR** (levodopa/carbidopa) (APX) **100 mg/25 mg sustained release tablet** is a first entry generic product that was deemed interchangeable with the innovator, Sinemet CR 100 mg/25 mg. This product will be added to the *AHWDBL* in an interchangeable grouping, and has the potential to save over $79,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

■ **GEN-CLOZAPINE** (clozapine) (GPM) **25 mg & 100 mg tablets** were designated as interchangeable with the innovator, CLOZARIL 25 mg & 100 mg tablets, effective May 1, 2009, with the Least Cost Alternative (LCA) policy to be applied effective September 1, 2009. As a result of the savings with the application of LCA pricing, this recommendation met criteria for fast-track with over $2.4 million in savings to all government-sponsored drug programs over the first year of listing.

■ **MEDROXYPROGESTERONE ACETATE** (medroxyprogesterone acetate) (SDZ) **150 mg/mL injection** is a first entry generic product which has been designated as interchangeable with the innovator, DEPO-PROVERA.

■ **PMS-OXYCODONE** (oxycodone hydrochloride) (PMS) **5 mg, 10 mg & 20 mg tablets** were designated as interchangeable and will be listed in interchangeable groupings with the corresponding strengths of OXY-IR and SUPEUDOL.

■ **SUPEUDOL** (oxycodone hydrochloride) (SDZ) **20 mg tablets** were also added to the *AHWDBL* and will be listed in an interchangeable grouping with OXY-IR & PMS-OXYCODONE 20 mg tablets.

Change in Benefit Status of Cyclobenzaprine 10 mg tablets

As part of the Review of Benefit Status (ROBS) process, a comprehensive clinical review of select skeletal muscle relaxants listed on the *AHWDBL*, was undertaken. The Expert Committee gave due consideration to the information available and recommended that the **CYCLOBENZAPRINE 10 mg tablet** products be moved to a listing as a RESTRICTED BENEFIT. Coverage will be limited to 126 tablets per plan participant per year (beginning with the first claim filled once this benefit status change becomes effective), as an adjunct to rest and physical therapy for the treatment of acute muscle spasm. The following **CYCLOBENZAPRINE 10 mg** products are affected:

- **APO-CYCLOBENZAPRINE**
- **DOM- CYCLOBENZAPRINE**
- **GEN-CYCLOBENZAPRINE**
- **NOVO-CYCLOPRINE**
- **NU-CYCLOBENZAPRINE**
- **PMS-CYCLOBENZARPINE**
- **RATIO-CYCLOBENZAPRINE**

the DBL report

UPDATE

Update, May 2009

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:

James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:

Steve Long, BSc (Pharm), MBA
Mark Harasymuk, BSc (Pharm)

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

Application of Least Cost Alternative to Gen-Clozapine 25 mg and 100 mg

In April 2009, the Expert Committee on Drug Evaluation and Therapeutics—the advisory committee to the Minister of Health and Wellness on issues that pertain to the *Alberta Health and Wellness Drug Benefit List* (*AHWDBL*)—reviewed a resubmission from Genpharm ULC requesting that Gen-Clozapine be deemed interchangeable with the brand name product, Clozaril. Like Clozaril, Gen-Clozapine is available only through a distribution system (GenCAN®) that requires regular hematological testing (weekly, every two weeks, or every four weeks) prior to dispensing the next period's supply. A request to list Gen-Clozapine in an interchangeable grouping with Clozaril was first considered by the Expert Committee in 2003. At that time, Genpharm ULC had successfully demonstrated bioequivalence between the two products, however, the Committee withheld a recommendation of interchangeability pending evidence of successful interaction between clozapine monitoring systems. In the resubmission, the manufacturer provided information supporting the successful interface between GenCAN® and the monitoring and distribution system for Clozaril (CSAN). Based on the information provided, the Expert Committee recommended that Gen-Clozapine be designated as interchangeable with Clozaril and the Least Cost Alternative (LCA) policy applied.

Effective May 1, 2009, Gen-Clozapine (clozapine) (GPM) 25 mg and 100 mg tablets will be designated as interchangeable with the innovator, Clozaril 25 mg and 100 mg tablets.

Gen-Clozapine 25 mg and 100 mg tablets will be designated as interchangeable with the innovator, Clozaril 25 mg and 100 mg tablets, effective May 1, 2009 and the LCA pricing policy will be applied effective September 1, 2009. With the application of the LCA pricing policy, savings of over $2.4 million to all government-sponsored drug programs over the first year of listing may be realized.

ABC 81171 (05/2009)

the DBL report

Issue #51, April 2009

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC 81171 (04/2009)

Highlights of Products Added

■ **SABRIL** (vigabatrin) (OVP) **500 mg tablet & 500 mg oral sachet** was previously listed on the *AHWDBL* but was removed effective April 1, 2008, when the manufacturer had failed to submit a Request For Quotation (RFQ). The Committee reviewed the submission from the manufacturer and concluded this product should be re-listed.

■ **TRAVATAN Z** (travoprost) (ALC) **0.004% ophthalmic solution** is a line extension to the currently listed TRAVATAN product. The **TRAVATAN Z** formulation differs from the original product in that **TRAVATAN Z** does not contain the preservative benzalkonium chloride. Rather, it utilizes an alternative preservative system called SofZia®. The Committee reviewed the information provided by the manufacturer and recommended **TRAVATAN Z** be listed in an interchangeable grouping with TRAVATAN.

■ **GEN-NIFEDIPINE XL** (nifedipine) (GEN) **60 mg extended release tablet** was added to the *AHWDBL* effective February 1, 2009, as it met criteria for fast-track addition with over $1,000,000 in savings to government-sponsored drug programs in the first year of listing.

■ The following table highlights additional products recently added to the *AHWDBL*:

Brand (Man.)	Ingredient	Strengths
DIOVAN-HCT (NOV)	Valsartan/ hydrochlorothiazide	320 mg/12.5 mg & 320 mg/25 mg tablets
DOVOBET (LEO)	Calcipotriol/ betamethasone dipropionate	50 mcg/g/0.5 mg/g topical ointment
NOVO-QUETIAPINE (NOP)	Quetiapine fumarate	150 mg tablet
STALEVO (NOV)	Carbidopa/ levodopa/ entacapone	50 mg/12.5 mg/200 mg, 100 mg/25 mg/200 mg & 150 mg/375 mg/200 mg tablets
SUBOXONE (SCH)	Buprenorphine hydrochloride/ naloxone	2 mg/0.5 mg & 8 mg/2 mg sublingual tablets
ZELDOX (PFI)	Ziprasidone hydrochloride monohydrate	20 mg, 40 mg, 60 mg & 80 mg tablets

Highlights of Restricted Benefits Added

■ **AC BOYZ & AC GIRLZ** (TMI) **aerosol holding chambers** were added to the *AHWDBL* as Restricted Benefits, at parity with the currently listed aerosol holding chambers. The Committee commented that they may provide a therapeutic advantage. This benefit is restricted to one unit per plan participant per year.

■ **XARELTO** (rivaroxaban) (BAI) **10 mg tablet** was originally reviewed via the Common Drug Review. The Expert Committee considered the CEDAC recommendation that **XARELTO** be listed for prophylaxis of venous thromboembolism following total knee replacement or total hip replacement surgery, for up to two weeks, as an alternative to low molecular weight heparins. Accordingly, the Committee recommended this product be listed on the *AHWDBL* as a Restricted Benefit, **allowing one course of therapy, up to 14 days, for patients that have undergone elective total hip or total knee replacement**. A second course of therapy (i.e. up to an additional 14 days) is available within a 12-month period should the patient undergo an additional hip or knee replacement procedure. Please refer to the current *AHWDBL* for full listing details.

Highlights of Changes in Benefit Status or Coverage Criteria

(Please refer to the current AHWDBL for full listing details of all products.)

■ **AGGRENOX** (dipyridamole/ASA) (BOE) **200 mg/25 mg capsule** is indicated for the prevention of stroke in patients who have had a previous stroke or a transient ischemic attack (TIA). This product was originally added to the *AHWDBL* with coverage available via Special Authorization (SA). The Committee reviewed the listing status of **AGGRENOX** and concluded it should be moved to an unrestricted listing.

■ **ALDARA** (imiquimod) (GRC) **50 mg/g topical cream** is currently available via SA for the treatment of actinic keratosis of the head and neck. The SA criteria have been amended to clarify that a patient must fail treatment with cryotherapy (where appropriate) and 5-Fluorouracil, before being eligible for coverage.

■ The listing status of **KEPPRA** (UCB), **APO-LEVETIRACETAM** (APX), **CO LEVETIRACETAM** (COB), **PMS-LEVETIRACETAM** (PMS) **250 mg, 500 mg & 750 mg tablets** was also reviewed by the Committee, and these products were recommended to be moved to an unrestricted listing (i.e. without the requirement of an SA request).

■ **HUMIRA** (adalimumab) (ABB) **40 mg/syringe injection** is now eligible for coverage via SA for the additional indication of the reduction of signs and symptoms of severe, debilitating psoriasis.

■ **RITUXAN** (rituximab) (HLR) **10 mg/mL injection** has been added to the *AHWDBL* via SA for Rheumatoid Arthritis.

■ Biologic products listed via SA for the treatment of Rheumatoid Arthritis will now be eligible for coverage for a period of 12 months upon renewal, providing the SA criteria have been met. Previously, these products required renewal requests every 6 months.

■ Products formerly covered through SA for the treatment of **chronic hepatitis B** will now be available for coverage as Restricted Benefits, when prescribed, or in the case of **HEPTOVIR** initiated, by a Specialist in Internal Medicine or a designated prescriber. The affected products are:

- **BARACLUDE** (entecavir) (BMS) **0.5 mg tablet**
- **HEPSERA** (adefovir dipivoxil) (GIL) **10 mg tablet**
- **HEPTOVIR** (lamivudine) (GSK) **100 mg tablet**
- **PEGASYS** (peginterferon alfa-2a) (HLR) **180 mcg/mL & 180 mcg/syringe injections**

the DBL report

Issue #50, January 2009

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Robert J. Herman, MD, FRCPC (Vice-Chair)
Mark Armstrong, BSc, MD, FCFP
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC
Kelly Zarnke, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (01/2009)

Highlights of New Products Added

■ **ATACAND** (candesartan cilexetil) (AZE) **32 mg tablet**, a line extension of the currently listed Atacand product line, was recommended for addition to the *AHWDBL*. The manufacturer indicated that they had introduced this product as the dosing range lies within 4 mg to 32 mg daily. In addition, it was noted that the 32 mg product is priced at parity with the available 8 mg and 16 mg tablets. The Expert Committee considered the information provided and recommended that this product be listed as it offers a cost and therapeutic advantage.

■ **METROGEL** (metronidazole) (GAL) **1% topical gel** is a once daily formulation indicated for the treatment of inflammatory papules, pustules and erythema of rosacea. The Committee considered a resubmission for this product in which the manufacturer asserted that the listing of **Metrogel 1%** may offer savings to the drug program as it is priced at parity with Metrogel 0.75% gel, but is indicated for use only once daily (i.e., as opposed to the 0.75% gel that is dosed twice daily). Based on this information, as well as, additional clinical data provided, the Committee recommended that this product be granted an unrestricted listing on the *AHWDBL*.

■ **PMS-TOPIRAMATE** (topiramate) (PMS) **50 mg tablet** is a line extension of the currently listed PMS-Topiramate product line. The manufacturer indicated that this strength had been introduced to assist in dosage titration. In addition, it was noted that the availability of the 50 mg strength would be useful for the indication of migraine prophylaxis, which is usually dosed at 50 mg twice daily. The Committee recommended that this product be added as it offers a therapeutic advantage.

Highlights of Special Authorization Products Added

■ **APO-CYCLOSPORINE** (cyclosporine) (APX) **100 mg/mL oral solution** was recommended for addition to the *AHWDBL* via special authorization. This product had been previously listed on the *AHWDBL* but was removed when the manufacturer discontinued the product. The Committee recommended that this product be listed via special authorization with criteria at parity with the innovator as it offers a cost advantage. Please refer to the *AHWDBL* for a detailed listing of the coverage criteria.

■ **RATIO-FENTANYL** (fentanyl) (RPH) **12 mcg/hour transdermal system** is a first entry interchangeable product that is priced approximately 30% less than the innovator. The Committee recommended that this product be listed via special authorization in an interchangeable grouping with the innovator, Duragesic (JOI). Please refer to the AHWDBL for a detailed listing of the coverage criteria.

Highlights of Products Not Added

■ **CYMBALTA** (duloxetine hydrochloride) (LIL) **30 mg and 60 mg delayed-release capsules** were originally reviewed via the Common Drug Review (CDR) for the indications of symptomatic relief of major depressive disorder (MDD) and the management of neuropathic pain associated with diabetic peripheral neuropathy (DPNP). The CDR had not recommended that provincial plans reimburse this product for the indication of MDD; therefore, the Expert Committee was asked to review only the indication of DPNP for potential coverage via the *AHWDBL*. Committee members noted that this product produced significant improvements in pain rating scales and quality of life measurements compared to placebo. However, it was noted that there was a lack of randomized controlled trials comparing **Cymbalta** to other currently available therapies. Accordingly, the Committee recommended that this product should not be added as it fails to offer a therapeutic advantage.

the DBL report

Issue #49, October 2008

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

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EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Steve Long, BSc (Pharm), MBA
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (10/2008)

Highlights of Products New Products Added

■ **ALDARA** (imiquimod) (GRC) **5% cream** was recommended for addition to the *AHWDBL* as a special authorization benefit for the treatment of Actinic Keratosis (AK). The manufacturer submitted new information in the form of a resubmission comparing **ALDARA** with cryotherapy and 5-fluorouracil. The Committee acknowledged that this product may be useful for a subset of individuals with small, discrete lesions. Further, it was noted that other jurisdictions have listed this product with criteria. The Committee recommended that **ALDARA** be made available via special authorization with the following criteria for coverage: "For the treatment of Actinic Keratosis located on the head and neck in patients who have failed treatment with 5-fluorouracil (5-FU) and cryotherapy." Please refer to the *AHWDBL* for additional details.

■ **EMEND TRI-PACK** (aprepitant) (MFC) **80 mg x 2 and 125 mg capsule** was originally reviewed by the Common Drug Review (CDR) and recommended for addition to provincial drug plans with criteria for coverage. The Expert Committee was consulted to assist in developing appropriate coverage criteria for the *AHWDBL*. It was noted that the CDR had placed **EMEND** regimens as second line for patients taking highly emetogenic chemotherapy who had already failed a treatment with dexamethasone and a 5HT3-antagonist on a prior chemotherapy cycle. The Committee recommended that this product be listed as a restricted benefit when prescribed by the Directors of the Alberta Cancer Board or their designates. Please refer to the *AHWDBL* for additional details.

■ **ORENCIA** (abatacept) (BMS) **250 mg/vial powder for solution** was recommended for coverage via special authorization for select patients with severely active Rheumatoid Arthritis. **ORENCIA** was originally reviewed by the CDR and recommended for coverage with restrictions; hence, the Committee was asked to assist in criteria development. During their consideration of this product, the Committee consulted with Alberta Rheumatologists to assist in refining the proposed criteria for coverage. Please consult the *AHWDBL* for a full listing of the special authorization criteria.

Highlights of Interchangeable Products Added August 1, 2008

■ **GEN-PANTOPRAZOLE, NOVO-PANTOPRAZOLE, RATIO-PANTOPRAZOLE and SANDOZ PANTOPRAZOLE** (pantoprazole sodium sesquihydrate) **40 mg tablets** have been added to the *AHWDBL* as subsequent-entry generic products interchangeable with the innovator product, Pantoloc (NYC). Additional savings of greater than $550,000 over the current LCA cost may be provided to all government-sponsored drug programs in the first year of listing.

■ **PMS-VALACYCLOVIR** (valacyclovir hydrochloride (PMS) **500 mg caplets** has been added to the *AHWDBL* as first-entry generic product interchangeable with Valtrex (GSK). This product is priced approximately 35% less than the innovator and offers potential savings of greater than $840,000 to all government-sponsored drug programs in the first year of listing.

Changes to Special Authorization Criteria for Medications Used in the Treatment of Alzheimer's Disease

The Committee was advised that the Mainpro-M1 course entitled, "Module 2: Advanced Alzheimer's Disease" was no longer available to assist clinicians in acquiring designated prescriber status. In addition, it was noted that no other continuing education programs on this topic were currently available. Accordingly, Committee members questioned whether it would be appropriate to remove the requirement for physicians initiating therapy for patients with MMSE scores between 10 and 13 from the special authorization criteria. Given that the majority of clinicians are comfortable with this class of medications and that a small minority of patients with low MMSE scores are initiated on these therapies, the Committee recommended that it would be appropriate to revise the special authorization coverage criteria to read: "For the treatment of Alzheimer's Disease in patients with MMSE scores between 10-26. Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's Disease (donepezil, galantamine, rivastigmine) when those medications are used in combination."

Highlights of Products Not Added

■ **DOVOBET** (calcipotriol and betamethasone dipropionate) (LEO) **50 mcg/g and 0.5 mg/g ointment** was not recommended for addition to the *AHWDBL.* The Committee considered a resubmission for this product that contained new clinical and economic information. However, Committee members reiterated their concerns regarding the continuous use of a fixed combination product containing a steroid. It was noted that the individual components of **DOVOBET** are currently benefits on the *AHWDBL*. Accordingly, the Committee recommended that this product should not be added as it fails to offer a therapeutic advantage.

the DBL report

Issue #48, July 2008

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:

James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:

Steve Long, BSc (Pharm), MBA
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (7/2008)

Highlights of Products Not Added

■ **LIPIDIL EZ** (fenofibrate) (SLO) **48 mg and 145 mg tablets** were not recommended for addition to the *AHWDBL*. The Committee noted that no clinical information had been provided to justify the additional cost of **LIPIDIL EZ** as compared to other fibrate therapies. Further, **LIPIDIL EZ** is priced almost identically to the LCA for micronized fenofibrate but is more expensive than the Supra formulation. Hence, the Committee concluded that this product should not be added as it fails to offer a cost and/or therapeutic advantage.

■ **METROGEL** (metronidazole) (GAL) **1% topical gel** was considered for potential addition to the *AHWDBL*. The Committee noted that once daily use of **METROGEL 1%** may provide cost savings as compared to the twice-daily regimen of Metrogel 0.75% because they are priced identically on a cost per gram basis. However, the submission did not provide clinical evidence to support the efficacy of once daily dosing of **METROGEL 1%** vis-à-vis Metrogel 0.75% applied twice daily. The Committee concluded that this product should not be added as it failed to demonstrate a therapeutic advantage.

■ **MEZAVANT** (mesalamine) (SHB) **1.2 delayed and extended release tablet** was not recommended for addition to the *AHWDBL* as it failed to offer a cost and/or therapeutic advantage. The Committee indicated that the manufacturer had not provided evidence to support that the use of **MEZAVANT** resulted in improved patient compliance rates and that the improved compliance resulted in better clinical outcomes (i.e., such as decreases in disease recurrence).

Highlights of Interchangeable Products Added May 1, 2008

■ **GEN-CLARITHROMYCIN, pms-CLARITHROMYCIN and RATIO-CLARITHROMYCIN** (clarithromycin) **500 mg tablets** have been added to the *AHWDBL* as first-entry generic products interchangeable with the innovator product, Biaxin BID (ABB). Savings of over $250,000 may be provided to all government-sponsored drug programs in the first year of listing.

■ **RAN-PANTOPRAZOLE** (pantoprazole sodium sesquihydrate) (RAN) **40 mg enteric-coated tablets** have been added to the *AHWDBL* as first-entry generic products interchangeable with Pantoloc (NYC). Savings of over $7,500,000 to all government-sponsored drug programs may be provided in the first year of listing.

■ **NOVO-MORPHINE SR** (morphine sulfate) (NOV) **100 mg and 200 mg sustained release tablets** have been added to the *AHWDBL* as first-entry generic products interchangeable with the innovator product, MS Contin (PUR). Savings of almost $300,000 may be provided to all government-sponsored drug programs in the first year of listing.

Highlights of Changes to Benefit Status

■ The special authorization criteria for **ENBREL** (etanercept) (AMG) **25 mg vials and 50 mg pre-filled syringes for injection** have been revised to include its use in the reduction of the signs and symptoms of Plaque Psoriasis (PsO). After review of a product resubmission and consultation with Alberta Dermatologists, the Committee recommended listing via special authorization as Enbrel offers a therapeutic advantage in select patients with severe, debilitating PsO. Please refer to the current *AHWDBL* for a complete listing of the special authorization criteria.

■ **ENBREL** (etanercept) (AMG) **25 mg vials and 50 mg pre-filled syringes for injection** and **HUMIRA** (adalimumab) (ABB) **40 mg/0.8 mL pre-filled syringes** may be covered for select individuals with Ankylosing Spondylitis (AS). After consultation with Alberta Rheumatologists, the Expert Committee recommended coverage via special authorization for these products for the reduction of signs and symptoms of AS. Please refer to the current *AHWDBL* for a complete listing of the special authorization criteria.

Highlights of New Products Added

■ **EPREX** (epoetin alfa) (JOI) **30,000 IU/0.75 mL pre-filled syringes** are a line extension of the product line, Eprex. The Committee recommended that this formulation be added to the *AHWDBL* via special authorization for the treatment of chemotherapy induced anemias in patients with non-myeloid malignancies as its use may reduce wastage for those patients currently taking 40,000 IU weekly that require a 25% dose reduction due to increasing hemoglobin levels, minimize possibility of dosing errors and enhance patient compliance and convenience. Please refer to the *AHWDBL* for a complete listing of the special authorization criteria.

■ **RAPTIVA** (efalizumab) (SRO) **150 mg/vial injection** has been added to the *AHWDBL* as a special authorization benefit for the reduction of the signs and symptoms of Plaque Psoriasis (PsO). This product was originally reviewed via the Common Drug Review and given a positive listing recommendation. Prior to **RAPTIVA**'s listing on the *AHWDBL*, the Expert Committee consulted with Alberta Dermatologists to assist in the development of special authorization criteria for coverage for this indication. Please refer to the current *AHWDBL* for a complete listing of the coverage criteria.

the DBL report

Issue #47, April 2008

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:

James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:

Steve Long, BSc (Pharm), MBA
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Sherry Dieleman, BSc (Pharm), MSc
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (04/2008)

Highlights of New Products Added

■ **BARACLUDE** (entecavir) (BMS) **0.5 mg tablet** is a guanosine nucleoside analogue used in the treatment of chronic hepatitis B virus (HBV) infection in adults. This product was originally reviewed via the Common Drug Review and recommended for listing with criteria and/or conditions. The Expert Committee recommended that this product be added to the AHWDBL via special authorization with the following criteria for coverage: *"For the treatment of chronic hepatitis B infection in patients with advanced fibrosis or cirrhosis documented on radiologic or histologic grounds and a HBV DNA concentration above 2,000 IU/mL. Entecavir will not be reimbursed in combination with other anti-viral therapy."* Please refer to the current *AHWDBL* for additional details.

■ **HEPSERA** (adefovir dipivoxil) (GIL) **10 mg tablet** is a prodrug of adefovir indicated for use in the treatment of chronic HBV in adults with compensated and decompensated liver disease with evidence of active viral replication and either evidence of histologically active disease or elevation in serum aminotransferases (ALT or AST). This product was originally reviewed by the Common Drug Review and recommended for listing with criteria and/or conditions. The Expert Committee recommended that this product be listed via special authorization. Please refer to the current *AHWDBL* for special authorization criteria.

■ **HYZAAR** (losartan potassium/hydrochlorothiazide) (MFC) **100 mg/12.5 mg tablet** is a line extension to the currently listed 50 mg/12.5 mg and 100 mg/25 mg strengths of HYZAAR. The manufacturer estimated that approximately 33% of current claims for the single entity products (Cozaar 100 mg and hydrochlorothiazide 12.5 mg) would be replaced by the addition of **HYZAAR** 100/12.5 to the AHWDBL. Accordingly, the Committee recommended that this product be added as it offered a therapeutic and cost advantage.

Highlights of Interchangeable Products Added February 1, 2008

■ **APO-PIOGLITAZONE, CO PIOGLITAZONE, GEN-PIOGLITAZONE, NOVO-PIOGLITAZONE, pms-PIOGLITAZONE, RATIO-PIOGLITAZONE AND SANDOZ PIOGLITAZONE** (pioglitazone hydrochloride) **15 mg, 30 mg and 45 mg tablets** have been added to the *AHWDBL* as first-entry generic products interchangeable with the innovator product, Actos (LIL). The addition of these products is expected to provide savings of over $1,950,500 to all government-sponsored drug programs in the first year of listing.

■ **RAN-RABEPRAZOLE** (rabeprazole sodium) (RAN) **10 mg and 20 mg tablets** have been added to the *AHWDBL* as first-entry generic products interchangeable with the innovator product, Pariet (JOI). The addition of these products is expected to provide savings of over $900,000 to all government-sponsored drug programs in the first year of listing.

Highlights of Products Not Added

■ **SEROQUEL XR** (quetiapine fumarate) (AZE) **50 mg, 100 mg, 200 mg, 300 mg and 400 mg extended release tablet** is a line extension of the product line, Seroquel. The XR formulation is dosed once daily and is indicated for the management of the manifestations of schizophrenia. The Committee indicated that submitted data did not clearly show that **SEROQUEL XR** offered a therapeutic advantage over the listed product, Seroquel. Further, the Committee expressed concern that the XR formulation possessed only one indication whereas; Seroquel is indicated for both schizophrenia and bipolar disorder - mania. Accordingly, **SEROQUEL XR** was not recommended for addition to the *AHWDBL*.

Highlights of Changes to Benefit Status

■ **LOSEC** (omeprazole magnesium) (AST) **10 mg sustained release tablet** has been changed to an unrestricted listing. During the review of a first entry interchangeable 10 mg product, the Expert Committee recalled that Losec 10 mg had originally been recommended for listing via special authorization due to cost concerns. Given the low utilization of this strength and the April 1, 2008 addition of **SANDOZ OMEPRAZOLE** (omeprazole) (SDZ) **10 mg capsule**, the Committee recommended that this product be changed from a special authorization listing to an unrestricted listing.

the DBL report

Issue #46, January 2008

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Micheal S. Guirguis, BSc (Pharm), PhD
Sherry Dieleman, BSc (Pharm), MSc
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (2008/01)

Highlights of New Products Added

■ **EPREX** (epoetin alfa) (JOI) **20,000 unit/syringe injection syringe** is a line extension to the **EPREX** products currently available via special authorization on the *AHWDBL*. The Expert Committee recommended the **20,000 unit/syringe** be added as a benefit, subject to coverage under special authorization. Please refer to the current *AHWDBL* for a full listing of available strengths, special authorization criteria and applicable special authorization request forms.

■ **PMS-AMIODARONE** (amiodarone hydrochloride) (PMS) **100 mg tablet** was reviewed as a line extension to the **PMS-AMIODARONE** 200 mg strength currently listed on the *AHWDBL*. The Committee reviewed the manufacturer's product submission and recommended inclusion as an unrestricted benefit after noting that the availability of a lower strength of amiodarone may offer a therapeutic advantage in select patients, and that the price of the 100 mg tablet is half the cost of a 200 mg tablet.

■ **PMS-PAROXETINE** (paroxetine hydrochloride) (PMS) **40 mg tablet** is a line extension to the currently listed 20 mg & 30 mg strengths of **PMS-PAROXETINE**. Paroxetine is indicated in the treatment of a number of conditions where the recommended daily dose is 40 mg, and where the maximum daily dosage recommendation may exceed 40 mg (up to 60 mg/day). It was also noted that the cost of the 40 mg tablet is at parity with the price of two 20 mg tablets. Accordingly, the Committee recommended **PMS-PAROXETINE 40 mg tablet** be added to the list as it offered a therapeutic advantage for certain conditions.

Highlights of Interchangeable Products Added

■ . **APO-METOPROLOL SR** (metoprolol tartrate) (APX) **100 mg & 200 mg sustained-release tablets** will be listed in interchangeable groupings with LOPRESOR SR 100 mg & 200 mg sustained-release tablets, respectively.

■ **PORTIA 21 & 28** (levonorgestrel/ethinyl estradiol) (APX) **150 mcg/30 mcg oral tablet** is a first-entry generic product that has been added as interchangeable with MIN-OVRAL 21 & 28.

■ **RATIO-VENLAFAXINE XR** (venlafaxine hydrochloride) (RPH) **37.5 mg, 75 mg & 150 mg extended-release capsules** have been added as subsequent-entry generic products interchangeable with the currently listed venlafaxine XR products. The addition of **RATIO-VENLAFAXINE XR** to the *AHWDBL* is expected to provide savings of over $780,000 to all government-sponsored drug programs in the first year of listing and therefore, these products were added to the list **effective November 1, 2007**.

Highlights of Products Not Added

■ . **ACTONEL** (risedronate sodium) (PGA) **75 mg tablet** was reviewed as a line extension to the currently listed **ACTONEL** products. This new strength is approved for treatment of post-menopausal osteoporosis, dosed as one tablet daily for two consecutive days each month. Due to concerns regarding patient compliance issues, it was not recommended for addition to the AHWDBL.

■ **MEZAVANT** (mesalamine) (SHB) **1.2 g delayed and extended release tablet** is indicated for the induction of remission (clinical and endoscopic) in patients with active, mild to moderate ulcerative colitis. Upon review, the Committee indicated this product fails to offer a therapeutic and/or cost advantage. Accordingly, this product was not recommended for addition to the *AHWDBL*.

Special Authorization Criteria Change: Ketek

The Expert Committee considered recent Health Canada-endorsed safety information from the manufacturer of **KETEK** (telithromycin) (SAV) **400 mg tablet**, indicating that **KETEK** is no longer approved for the treatment of bronchitis, sinusitis or tonsillitis/pharyngitis. As a result, the current special authorization (SA) criteria is revised to the following:

"For the treatment of community acquired pneumonia after failure of first line therapy, as defined by clinical deterioration after 72 hours of antibiotic therapy or lack of improvement after completion of antibiotic therapy."

In order to comply with the above criterion, information is required regarding the type of infection and organisms involved, previous antibiotic therapy that has been utilized and the patient's response to therapy. Information is also required regarding the first line agents the organism is resistant to or why other first-line therapies cannot be used in this patient.

the RxDBL report

Issue #45, October 2007

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of New Products Added

■ **DUOTRAV** (travoprost/timolol maleate) (ALC) **0.004%/0.5% ophthalmic solution** is a fixed dose combination of travoprost and timolol maleate, approved for the treatment of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension who are insufficiently responsive to beta-blockers, prostaglandins, or other IOP lowering agents and when the use of the fixed combination drug is considered appropriate. Following the Review of Benefit Status (ROBS) review of agents used in the treatment of glaucoma it was recommended that **DUOTRAV** be added to the *AHWDBL* with an unrestricted listing.

■ **NOVO-ATENOL** (atenolol) (NOP) **25 mg tablet** was reviewed as a line extension to the 50 mg & 100 mg strengths currently listed on the *AHWDBL*. The Committee reviewed the manufacturer's product submission and concluded that this product should be added in an interchangeable grouping with PMS-ATENOLOL (atenolol) (PMS) 25 mg tablet.

Highlights of Special Authorization Products Added

■ **XALACOM** (latanoprost/timolol maleate) (PFI) **0.005%/0.5% ophthalmic solution** is a combination product used in the treatment of open-angle glaucoma or ocular hypertension, where a combination product is appropriate. Following the ROBS review of agents used in the treatment of glaucoma, this product was recommended for listing via special authorization (SA). In addition, a number of other recommendations were made regarding the benefit status of products used in the treatment of glaucoma (see next page for on overview). A full listing of the SA criteria may be found in the current *AHWDBL*.

Highlights of Interchangeable Products Added

■ **NOVO-OLANZAPINE** (olanzapine) (NOP) **2.5 mg, 5 mg, 7.5 mg, 10 mg & 15 mg tablets** are first entry generic products that will be listed in interchangeable groupings with the currently listed ZYPREXA tablets. Priced at a 30% savings over ZYPREXA, these products will provide estimated savings of $5 million to all government-sponsored drug programs. **NOVO-OLANZAPINE tablets** were added to the *AHWDBL* **effective September 1, 2007**.

■ **APO-ENALAPRIL** (enalapril maleate) (APX) **2.5 mg, 5 mg, 10 mg & 20 mg tablets** will be listed as interchangeable with the innovator, VASOTEC tablets **effective October 17, 2007**. The addition of **APO-ENALAPRIL** to the *AHWDBL* will provide an estimated $2 million in savings to the Alberta Health and Wellness-sponsored drug programs.

■ **APO-LISINOPRIL** (lisinopril) (APX) **5 mg, 10 mg & 20 mg tablets** will also be added to the *AHWDBL* in an interchangeable grouping with an **effective date of October 17, 2007**.

Special Authorization Criteria Change: Aranesp and Eprex

The Expert Committee has initiated a review of the current special authorization (SA) criteria for **ARANESP** (darbepoetin) (AMG) and **EPREX** (epoetin alfa) (JOI). The use of these products in non-myeloid malignancies has been clarified to anemia induced by chemotherapy. A full listing of SA criteria, and applicable SA request forms are available in the current *AHWDBL*.

Changes in Benefit Status:

Glaucoma Treatments

As part of the Review of Benefit Status (ROBS) process, a comprehensive clinical review of glaucoma treatments currently listed on the *AHWDBL* was undertaken. The Expert Committee gave due consideration to the information available and recommended the following changes to the listing of specific products:

■ **COMBIGAN** (brimonidine tartrate/timolol maleate) (ALL) **0.2%/0.5% ophthalmic solution** will be moved from a listing via special authorization (SA) to an unrestricted listing.

■ **LUMIGAN** (bimatoprost) (ALL) **0.03%** and **XALATAN** (latanoprost) (PFI) **0.005% ophthalmic solutions** have been recommended to be moved from unrestricted listing to listing via SA. Please refer to the current *AHWDBL* for a full listing of SA criteria.

■ **PMS-DIPIVEFRIN** (dipivefrin hydrochloride) (PMS) **0.1% ophthalmic solution** has been recommended to be removed from the *AHWDBL* as it was found to no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments. Following their recommendation, the Expert Committee was informed that this product is also being discontinued by the manufacturer.

■ **MIOSTAT** (carbachol) (ALC) **0.01% ophthalmic solution** has also been recommended to be removed from the *AHWDBL*, in order to enable broader coverage of higher priority products.

In addition to these recommended changes, **DUOTRAV** (travoprost/timolol maleate) (ALC) and **XALACOM** (latanoprost/timolol maleate) (PFI) **ophthalmic solutions** have been added to the *AHWDBL* (see previous page for details).

Antiviral Agents

A review of antiviral agents currently listed on the *AHWDBL* was also conducted via the ROBS process. Upon consideration of the information provided, the Expert Committee recommended the following products be removed from the *AHWDBL*:

■ **FAMVIR** (famciclovir) (NOV) **500 mg tablet**

■ **HERPLEX-D LIQUIFILM** (idoxuridine) (ALL) and **SANDOZ IDOXURIDINE** (idoxuridine) (SDZ) **0.1% topical solutions**

■ **ZOVIRAX** (acyclovir) (GSK) **5% topical**

These products were either found to no longer possess demonstrated therapeutic advantage or were no longer cost-effective compared to other presently accepted therapies or treatments. In light of the recommendation to remove **FAMVIR 500 mg tablets** from the list, the Committee also recommended that interchangeable products **APO-FAMCICLOVIR** (APX), **PMS-FAMCICLOVIR** (PMS) and **SANDOZ FAMCICLOVIR** (SDZ) **500 mg tablets** not be added to the *AHWDBL*.

the DBL report

Issue #44, July 2007

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:

James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:

Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Micheal S. Guirguis, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (07/2007)

Highlights of New Products Added

■ **DIOVAN** (valsartan) (NOV) **320 mg tablet** is a line extension to the currently listed 80 mg & 160 mg tablets. According to the manufacturer, this new, higher strength has been introduced as an alternative to the addition of a thiazide diuretic in patients with essential hypertension who are currently on DIOVAN 160 mg but are not adequately controlled. In the product submission the manufacturer provided evidence to support additional blood pressure lowering effect from dose increases. The updated product monograph indicates that it is "not recommended to prescribe the maximum dose of **320 mg** without prior up-titration." The Committee noted that higher strengths of DIOVAN may confer additional clinical benefit in select patients, and acknowledged that the use of the **320 mg tablet** would provide a cost savings for those who require 2 x 160 mg daily. Accordingly, the Committee recommended that this product be listed.

■ **APO-DESMOPRESSIN** (desmopressin acetate) (APX) **0.1 mg & 0.2 mg tablets** are first-entry generic products that have been deemed interchangeable with DDAVP 0.1 mg & 0.2 mg tablets. These products offer 30% savings compared to DDAVP tablets, with anticipated savings of over $165,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Accordingly, the Committee recommended the addition of these products to the *AHWDBL*.

■ **APO-ONDANSETRON** (ondansetron hydrochloride dihydrate) (APX) **4 mg & 8 mg tablets** were reviewed by the Committee and found to be interchangeable with ZOFRAN 4 mg & 8 mg tablets. **APO-ONDANSETRON** tablets are subsequent-entry generic products that offer just over 40% savings over the innovator, ZOFRAN, as well as additional savings over the listed least-cost alternative (LCA) price. The addition of these products to the *AHWDBL* could offer potential savings of over $113,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Accordingly, they have been added to the *AHWDBL* in the respective interchangeable groupings.

■ **APO-PERINDOPRIL** (perindopril erbumine) (APX) **8 mg tablet** was found to be interchangeable with COVERSYL 8 mg. The addition of this first-entry generic product to the *AHWDBL*, has the potential to bring over $131,000 in savings to the government-sponsored drug programs. Accordingly, **APO-PERINDOPRIL 8 mg tablet** has been added to the *AHWDBL*.

Highlights of Special Authorization Products Added

■ **SANDOZ ALENDRONATE** (alendronate sodium) (SDZ) **10 mg & 70 mg tablets** were reviewed and found to be interchangeable with the respective strengths of the innovator, FOSAMAX tablets. As a result, these products will be added to the *AHWDBL* in the applicable interchangeable groupings, and will be subject to special authorization with criteria at parity with the currently listed alendronate sodium 10 mg & 70 mg products.

Highlights of Products Not Added

■ **HUMALOG MIX50** (insulin lispro/insulin lispro protamine) (LIL) **50%/50% injection cartridge** is a line extension to the currently listed HUMALOG products. Upon review of the product submission provided by the manufacturer, the Committee noted that the clinical data did not demonstrate a clear therapeutic advantage for this product over other currently listed alternatives. As a result, the Committee recommended that this product should not be added to the *AHWDBL*.

Highlights of Special Authorization Criteria Changes

■ **PEGASYS RBV** (peginterferon alfa-2a/ribavirin) (HLR) and **PEGETRON** (peginterferon alfa-2b/ribavirin) (SCH) combination products are currently covered on the *AHWDBL* via special authorization for the treatment of chronic hepatitis C. The published special authorization criteria provide consideration for reimbursement for treatment in patients that have previously received therapy, only in specified situations. The Committee clarified that requests for patients with advanced fibrosis or cirrhosis will be eligible for coverage of 48 weeks, without the requirement for further qualitative or quantitative testing for HCV RNA at 12 or 24 weeks. The special authorization criteria have been modified to reflect this clarification. Please refer to the current *AHWDBL* for a full listing of special authorization criteria.

■ **PLAVIX** (clopidogrel bisulfate) (BMS) **75 mg tablet** is available on the *AHWDBL* as both a *limited restricted benefit* (LRB) and via *special authorization* (SA) coverage, for a number of indications. As a result of their ongoing commitment to refining coverage criteria of this product through the *AHWDBL*, the Committee continues to review information regarding the use of **PLAVIX** in the prevention of thrombosis following intravascular stent placement.

Coverage following placement of an intravascular stent: PLAVIX is currently accessible through the LRB for one month of coverage following the first intravascular stent placement when prescribed by a designated specialist, through SA for one month of coverage following a subsequent intravascular stent placement, or following the first intravascular stent placement when prescribed by an individual other than a designated specialist (please refer to the LRB criteria for the definition of designated prescriber). In light of emerging information, the Committee has recommended that SA coverage be extended for up to a total of 12 months if the intravascular stent being placed is a **drug-eluting stent (DES)**.

*Please note: The LRB will remain available for the first month following the placement of an intravascular stent when prescribed by a designated specialist, regardless of the type of stent (i.e. bare metal stent or drug-eluting stent); however, if the patient has received a drug-eluting stent, an SA request will need to be submitted by the prescriber for additional coverage (up to 12 months). For a full listing of limited restricted benefit and special authorization criteria for **PLAVIX**, please refer to the current AHWDBL.*

Changes in Benefit Status

■ **VENTOLIN NEBULES P.F.** (salbutamol sulfate) (GSK) **2 mg/mL (base) inhalation unit dose solution**, as well as all other brands of this product currently listed in the interchangeable grouping published within the *AHWDBL*, have been recommended to be moved to an open listing. These products, previously available via special authorization for patients unable to use, or allergic to preservatives contained in, the multi-dose solution, will be available as unrestricted benefits. The additional affected brands include: APO, GEN, NU, PMS and RATIO.

■ **EUMOVATE** (clobetasone butyrate) (GKC) **0.05% topical cream** has been moved from prescription status to being available over-the-counter (OTC). As a result of this change in prescription status, the Committee conducted a review of this product and recommended that it be de-listed from the *AHWDBL*.

the DBL report

Issue #43, April 2007

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Marcello Tonelli, MD, SM, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Micheal S Guirguis, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (01/2007)

Highlights of Products Added

■ **APO-DIGOXIN** (digoxin) (APX), **0.0625 mg, 0.125 mg, and 0.25 mg** tablets. This product was added to the *AHWDBL* on February 1, 2007 as interchangeable with Lanoxin. This product offers greater than 30% savings over the innovator and is expected to offer savings of approximately $366,000 to the government-sponsored programs in the first year of listing.

■ **NOVO-VENLAFAXINE XR** (venlafaxine hydrochloride) (NOP) **37.5 mg, 75 mg and 150 mg** Extended-Release Capsules. This product was added to the *AHWDBL* on February 1, 2007 as interchangeable with Effexor XR. This product offers 30% savings over the innovator and is expected to offer savings of approximately $4,184,120 to the government-sponsored programs in the first year of listing.

■ **SANDOZ BUPROPION SR** (bupropion hydrochloride) (SDZ) **100 mg and 150 mg** Sustained-Release Tablets were added to the *AHWDBL* on February 1, 2007 as interchangeable with Wellbutrin SR. This product offers greater than 30% savings over the innovator and is expected to offer savings of approximately $583,824 to the government-sponsored programs in the first year of listing.

Changes in Benefit Status of vaginal anti-infective products, parasympathomimetics, papaverine and Intron A

Comprehensive reviews of clinical evidence to support the efficacy of vaginal anti-infective products, parasympathomimetics and papaverine were undertaken by the Sub-Committee on the Review of Benefit Status of Products, Classes and Categories on the *AHWDBL*. Following review of the information obtained in the literature, as well as input from the manufacturers and other stakeholders, the Expert Committee recommended changes in the benefit status of vaginal anti-infective products, parasympathomimetics and papaverine effective April 11, 2007. Please refer to the *AHWDBL* for the listing status of such agents.

In addition, a review of utilization of Intron A (interferon-alfa-2b) was performed. It was noted that there was no utilization for this product during the time period ranging from 2005 to 2006. Consultations with the manufacturer and other stakeholders did not provide any additional information to merit the continued listing of this product on the *AHWDBL*. Accordingly, it was recommended that this product be delisted effective April 1, 2007.

Highlights of Products Added via Special Authorization

- **COSOPT** (dorzolamide hydrochloride / timolol maleate) (MFC) **2%/0.5% PRESERVATIVE-FREE SINGLE DOSE** ophthalmic solution has been recommended for listing on the *AHWDBL*. This product will be added to the AHWDBL via special authorization with the following criteria for coverage: "For the treatment of elevated intraocular pressure in patients who have a documented sensitivity to preservatives". Please refer to the *AHWDBL* for a complete listing of special authorization criteria.

- **TRUSOPT** (dorzolamide hydrochloride) (MFC) **2% PRESERVATIVE-FREE SINGLE DOSE** ophthalmic solution has been recommended for listing on the *AHWDBL*. This product will be added to the AHWDBL via special authorization with the following criteria for coverage: For the treatment of elevated intraocular pressure in patients who have a documented sensitivity to preservatives. Please refer to the *AHWDBL* for a complete listing of special authorization criteria.

- **HUMIRA** (adalimumab) (ABB) **40 mg/0.8 mL** injection has been recommended for listing on the *AHWDBL* via special authorization for the treatment of psoriatic arthritis. This product has been recommended for addition via Special Authorization with the following criteria for coverage: “For use in combination with methotrexate for reducing signs and symptoms and inhibiting the progression of structural damage of active arthritis in adult patients (>/=18 years of age) with moderate to severe polyarticular psoriatic arthritis (PsA) or pauciarticular PsA with involvement of knee or hip joint who are refractory to methotrexate and another disease modifying anti-rheumatic agent(s)”. Please refer to the *AHWDBL* for a complete listing of special authorization criteria.

- **SANDOZ CYCLOSPORINE** (cyclosporine) (SDZ) **25 and 50 mg** capsules have been recommended for listing on the *AHWDBL* as interchangeable with Neoral. This product will be added to the AHWDBL via special authorization with the following criteria for coverage: For the treatment of severe psoriasis, severe rheumatoid arthritis and treatment of steroid dependent and steroid resistant nephrotic syndrome. Please refer to the *AHWDBL* for a complete listing of special authorization criteria.

Highlights of Products Not Added

- **BETASERON** (interferon beta-1b) (BEX), **0.3 mg** injection indicated for the new indication of single demyelinating event, alternatively known as clinically isolated syndrome (CIS). The Committee noted that the MS Drug Coverage Program does not currently cover any medications for the indication of CIS. In addition, it was noted that this product appears to be similar in efficacy to other agents available for this indication, but slightly more expensive. Accordingly, the Committee concluded that this product should not be added for the indication of CIS.

the Rx DBL report

Issue #42, January 2007

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD

ALBERTA HEALTH AND WELLNESS LIAISON:
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Micheal S Guirguis, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (01/2007)

Highlights of Products Added

■ **AVALIDE** (irbesartan/hydrochlorothiazide) (SAV), **300 mg/25 mg** tablets are a line extension of the currently listed Avalide product line. This product provides a rational titration alternative for hypertensive patients requiring optimal blood pressure control with fixed dose combinations of irbesartan and hydrochlorothiazide. Further, the availability of this product eliminated the need to add 12.5 mg hydrochlorothiazide to the currently listed Avalide 300/12.5 mg strength when required. Accordingly, this product was recommended for listing.

■ **LINESSA** (desogestrel/ethinyl estradiol) (ORG), **21 and 28 Day** packages are indicated for the prevention of pregnancy. Although offering only a slight cost savings over other oral contraceptives containing desogestrel, Linessa has a lower dose of estrogen and reported improvements in cycle control. Hence, the Committee recommended the addition of Linessa.

■ **NOVO-BETHAHISTINE** (bethahistine) (NOP) **16 mg** was added to the *AHWDBL* on November 1, 2006 as interchangeable with Serc. This product offers greater than 30% savings over the innovator and is expected to offer savings of approximately $260,000 to the government-sponsored programs in the first year of listing.

■ **PARIET** (rabeprazole sodium) (JOI) **20 mg** tablets are a line extension of the currently listed Pariet product line. Pariet is a proton pump inhibitor (PPI) that is indicated in the treatment of conditions where a reduction of gastric acid secretion is required. This product is priced equivalent to 2 x Pariet 10mg and offers a significant cost advantage over other currently listed PPIs. Accordingly it was recommended that this product be added to the *AHWDBL*.

■ **SANDOZ FELODIPINE** (felodipine) (SDZ) **5 mg and 10 mg** was added to the *AHWDBL* on November 1, 2006 in an interchangeable grouping with Plendil and Renedil. This product offers greater than 30% savings over the innovator and is expected to offer approximately $2,900,000 in savings to the government-sponsored programs in the first year of listing.

Change in Benefit Status of Topical Antibiotic, EENT Antibiotic Products and Stemgen

Comprehensive reviews of clinical evidence to support the efficacy of topical and EENT antibiotic products were undertaken by the Sub-Committee on the Review of Benefit Status of Products, Classes and Categories on the *AHWDBL*. Following review of the information obtained in the literature, as well as input from the manufacturers and other stakeholders, the Expert Committee recommended a change in the benefit status of select topical and EENT antibiotic products effective January 1, 2007. Please refer to the *AHWDBL* for the listing status of such agents.

In addition, a review of utilization of Stemgen (ancestim) was performed. It was noted that there was no utilization for this product during the time period ranging from 2002 to 2005. Consultations with the manufacturer and other stakeholders did not provide any additional information to merit the continued listing of this product on the *AHWDBL*. Accordingly, it was recommended that this product be delisted effective January 1, 2007.

Highlights of Products Added via Special Authorization

- **APO-MIDODRINE** (midodrine hydrochloride) (APX) **2.5 mg and 5 mg** was added to the *AHWDBL* on January 1, 2007 in an interchangeable grouping with Amatine. This product has been recommended for addition via Special Authorization with the following criteria for coverage: "For the treatment of neurogenic types of idiopathic hypotension where the response to standard therapy is inadequate. Special Authorization may be granted for 24 months."

- **DURAGESIC** (fentanyl) (JOI) **12 mcg/hr** transdermal patches have been recommended for listing on the *AHWDBL* via special authorization for the treatment of persistent, severe chronic pain. The Committee indicated that this product may offer a therapeutic advantage when titrating fentanyl dosage. It should be noted that this product is listed as an unrestricted benefit for the Palliative Care Drug Benefit program. Please refer to the *AHWDBL* for a complete listing of special authorization criteria.

Highlights of Products Added to MS Drug Coverage Program

- **REBIF** (interferon beta-1A) (SRO), **8.8 mcg/0.2 mL & 22.0 mcg/0.5 mL** Initiation Pack has been recommended for listing via the MS Drug Coverage Program on the *AHWDBL*. The Committee indicated that the introduction of the Rebif Initiation Pack would replace the use of the spacer devices during dosage titration and thereby increase patient convenience, decrease drug wastage and potentially decrease drug program costs. Accordingly, the Committee recommended that this product be listed.

Highlights of Products Not Added

- **ALTACE** (ramipril) (SAV) **15 mg** capsules-The Committee determined there currently is no need for a 15 mg capsule on the AHWDBL given available utilization data and that a 15 mg daily dose may be achieved using a combination of the other listed strengths.

- **BIPHENTIN** (methylphenidate hydrochloride) (PUR), **10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 50 mg and 60 mg** are controlled-release capsules that are indicated in the treatment of Attention-Deficit Hyperactivity Disorder. The Committee indicated that the available evidence did not support that Biphentin offered a therapeutic advantage over other currently listed alternatives. Accordingly, the Committee recommended that this product should not be added.

the DBL report

Issue #41, October 2006

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Braden Manns, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (10/2006)

Highlights of Products Added

■ **APO-FENO-SUPER** (fenofibrate) (APX), **100 mg and 160 mg tablets** were added to the *AHWDBL* on August 1, 2006 in an interchangeable grouping with Lipidil Supra. This product is priced over 30% less than the innovator and is expected to offer savings of approximately $712,000 to the government-sponsored programs in the first year of listing.

■ **METADOL** (methadone hydrochloride) (PMS) **1 mg/mL oral solution** is a line extension of the currently listed Metadol product line. This product reportedly offers an advantage to clinicians and patients by decreasing the dilutions needed to achieve required dosing, thereby decreasing dispensing errors. The Committee agreed that the availability of the 1 mg/mL strength may decrease the complexity associated with dispensing methadone in many instances. Accordingly, they recommended that **METADOL** be added to the *AHWDBL* as it offered a therapeutic advantage.

■ **NOVO-ONDANSETRON** (NOP), **PMS-ONDANSETRON** (PMS), **RATIO-ONDANSETRON** (RPH) **AND SANDOZ-ONDANSETRON** (SDZ) (ondansetron HCl dihydrate) **4 mg and 8 mg tablets** were added to the *AHWDBL* effective August 1, 2006. These products offer between 30% and 40% savings over the cost of the innovator product, Zofran, and a potential savings for the government-sponsored drug programs of $868,000 in the first year of listing.

■ **RAN-RISPERIDONE** (risperidone) (RAN) **0.25 mg, 0.5 mg, 1 mg, 2 mg, 3 mg and 4 mg tablets** are first-entry interchangeable products for Risperdal. **RAN-RISPERIDONE** is cross-licensed with Risperdal and is priced over 30% less than the innovator. The Committee recommended that this product be added effective August 1, 2006 as it has the potential to offer greater than $3,000,000 to the government-sponsored drug programs in the first year of listing.

Highlights of Changes to Special Authorization Criteria

■ The special authorization criteria for **PEGASYS** (peginterferon alfa-2a) (HLR) **180 mcg/mL vial and 180 mcg/0.5 mL pre-filled syringe** were changed to include the indication of treatment of chronic hepatitis B as the product was deemed to offer a therapeutic advantage over presently available therapies. Please refer to the *AHWDBL* for complete listing of the special authorization criteria for **PEGASYS**.

Special Authorization Criteria Change for Drugs Used in the Treatment of Alzheimer's Disease

The Expert Committee was advised that the accreditation for the Mainpro-C dementia course had lapsed on March 31, 2006. The Committee recalled that designated prescribers are able to apply for coverage for patients initiating therapy with MMSE scores between 10 and 13. Prescribers may be deemed to be designated by virtue of their specialty or by completing the Mainpro-C dementia course or the care of the Elderly Six-month/One-year Fellowship Program. The Committee reviewed available continuing education courses in order to determine whether there was a course available that could replace the Mainpro-C course. After their review of several courses, Committee members recommended that the criteria for **ARICEPT** (donepezil) (PFI), **EXELON** (rivastigmine) (NOV) and **REMINYL ER** (galantamine) (JOI) be revised to include the following:

"Specialists in Geriatric Medicine, Neurology, and Psychiatry are deemed designated prescribers by virtue of their specialty in medical practice. All other practitioners will be added to the list of designated prescribers if they have successfully completed Mainpro-C credits through the College of Family Practice (Physicians) [prior to March 31, 2006], the Care of the Elderly Six-month/One-year Fellowship program through the department of Medicine or the Mainpro-M1 course entitled, "Module 2: Advanced Alzheimer's Disease."

Highlights of Products Added via Special Authorization

- **EPREX** (epoetin alfa) (JOI) **40,000 IU/mL pre-filled syringe** has been recommended for listing on the *AHWDBL* via special authorization for the treatment of anemia of cancer in patients with non-myeloid malignancies. The Committee has recommended that patients be allowed a maximum dosage of 40,000 IU per week when an authorization is granted for this product presentation. Please refer to the *AHWDBL* for a complete listing of the special authorization criteria.

- **NORPROLAC** (quinagolide hydrochloride) (FEI) **0.075 mg and 0.150 mg tablets** are indicated for the treatment of hyperprolactinemia. This product was originally reviewed via the Common Drug Review (CDR) Process and recommended for listing for patients with hyperprolactinemia who have failed or are intolerant to bromocriptine. The manufacturer had since requested that **NORPROLAC** be granted an unrestricted listing; hence, the product was placed before the Expert Committee for consideration. After reviewing the CDR recommendations and additional material, the Committee concurred with the CDR's recommendation and indicated that this product should be listed via special authorization. Please refer to the *AHWDBL* for a full listing of the coverage criteria.

Highlights of Products Not Added

- **ADVICOR** (niacin/lovastatin) (ORY) **500 mg/20 mg and 1000 mg/20 mg extended-release tablets** were not recommended for addition to the *AHWDBL*. This product was originally reviewed via the CDR process and recommended for listing. However, **ADVICOR** was placed before the Expert Committee because one of its components, extended-release niacin, was previously not recommended for listing via the *AHWDBL*. The Committee concluded that since the niacin component of the product was not currently listed on the *AHWDBL*, **ADVICOR** should remain unlisted as it fails to offer a cost and/or therapeutic advantage.

- **ARICEPT RDT** (donepezil hydrochloride) (PFI) **5 mg and 10 mg rapid dissolving tablet** is reported to offer a therapeutic advantage in select patient groups because it rapidly dissolves into a paste once in the mouth, at which time it may be swallowed with water. The Committee questioned the need for such a dosage form in the Aricept product line given that the original tablets are quite small. In addition, Committee members indicated that patients with Alzheimer's Disease often require compliance packaging. Unfortunately, **ARICEPT RDT** must remain in the original package until administration; therefore, it would be difficult to maintain tablet integrity when compliance aids are used. Accordingly, the Committee recommended that this product not be added as it fails to offer a therapeutic advantage.

- **RISPERDAL CONSTA** (risperidone) (JOI) **25 mg/vial, 50 mg/vial and 75 mg/vial powder for injectable prolonged-release suspension** was not recommended for listing as it failed to offer a cost and/or therapeutic advantage. The Committee concluded that the manufacturer had not provided any information that would merit a change in their previous recommendation.

the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

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EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Braden Manns, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of Products Added

■ **APO-OMEPRAZOLE** (omeprazole) (APX), a first-entry interchangeable product, was added to the *AHWDBL* on June 1, 2006**,** as the manufacturer provided direct evidence of comparative therapeutic efficacy between Apo-Omeprazole capsules and Losec tablets. Further, it was noted that this product is priced 43% less than the innovator and has the potential to offer savings of $10,900,000 in the first year of listing.

■ **CLARUS** (isotretinoin) (PRP) **10 mg and 40 mg capsules** have been recommended for addition to the *AHWDBL* in an interchangeable grouping with Accutane. Clarus is a first-entry interchangeable product offering 26% savings over the innovator product. As isotretinoin is a known teratogen, and in keeping with the commitment required of the innovator's manufacturer, Prempharm, was required to develop a risk management program. This program is entitled, CLEAR (Clinical Education and Awareness Resource) and is intended to assist physicians and pharmacists with counseling patients on effective use of contraception while taking these products.

■ **CO LEVETIRACETAM** (levetiracetam) (COB) **250 mg, 500 mg and 750 mg tablets** are indicated as adjunctive therapy in the management of patients with epilepsy who are not satisfactorily controlled by conventional therapy. Co Levetiracetam was recommended for addition to the *AHWDBL* via special authorization as it is a first-entry interchangeable product that offers 26% savings over Keppra.

■ **FLOMAX CR** (tamsulosin HCl) (BOE**) 0.4 mg controlled-release tablets** are a line extension of the currently listed, Flomax product. Flomax CR uses an Oral Controlled Absorption System (OCAS) that involves a controlled-release matrix, which reportedly provides a constant release of drug throughout the large intestine, regardless of whether it is taken with or without food. The manufacturer stressed that Flomax CR and the currently listed Flomax are not interchangeable. The Committee recommended that this product be added to the *AHWDBL* as an unrestricted benefit.

■ **PMS-CITALOPRAM** (citalopram hydrobromide) **10 mg tablets** and **PMS-MIRTAZAPINE** (mirtazapine) **15 mg tablets** (PMS) are line extensions of currently listed benefits on the *AHWDBL*. The manufacturer indicated that these products were introduced to allow patients to take lower doses of medication without the need to split tablets. The Expert Committee recommended the addition of **PMS-CITALOPRAM 10 mg and PMS-MIRTAZAPINE 15 mg tablets** because they offer a therapeutic advantage.

ABC 81171 (07/2006)

Special Authorization Criteria Change for Duragesic Patches

Correspondence from an Alberta physician prompted the Expert Committee to review the current special authorization criteria for **DURAGESIC (fentanyl) 25 mcg, 50 mcg, 75 mcg and 100 mcg transdermal patches** (JOI). The Committee noted that the special authorization criteria were quite lenient in light of the safety concerns and abuse potential related to this agent. Accordingly, it was recommended that the special authorization criteria be revised to read:

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who cannot swallow."

and

"For the treatment of persistent, severe chronic pain in those patients who require continuous around-the-clock analgesia for an extended period of time in those patients who require opioid therapy at a total daily dose of at least 60 mg/day oral morphine equivalents. Patients must have tried and not been able to tolerate at least two discrete courses of therapy with two of the following agents: morphine, hydromorphone and oxycodone, if not contraindicated."

At the direction of the Committee, "two discrete courses" are defined as separate courses of therapy containing one or more of the agents noted above. For example, a patient who reported only taking morphine and an oxycodone product concomitantly prior to requesting coverage for Duragesic would only be considered to have tried one discrete course of therapy and would not meet the criteria.

Change in Benefit Status of EENT Anti-Allergy Products

A comprehensive review of clinical evidence to support the efficacy of topical Eye, Ear, Nose and Throat (EENT) products used in the treatment of allergies was conducted. Following their review of the information obtained in the literature, as well as input from the manufacturers, the Committee recommended that the following EENT anti-allergy products be de-listed from the *AHWDBL* effective July 1, 2006: lodoxamide tromethamine (Alomide®), sodium cromoglycate (Apo-Cromolyn®, Cromolyn®, Opticrom®, Solu-Crom®), and levocabastine HCl (Livostin®).

Review of Benefit Status of Plavix

The Committee considered a resubmission from the manufacturer requesting that the length of authorization for the Limited Restricted Benefit (LRB) of Plavix be extended from 30 days to one year. In addition to the manufacturer's submission, an extensive literature review was conducted to examine the clinical evidence supporting an extension of coverage beyond 30 days post-stent placement. After considering the available information, the Committee concluded that the strongest evidence for the use of Plavix lies within the first 30 days after stent placement, regardless of whether the patient received a drug-eluting or bare metal stent. Accordingly, the Committee recommended that the benefit status of Plavix remain unchanged. Please refer to the *AHWDBL* for a detailed overview of the coverage criteria for Plavix.

Products Not Added to the AHWDBL

■ **PAMIDRONATE DISODIUM OMEGA** (pamidronate disodium) (OMG) was not recommended for addition to the *AHWDBL*. While the Committee indicated that the comparative data supported the interchangeability of this product with the innovator, Aredia, it was noted that there was a substantial price disparity between the price of Pamidronate Disodium Omega and other currently listed interchangeable products. Accordingly, the Committee recommended that this product not be added as it fails to offer a cost advantage.

■ **PREVACID FASTABS** (lansoprazole) (ABB) **30 mg delayed-release tablets** disintegrate on the tongue into enteric-coated microgranules that are swallowed with saliva. The manufacturer stated that this product would offer an advantage for patients with dysphagia or who are being fed via nasogastric tube. The Committee noted that the currently listed product, Prevacid, allows for dosing of such patients. Therefore, it was recommended this product not be added as it fails to offer a therapeutic advantage over currently listed products.

Removal of Interchangeability Designation of Novo-Bupropion SR 150 mg Tablets

Effective June 1, 2006, the interchangeability designation of Novo-Bupropion SR 150 mg with Wellbutrin SR 150 mg has been removed. Following reports of stability issues associated with the Novopharm product, the Expert Committee completed additional investigation. The Committee concluded that stability issues preclude the ability to blister-pack or compliance-pack the medication. Accordingly, the Committee concluded that it was not appropriate to continue to have Novo-Bupropion SR 150 mg designated as interchangeable with Wellbutrin SR 150 mg on the *AHWDBL*.

the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
James L. Silvius, BA, MD, FRCPC (Chair)
Judith M. Baker, BSP, MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Jeffrey Johnson, BSP, MSc, PhD
Braden Manns, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC 81171 (04/2006)

Highlights of New Products Added

■ **ACLASTA** (zoledronic acid) (NOV) is indicated as a single-dose infusion for the treatment of Paget's disease of bone in patients with elevations in serum alkaline phosphatase of at least two times the upper limit of the age-specific normal reference range, or who are symptomatic, or those at risk for complications from their disease. The **5 mg/100 mL** injection is available via special authorization with the following criteria for reimbursement: *"For the treatment of Paget's disease. Special authorization for this criterion may be granted for one dose per 12-month period. Coverage cannot be provided for two or more medications used in the treatment of Paget's disease when these medications are intended for use in combination or when therapy with two or more medications overlap."*

■ **FUCITHALMIC** (fusidic acid) (LEO) **1% viscous ophthalmic drops (unpreserved)** have been recommended for addition to the *AHWDBL*, via special authorization, as a preservative-free alternative to other currently listed ophthalmic antibiotics. The criteria for coverage will be as follows: *"For the treatment of ophthalmic infections in patients with documented sensitivity to preservatives."*

■ **SAIZEN** (somatropin) (SRO) is now indicated for replacement therapy in adult patients with acquired or idiopathic growth hormone deficiency. In addition, this product is less expensive than the currently listed somatropin product, HUMATROPE. [Please note: These products are not interchangeable.] Accordingly, the Expert Committee recommended the **3.3 mg & 5 mg vials for injection** be listed on the *AHWDBL* with the following criteria for coverage: *"For replacement of endogenous growth hormone in adults with severe growth hormone deficiency. Information is required regarding the results of a diagnostic insulin tolerance test. Growth hormone values less than 3 mcg/litre during hypoglycemia are indicative of severe growth hormone deficiency."*

■ **TWINJECT** (epinephrine) (PAL) **0.15 mg auto-injector** is a line-extension to the currently listed 0.3 mg strength. The **0.15 mg** strength is indicated for use in children and adults weighing 15 – 30 Kg, while the 0.3 mg strength is for patients > 30 Kg. **TWINJECT** is a single-use, auto-injection device that once activated will administer one dose, with a second dose available by manual administration. The Committee felt the second dose may offer a clinical advantage in situations where patients require additional dosing of epinephrine following an anaphylactic episode. Accordingly, the Committee recommended this product be added to the *AHWDBL* as a single source product.

Special Authorization Criteria Change for Alzheimer's Drugs

The Committee considered the issue of combination use of agents for the treatment of Alzheimer's disease (AD). It was noted that there are currently no published studies available to evaluate such use of these products. As a result, the Committee indicated that special authorization coverage of agents used in the treatment of AD should not be considered when intended for use in combination. Therefore, the following will be added to special authorization criteria for coverage of Alzheimer's agents currently listed on the *AHWDBL*:

"*Coverage cannot be provided for two or more medications used in the treatment of Alzheimer's disease (donepezil, rivastigmine, galantamine) when these agents are intended for use in combination.*"

Affected products include the following:

- **ARICEPT** (donepezil hydrochloride) (PFI) 5 mg & 10 mg tablets
- **EXELON** (rivastigmine hydrogen tartrate) (NOV) 1.5 mg, 3 mg, 4.5 mg & 6 mg capsules and 2 mg/mL oral solution
- **REMINYL** (galantamine hydrobromide) (JOI) 4 mg, 8 mg & 12 mg tablets
- **REMINYL ER** (galantamine hydrobromide) (JOI) 8 mg, 16 mg & 24 mg extended-release capsules

Highlights of Interchangeable Products Added

- **APO-METHYLPHENIDATE SR** (methylphenidate hydrochloride) (APX) **20 mg extended-release tablet** is a first-entry generic product that was deemed interchangeable with the innovator, RITALIN SR 20 mg. The Committee recommended this product be added to the *AHWDBL* as it provides a 39% savings over the innovator product.

- **CO AZITHROMYCIN** (azithromycin monohydrate) (COB) **250 mg tablet** is a first-entry generic product that has been deemed interchangeable with ZITHROMAX 250 mg tablet. This product qualified for fast-track addition to the *AHWDBL* by virtue of the savings offered to the government-sponsored programs. As a result, this product was added **effective March 1, 2006**.

In addition, **APO-AZITHROMYCIN** (APX), **NOVO-AZITHROMYCIN** (NOP) and **SANDOZ AZITHROMYCIN** (SDZ) (azithromycin monohydrate) **250 mg tablets** were added, **effective April 1, 2006**.

- **SANDOZ DILTIAZEM T** (diltiazem hydrochloride) (SDZ) **120 mg, 180 mg, 240 mg, 300 mg & 360 mg extended-release capsules** have been deemed interchangeable with the respective strengths of the innovator, TIAZAC extended-release capsules. As a result of the substantial savings offered, this first-entry generic product also met fast-track criteria for addition to the *AHWDBL*. Accordingly, **SANDOZ DILTIAZEM T** was added in an interchangeable grouping with TIAZAC, **effective March 1, 2006**.

Highlights of Products Not Added

- **BIAXIN XL** (clarithromycin) (ABB) is a **500 mg extended-release tablet** formulation of the currently listed BIAXIN BID. This product is dosed as 1000 mg (i.e. 2 tablets) every 24 hours. Overall, the Committee indicated that no new information had been provided to warrant a change in their previous recommendation not to list this product.

- **DIOVAN** (valsartan) (NOV) **40 mg tablet** is a line extension to the currently listed 80 mg & 160 mg tablets. This new, lower strength has been introduced to support dose titration for the new indication to reduce cardiovascular mortality in clinically stable patients with signs or symptoms of left ventricular dysfunction in conjunction with acute MI when the use of an ACE inhibitor is inappropriate. The Committee indicated that it was likely the 40 mg strength would be used during a patient's hospital stay post-MI and therefore not largely used by the outpatient population. The Committee recommended that this product should not be added, as it does not offer a therapeutic and/or cost advantage over other available therapies.

New Criterion for Optional Special Authorization of Select Quinolones

Please note, the following will be added to the Optional Special Authorization (OSA) criteria for the quinolone antibiotics currently available via OSA:

"*For use in other current Health Canada approved indications when prescribed by a specialist in Infectious Diseases.*"

Please refer to section 3A of the current *AHWDBL* for a full listing of products and criteria.

the DBL report

Issue #38, January 2006

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

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Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC 81171 (01/2006)

Highlights of New Products Added

■ **ASACOL** (5-aminosalicylic acid) (PGA) **800 mg enteric-coated tablet** is a line extension to the currently listed 400 mg tablet. The Expert Committee noted that patients receiving ASACOL 400 mg for the treatment of ulcerative colitis may be required to take up to 12 tablets daily. With the introduction of the **800 mg** strength, patients would be able to take fewer tablets. In addition, it was noted that the **800 mg** strength is priced at parity with 2 x 400 mg. Accordingly, this product was recommended for addition as it provides an advantage of more convenient dosing for patients requiring higher doses of **ASACOL**.

■ **RISPERDAL M-TAB** (risperidone) (JOI) is an orally disintegrating or quick-dissolve tablet formulation of risperidone. The 0.5 mg, 1 mg & 2 mg strengths have been available on the *AHWDBL* since February 1, 2004. The manufacturer requested that the **3 mg & 4 mg** strengths also be considered for coverage, with the justification that these additional strengths would offer better dosing flexibility and ease of use. In addition, the Committee noted that they are available at lower cost than the corresponding strengths of the traditional tablet formulation. Accordingly, **RISPERDAL M-TAB 3 mg & 4 mg** have been added to the *AHWDBL*.

Highlights of Interchangeable Products Added

■ **APO-SUMATRIPTAN** (APX)**, CO SUMATRIPTAN** (COB)**, GEN-SUMATRIPTAN** (GEN) and **PMS-SUMATRIPTAN** (PMS) (sumatriptan succinate) **50 mg & 100 mg tablets** are all first-entry generic products that have been deemed interchangeable with IMITREX DF 50 mg & 100 mg tablets. These products qualified for fast-track addition to the *AHWDBL* by virtue of the savings offered to the government-sponsored programs. As a result, these products were added **effective November 1, 2005**.

■ **PMS-TOPIRAMATE** (topiramate) 25 mg, 100 mg & 200 mg tablets were deemed interchangeable with the innovator, TOPAMAX 25 mg, 100 mg & 200 mg, respectively. Due to the magnitude of savings offered by these products, they qualified for fast-track addition to the *AHWDBL*. Accordingly, **PMS-TOPIRAMATE** was added to the list effective **November 1, 2005**.

■ **PMS-OXYCODONE/ACETAMINOPHEN** (oxycodone HCl/acetaminophen) 5 mg/325 mg tablet was originally reviewed in 2003, at which time the Committee indicated that insufficient evidence had been provided to make a designation of interchangeability. In their resubmission, the manufacturer presented data from a recently conducted bioequivalence study that allowed **PMS-OXYCODONE/ACETAMINOPHEN** to be deemed interchangeable with the innovator, PERCOCET. As a result, this product was recommended for addition to the *AHWDBL*.

Optional Special Authorization (OSA)

New coverage criteria was introduced for the following quinolone antibiotics, **effective November 15, 2005**:

- **CIPROFLOXACIN** (all brands) 250 mg, 500 mg & 750 mg tablets
- **CIPRO** (ciprofloxacin HCl) (YNO) 2 mg/mL IV minibags for injection and 100 mg/mL oral suspension
- **LEVAQUIN** (levofloxacin) (JOI) 250 mg & 500 mg tablets
- **OFLOXACIN** (all brands) 200 mg, 300 mg & 400 mg tablets

In addition, also **effective November 15, 2005**, the following two new products were added to the *AHWDBL*, via OSA:

- **AVELOX** (moxifloxacin HCl) (YNO) 400 mg tablet
- **TEQUIN** (gatifloxacin) (BMS) 400 mg tablet

*Norfloxacin continues to be eligible for coverage as an unrestricted benefit.

Two options are available to prescribers to enable patient eligibility for coverage. Prescribers may choose to register as a 'designated prescriber', and will not be required to fill out special authorization (SA) documentation for coverage (i.e. as long as the prescription is written for a defined set of criteria); or they may choose not to register. Physicians not registering as 'designated prescribers' will be required to apply for SA coverage on a patient's behalf. In this case, a first forgiveness rule will apply allowing for payment of an initial claim; however, subsequent claims for the same active ingredient within a 90-day period will require SA coverage.

For further details and a full listing of criteria, please refer to section 3A in the current *AHWDBL*. Additional information is also available to prescribers via the OSA registration package (mailed to Alberta physicians in October 2005), and to pharmacy providers in *The Pharmacy Benefact* (Number 171, October 2005).

Highlights of Products Not Added

■ **ALDARA** (imiquimod) (MMH) 5% cream was resubmitted for consideration as a result of the new indication of clinically typical, nonhyperkeratotic, nonhypertrophic actinic keratosis on the face or balding scalp in adults. The Expert Committee gave due consideration to the information provided; however, the evidence failed to support that **ALDARA** offered a therapeutic and/or cost advantage over other topical and ablative therapies. Hence, the Committee concluded that this product should not be added to the *AHWDBL*.

■ **LIPIDIL EZ** (fenofibrate) (AOO) 48 mg & 145 mg tablets were submitted as line extensions to the currently listed LIPIDIL MICRO and SUPRA products. According to the manufacturer, **LIPIDIL EZ** has no food effect and may allow for a dose reduction. However, the Committee noted that submitted bioequivalence data did not demonstrate that **LIPIDIL EZ** offered an advantage over LIPIDIL SUPRA in terms of food effect. As a result, this product was recommended not to be listed.

Topical Products Used in the Treatment of Acne

A comprehensive review of the medical literature pertaining to topical products used in the treatment of acne was conducted as a component of the Review of Benefit Status (ROBS) process. The Expert Committee gave due consideration to the available information and recommended changes to the benefit status of a number of these products, **effective January 1, 2006**. A transition period will apply to products recommended for removal from the *AHWDBL*, and therefore claims for these products will be honored for processing until March 1, 2006. More detailed information on the ROBS process, including ROBS criteria, can be found in the currently published *AHWDBL*.

The following products will be delisted:

- **BENZOYL PEROXIDE** products (all brands) of 5% or less
- **DALACIN T** (clindamycin phosphate) (PFI) 1% topical solution
- **SANS-ACNE** (erythromycin/alcohol) (GAL) 2%/44% topical lotion

The following products will be moved to coverage via special authorization (Please refer to the current *AHWDBL* for a full listing of available formulations and special authorization criteria):

- **BENZOYL PEROXIDE** products (all brands) of 10% or greater
- **TRETINOIN** products (all brands)
- **CLINDOXYL** (clindamycin phosphate/benzoyl peroxide) (STI) 1%/5% topical gel
- **STIEVAMYCIN** (erythromycin/tretinoin) **MILD, MODERATE & FORTE**
- **NEO-MEDROL ACNE** (methylprednisolone acetate/neomycin sulfate/aluminum chlorhydroxide complex/sulfur) (PFI) 2.5 mg/mL/2.5 mg/mL/100 mg/mL/50 mg/mL topical lotion
- **MEDROL ACNE** (methylprednisolone acetate/aluminum chlorhydroxide complex/sulfur) (PFI) 2.5 mg/mL/100 mg/mL/50 mg/mL topical lotion
- **SULFACET-R** (sulfur/sulfacetamide sodium) (DER) 5%/10% topical lotion

Please note, the following product has also been added via special authorization **effective January 1, 2006** (Please refer to the current *AHWDBL* for full listing of special authorization criteria):

- **BENZACLIN** (clindamycin phosphate/benzoyl peroxide) (DER) 1%/5% topical gel

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ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC 81171 (10/2005)

Highlights of New Products Added

■ **CRESTOR** (rosuvastatin) (AZC) **5 mg tablet** is a line extension to the currently listed 10 mg, 20 mg and 40 mg tablets. The Expert Committee noted that the **CRESTOR** product monograph indicates 5 mg is the recommended starting dose for Asian patients, as well as patients with severe renal impairment. Also, initiation of therapy with 5 mg may be considered for patients requiring less aggressive LDL-C reductions or who have predisposing factors for myopathy. It was further noted that the 10 mg tablet is not scored. Accordingly, this product was recommended for addition to the *AHWDBL* as it offers the therapeutic advantage of being able to initiate therapy at a lower dose in select patients.

■ **EPREX** (epoetin alfa) (JOI) **5,000 IU pre-filled syringe** is a line extension to the currently listed pre-filled syringes, available in differing sizes ranging from 1,000 IU to 10,000 IU per syringe. The Expert Committee recognized that this additional size will provide increased dosing flexibility. In addition, the Committee noted that the cost per unit of the new syringe size is at parity with that of the other listed **EPREX** syringes. Accordingly, the Committee recommended that the **5000 IU/mL pre-filled syringe** be added as it offers a therapeutic advantage and is cost neutral. This product will be added via special authorization with the same criteria for coverage as the currently listed **EPREX** pre-filled syringes. Please refer to the current *AHWDBL* for a full listing of available formulations and special authorization criteria.

■ **OXYCONTIN** (oxycodone HCl) (PUR) **5 mg sustained-release tablet** is a line extension to the currently listed 10 mg, 20 mg, 40 mg and 80 mg strengths. The Committee acknowledged that there is a therapeutic advantage in being able to initiate patients at a lower dose and titrate more carefully and specifically to the lowest effective dose for pain management. In addition, it was acknowledged that a lower dose may also reduce opioid related side effects in opioid naïve patients. Accordingly, the Committee recommended that this product be added to the *AHWDBL* as it offers a therapeutic advantage.

■ **REMINYL ER** (galantamine hydrobromide) (JOI) **8 mg, 16 mg and 24 mg extended release capsules** are line extensions to the currently listed 4 mg, 8 mg and 12 mg immediate release (IR) tablets, which are currently available on the *AHWDBL* via special authorization for the treatment of Alzheimer's Disease. The Expert Committee considered the manufacturer's submission and justification for the new formulation, which is that the once daily administration schedule should improve adherence to therapy. In addition, the Committee recognized that the daily cost of therapy with the ER formulation is less than for the IR tablets. As a result, due to the potential therapeutic advantage of once daily dosing and the cost advantage over the IR product, the Committee recommended that **REMINYL ER** be added via special authorization at parity with the currently listed Reminyl tablets. Please refer to the current *AHWDBL* for a full listing of special authorization criteria.

Neulasta Addition

■ **NEULASTA** (pegfilgrastim) (AMG) 6 mg/0.6 mL syringe was reviewed through the Common Drug Review process. The Canadian Expert Drug Advisory Committee (CEDAC) recommended that **NEULASTA** be listed for patients with non-myeloid cancer receiving regimens with curative intent who are at high risk of developing prolonged neutropenia. However, CEDAC also expressed concerns about the cost effectiveness of **NEULASTA** and recommended that the cost effectiveness of granulocyte colony stimulating factors should be reviewed as a "class". In addition, they recommended that funding jurisdictions evaluate their current utilization of NEUPOGEN (filgrastim) (AMG), because both drugs are similar in efficacy and the relative cost of the two depend on the dose and length of use of NEUPOGEN. The Expert Committee reviewed current utilization and based on this, advised that **NEULASTA** should be covered for adult patients (18 years of age and older) subject to the following special authorization criteria for this population, effective October 1, 2005:

"To decrease the incidence of infection, as manifested by febrile neutropenia, in patients 18 years of age and older with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs with curative intent. This drug product must be prescribed by the Directors of Alberta Cancer Board Centres (or their designates)." Coverage cannot be considered for palliative patients.

Neupogen Criteria Change

Please note, the first special authorization criterion for **NEUPOGEN** have been revised to the following:

"To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with non-myeloid malignancies receiving myelosuppressive anti-neoplastic drugs with curative intent. This drug product must be prescribed by the Directors of Alberta Cancer Board Centres (or their designates)." Coverage cannot be considered for palliative patients.

Highlights of Interchangeable Products Added

■ **APO-ALENDRONATE** (alendronate sodium) (APX) **70 mg tablet** is a first-entry generic product that was deemed interchangeable with the innovator, FOSAMAX 70 mg. At a savings of 33% over the innovator, the addition of this product to the *AHWDBL* could offer potential savings of over $2,000,000 to the government-sponsored drug programs in the first year of listing, thereby meeting criteria for FAST-TRACK addition. Accordingly, it has been added to the *AHWDBL*, **effective August 1, 2005**, subject to the same special authorization criteria as the currently listed alendronate 70 mg tablet.

■ **APO-LITHIUM CARBONATE SR** (lithium carbonate) (APX) **300 mg sustained-release tablet** was deemed interchangeable, as a first-entry generic product, with the innovator, DURALITH 300 mg. The Committee recommended that this first-entry generic product be added to the *AHWDBL* as it offers just over 40% savings compared to DURALITH with anticipated savings of approximately $17,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

Highlights of Special Authorization Criteria Changes

■ **PEGASYS RBV** (peginterferon alfa-2a/ribavirin) (HLR) and **PEGETRON** (peginterferon alfa-2b/ribavirin) (SCH) have had further refinements made to their special authorization criteria. Due to recent numerous revisions to these criteria they have been redrafted to simplify and better clarify the requirements for specific Hepatitis C genotypes and patient populations. Please refer to the current *AHWDBL* for a full listing of available formulations and current special authorization criteria.

■ **SPORANOX** (itraconazole) (JOI) **10 mg/mL oral solution** special authorization criteria have been revised as follows:

"For the treatment of oral and/or esophageal candidiasis in immunocompromised patients who are intolerant to fluconazole, or who have failed fluconazole as evidenced by significant clinical deterioration due to the fungal infection during a course of therapy or no resolution after a full course of therapy."

■ **VFEND** (voriconazole) (PFI) 200 mg/vial injection and 50 mg & 200 mg tablets are antifungal products indicated in the treatment of invasive aspergillosis. **VFEND** was added to the *AHWDBL* via special authorization, effective July 1, 2005, in keeping with the recommendation by CEDAC. The Expert Committee recommended that further restriction was prudent and therefore the special authorization criteria have been revised to the following:

"For the treatment of invasive aspergillosis for post-hospital discharge only. This medication must be prescribed in consultation with a specialist in Infectious Diseases."

the DBL report

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Highlights of New Products Added

■ **SALOFALK** (5-aminosalicylic acid) (AXC) rectal suppositories are indicated in the management of ulcerative proctitis and as adjunctive therapy in more extensive distal ulcerative colitis. The Committee had previously reviewed the **1000 mg suppository** (a line extension to the currently listed enteric-coated oral tablet, rectal enema and the 500 mg suppository) in 2000 and 2001. On both occasions, they had recommended that it not be listed, as the data provided by the manufacturer did not convince the Committee that the release characteristics of the **1000 mg suppository** were comparable to that of the 250 mg and 500 mg suppositories. The Committee recently reviewed a resubmission for this product, and based on clinical evidence provided they concluded that therapeutically, the **1000 mg suppositories** administered daily and 500 mg suppositories administered BID are comparable. The Committee commented that they were impressed that the manufacturer undertook the initiative to conduct a clinical trial in support of listing this product. Accordingly, it was recommended that **SALOFALK 1000 mg rectal suppository** be added to the *AHWDBL* as it provides a therapeutic and cost advantage.

■ **TRI-CYCLEN LO** (norgestimate/ ethinyl estradiol) (JOI) is a new oral contraceptive, and the only low estrogen triphasic product on the market to date. The Committee acknowledged that current clinical practice guidelines advocate the use of the lowest estrogen dose possible for oral contraceptives. This product is priced comparably with other currently listed oral contraceptives. Accordingly, **TRI-CYCLEN LO** has been recommended for addition to the *AHWDBL*.

■ **ZOMIG** (zolmitriptan) (AZC) **5 mg nasal spray** is a line extension to the currently listed 2.5 mg oral tablet and 2.5 mg Rapimelt tablet. The Committee acknowledged the parity pricing vis-à-vis the 2.5 mg tablet and recommended adding this product to the *AWHDBL* at parity with the other Zomig formulations. Accordingly, **ZOMIG 5 mg nasal spray** has been recommended for addition to the *AHWDBL* as a restricted benefit for patients 18 to 64 years of age, and via special authorization for patients 65 years of age and older. (Please refer to the current *AHWDBL* for a full listing of restricted benefit and special authorization criteria.)

Common Drug Review

The Common Drug Review (CDR) is a national process for reviewing new drugs and new combination products and providing formulary listing recommendations to participating publicly-funded federal, provincial and territorial (F/P/T) drug benefit plans in Canada. To find out more about the CDR or to view recommendations for products evaluated through the CDR, log onto the Canadian Coordinating Office for Health Technology Assessment website at www.ccohta.ca.

ABC 81171 (07/2005)

The Review of Benefit Status (ROBS) Process

The Review of Benefit Status (ROBS) is a process by which the current *AHWDBL* products may be reviewed for continued value and appropriateness. In addition, Alberta Health and Wellness and/or the Expert Committee on Drug Evaluation and Therapeutics may at any time recommend that the benefit status of an individual product, class or category of drug products on the *AHWDBL* be reviewed. Developed in response to feedback from the Auditor General of Alberta, the ROBS process serves to assess the continued value of products after they have been added to the *AHWDBL*, thereby assisting with the sustainability of the government-sponsored drug programs.

As with the review of any product by the Committee, recommendations are made by considering the potential benefit to all patients covered by the government-sponsored drug programs. Following a ROBS review, the listing status of a product may remain unchanged, or could be revised or discontinued if one or more of the ROBS criteria, published in Section 1 of the *AHWDBL*, are met. If a change in benefit status is deemed to be warranted, manufacturers of the affected products are notified and provided with an opportunity to make a submission to the Committee prior to a final recommendation being made. The Expert Committee is the advisory committee to the Minister of Health and Wellness on matters pertaining to the coverage of products on the *AHWDBL*.

Highlights of Special Authorization Criteria Changes

■ **ARANESP*** (darbepoetin alfa) (AMG) was recently approved for the treatment of anemia in patients with non-myeloid malignancies, where anemia is due to the effect of concomitantly administered chemotherapy. The Expert Committee received a resubmission from the manufacturer to add this new indication to the current special authorization criteria. After careful consideration, the Committee recommended that the criteria for **ARANESP** be revised to include the following criterion: "For the treatment of anemia in patients with non-myeloid malignancies with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose of Aranesp should be reduced by about 25%. If hemoglobin exceeds 120 g/L, therapy should be discontinued until hemoglobin falls below 100 g/L, at which time Aranesp should be reinstituted at a dose 25% below the previous dose." Please refer to the current *AHWDBL* for a full listing of **ARANESP** special authorization criteria.

■ **IMITREX DF*** (sumatriptan succinate) (GSK) **50 mg tablet** will now be listed at parity with IMITREX DF 100 mg tablet. Previously available only for patients unable to tolerate the 100 mg tablet, the **50 mg tablet** will now be listed as a restricted benefit for patients 18 to 64 years of age inclusive for the treatment of acute migraine attacks in patients where other standard therapy has failed, and via special authorization with criteria for patients 65 years of age and older.

■ **PEGASYS RBV*** (peginterferon alfa-2a/ribavirin) (HLR), **PEGETRON*** (peginterferon alfa-2b/ribavirin) (SCH), and **PEGETRON REDIPEN*** (peginterferon alfa-2b/ribavirin) (SCH) have also had changes to their special authorization criteria. In response to feedback from, and in consultation with, physicians treating patients with chronic hepatitis C (HCV), the Committee has recommended the following changes:

- Patients with HCV genotype 2 or 3 and HIV co-infection will now be eligible for up to 48 weeks of treatment; however, these patients will be subject to the same testing requirements as required for patients with HCV genotype 1 (e.g. beginning with a stored baseline serum sample).
- Patients with HCV genotype 1 and who are post liver transplant will no longer be required to undergo HCV-RNA testing at the 12th week of treatment; however, these patients will still be required to meet requirements for testing at week 24.

***For a full listing of available formulations, restricted benefit and/or special authorization criteria, please refer to the current AHWDBL.**

Highlights of Interchangeable Products Added

■ **NOVO-BUPROPION SR** (bupropion hydrochloride) (NOP) 150 mg tablet is a first-entry generic product that was deemed interchangeable with the innovator, WELLBUTRIN SR 150 mg. At a savings of 32% over the innovator, the addition of this product to the *AHWDBL* could offer potential savings of over $290,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Accordingly, it has been added to the *AHWDBL* in an interchangeable grouping **effective July 1, 2005**.

■ **NOVO-CILAZAPRIL** (cilazapril) (NOP) 1 mg, 2.5 mg & 5 mg tablets have been deemed interchangeable with the innovator, INHIBACE 1 mg, 2.5 mg & 5 mg tablets. The Committee recommended this first-entry generic product be added to the *AHWDBL* as it offers 37% savings over INHIBACE and anticipated savings of over $450,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing, meeting criteria for FAST-TRACK addition. This product was added **effective May 1, 2005**.

the DBL report

Issue #35, April 2005

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCPC (Chair) (on sabbatical)
James L. Silvius, BA, MD, FRCPC (Acting Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Braden Manns, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Glenn Monteith, MA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC 81171 (04/2005)

Cancidas Added via Special Authorization

■ **CANCIDAS** (caspofungin) (MFC) is the first in a new class of antifungal agents called glucan synthesis inhibitors, which have a distinct mechanism of action unlike currently available antifungals. **CANCIDAS** acts to target the fungal cell wall and has shown activity (in vitro) against various pathogenic fungi of the *Aspergillus* species. The Expert Committee recommended that **CANCIDAS** be added to the *AHWDBL* via special authorization with the following criteria for coverage:

"For esophageal candidiasis in patients who are intolerant to fluconazole and itraconazole, or who have failed both agents as evidenced by significant clinical deterioration due to the fungal infection during a course of therapy or no resolution after a full course of therapy."

Highlights of New Products Added

■ **CESAMET** (nabilone) (VCL) is indicated in adults for the management of severe nausea and vomiting associated with cancer chemotherapy. The **0.5 mg capsule** is a line extension to the currently listed 1 mg tablet. According to the manufacturer, the 0.5 mg strength will offer dose flexibility and assist with the safety profile of nabilone. The Committee indicated that there may be a potential therapeutic advantage if the 0.5 mg strength is used and less adverse events are experienced by patients. In addition, while both strengths are priced at parity on a per mg basis, the Committee indicated that there may also be a potential cost advantage if the 0.5 mg strength is used in place of the 1 mg strength. Accordingly, it was recommended that **CESAMET 0.5 mg capsule** be added to the *AHWDBL*.

■ **PEGETRON** (peginterferon alfa-2b/ribavirin) (SCH) injection kits, previously only available with the peginterferon alfa-2b component in a vial of lyophylized powder requiring reconstitution, are now available in kits containing **REDIPEN** pre-filled injection syringes in the following strengths: 80 mcg/0.5 mL, 100 mcg/0.5 mL, 120 mcg/0.5 mL and 150 mcg/0.5 mL. The new format is intended to ensure convenient and accurate dosing. The Committee agreed that the availability of pre-filled syringes for the peginterferon alfa-2b component may provide a therapeutic advantage. Therefore, **PEGETRON REDIPEN** kits have been recommended for addition to the *AHWDBL* subject to the same special authorization criteria and testing requirements applied to the currently listed **PEGETRON** kits. (Please refer to the current *AHWDBL* for a full listing of special authorization criteria.)

Bacid Removed from the AHWDBL

■ **BACID** (lactobacillus acidophilus) (ERF) capsules – A comprehensive review of the medical literature for therapeutic efficacy of *Lactobacillus acidophilus* in the treatment of irritable bowel syndrome was conducted as a component of the Review of Benefit Status (ROBS) process. The Expert Committee gave due consideration to the information available, as well as a response submitted by the manufacturer in support of maintaining this product on the *AHWDBL*. Nonetheless, it was noted that there does not appear to be good literature evidence to support the use of *Lactobacillus acidophilus*. Accordingly the Expert Committee has recommended that **BACID** be removed from the *AHWDBL*, **effective April 1, 2005**, in order to enable broader coverage of higher priority products, classes or categories of drugs on the *AHWDBL*. A transition period will apply to this product, and therefore claims will be honored for processing until June 15, 2005. More detailed information on the ROBS process, including ROBS criteria, can be found in the currently published *AHWDBL*.

Highlights of Products Not Added

■ **CONCERTA** (methylphenidate HCl) (JOI) 18 mg, 36 mg & 54 mg extended release tablets – The Expert Committee gave due consideration to a resubmission for this product. The Committee had previously recommended against listing **CONCERTA** as the information provided failed to demonstrate a therapeutic and/or cost advantage over other presently accepted therapies. After reviewing the information provided within the resubmission, the Committee remained unconvinced that the addition of this agent would merit the incremental costs. The Committee indicated that no new information had been provided that would warrant a change in their previous recommendation not to add **CONCERTA** to the *AHWDBL*.

■ **CUTIVATE** (fluticasone propionate) (GKC) 0.05% cream is indicated for the relief of the inflammatory and pruritic manifestations of corticosteroid-responsive dermatoses. Upon review, the Committee advised that Cutivate does not appear to provide any therapeutic advantage vis-à-vis currently available less costly alternatives (e.g. betamethasone, hydrocortisone). Therefore, it was recommended that this product not be added to the *AHWDBL*.

■ **GENTLAX-S** (bisacodyl/docusate sodium) (PUR) is an enteric-coated combination product consisting of a stimulant laxative (bisacodyl) with a stool softener (docusate). Cathartics and laxatives are not currently listed as benefits on the *AHWDBL*; however, there are a number of products included in the *Palliative Care Drug Benefit Supplement*. The Committee gave due consideration to the submitted information and indicated that, as the individual agents are currently available, and given the nominal potential for savings, this product does not offer a therapeutic and/or cost advantage over other presently listed therapies. Accordingly, the Committee recommended that **GENTLAX-S** not be added.

Selective COX-2 Inhibitors: Emerging Safety Concerns

On December 22, 2004, Health Canada issued an Advisory that states accumulating evidence indicates the use of selective Cox-2 inhibitors, in certain individuals, to be associated with an increased risk of heart attack or stroke, and recommended that, until further information becomes available, one should consider that there is a strong possibility of an increased risk of cardiovascular events when using selective COX-2 inhibitors.

Subsequently, on April 7, 2005, an additional Advisory was issued regarding a request from Health Canada to Pfizer Canada Inc. to voluntarily discontinue sales of Bextra (valdecoxib) due to ongoing review of information with regard to serious, potentially life-threatening skin reactions. In the April 2005 Advisory, Health Canada also informed Canadians of new restrictions on the use of Celebrex (celecoxib). For more information, please log onto the Health Canada website at http://www.hc-sc.gc.ca, and follow the links through Health Protection to the Advisories/Warnings section.

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Issue #34, January 2005

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Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Braden Manns, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:

Glenn Monteith, MA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC 81171 (01/2005)

Highlights from the Review of Antimicrobials

As detailed in the *Alberta Health and Wellness Drug Benefit List (AHWDBL),* the Review of Benefit Status (ROBS) is a process by which the benefit status of products, classes or categories of drugs listed on the *AHWDBL* may be reviewed. At the request of the Minister of Health and Wellness, the Expert Committee on Drug Evaluation and Therapeutics recently completed a review of antimicrobials listed on the *AHWDBL*. This comprehensive review was performed in consultation with various health care professionals representing several areas of clinical practice, including individuals with expertise in infectious diseases. The goal was to evaluate antimicrobials that are currently listed and those under consideration for addition to the *AHWDBL*, and to provide advice and recommendations to encourage optimal utilization and aid in the control and prevention of antimicrobial resistance.

The following is a summary of the changes in benefit status of affected antimicrobials. For further information on the coverage of specific products or the ROBS process, please refer to the current *AHWDBL*.

Special Authorization

As a result of the antimicrobial review, the benefit status of the following products will be revised from unrestricted listing to special authorization (SA), ***effective March 1, 2005***:

- **AMPICILLIN** (ampicillin) (all brands)
  250 mg & 500 mg capsules and 25 mg/mL & 50 mg/mL oral suspensions
- **CEFADROXIL** (cefadroxil) (all brands)
  500 mg capsule
- **PRIMAXIN** (imipenem monohydrate) (MFC)
  250 mg/250 mg & 500 mg/500 mg injections
- **TAZOCIN** (piperacillin sodium/tazobactam sodium) (WAY)
  2 G/250 mg, 3 G/375 mg & 4 G/500 mg injections
- **VANCOCIN** (vancomycin HCl) (LIL)
  125 mg & 250 mg capsules

In addition, the following products had revisions to their SA criteria:

- **LINEZOLID** (zyvoxam) (PHD) 600 mg tablet
- **MERREM** (meropenem) (AZC) 500 mg & 1 G injections

Lastly, ***effective January 1, 2005***, the following new product has been added via SA:

- **KETEK** (telithromycin) (AVE) 400 mg tablet has been added to the *AHWDBL* for the treatment of community acquired pneumonia or acute exacerbation of chronic bronchitis, after failure of first line therapy.

For additional details and a full listing of SA criteria for these products, please refer to the current *AHWDBL*.

Highlights of Products Added

- **METHOTREXATE** (methotrexate) (MNP) 10 mg tablet is a line extension to the currently listed Mayne Pharma 10 mg/mL and 25 mg/mL injections. This product will facilitate dosing in patients who require higher doses of oral methotrexate and are currently required to take multiple tablets (e.g. 4 x 2.5 mg).

- **APO-ATENIDONE** (atenolol/chlorthalidone) (APX) 50/25 mg and 100/25 mg are first-entry generic products that were deemed interchangeable with the innovator, Tenoretic. These products are priced 32% < the innovator, and therefore, their addition to the *AHWDBL* could offer potential savings of over $90,000 in the first year of listing.

- **GEN-MIRTAZAPINE** (mirtazapine) (GPM) 30 mg tablet is a subsequent-entry generic product that was recommended for listing in an interchangeable grouping with the other currently listed mirtazapine 30 mg products. This product is priced 35% < the innovator, Remeron, and 12.5% < the current LCA. Therefore, the listing of this product on the *AHWDBL* will offer additional savings, as it will become the new LCA.

Discontinued Listings

The antimicrobial review also resulted in the following products being removed from the *AHWDBL*, effective January 1, 2005:

- **CEFACLOR** (cefaclor) (all brands) 250 mg & 500 mg capsules and 25 mg/mL, 50 mg/mL & 75 mg/mL oral suspensions
- **BACITRACIN** (bacitracin) (PHD) 50,000 U/vial injection
- **CEFIZOX** (ceftizoxime sodium) (GSK) 1 G/vial & 2 G/vial injections
- **CEFOTAN** (cefotetan disodium) (WAY) 1 G/vial & 2 G/vial injections
- **CEFOXITIN SODIUM** (NOP) 1 G/vial & 2 G/vial injections
- **HIP-REX** (methenamine hippurate) (MMH) 1 G tablet
- **MANDELAMINE** (methenamine mandelate) (PFI) 500 mg tablet
- **MONUROL** (fosfomycin tromethamine) (PUR) 3 G sachet
- **NEGGRAM** (nalidixic acid) (WIN) 500 mg caplet
- **PEDIAZOLE** (erythromycin ethylsuccinate/sulfisoxazole acetyl) (ABB) 40 mg/mL/120 mg/ml oral suspension
- **PONDOCILLIN** (pivampicillin) (LEO) 500 mg tablet & 35 mg/mL oral suspension
- **TIMENTIN** (ticarcillin disodium/potassium clavulanate) (GSK) 3 G/100 mg injection vial
- **ZINACEF** (cefuroxime sodium) (GSK) 750 mg/vial & 1.5 G/vial injections

Recently discontinued products also recommended for delisting include **SELEXID** (pivmecillinam HCl) (LEO) 200 mg tablet, **PENGLOBE** (bacampicillin HCl) (AZC) 400 mg tablet, **ROVAMYCINE-500** (spiramycin) (AVE) 1,500,000 U capsule and **NETROMYCIN** (netilmicin sulfate) (SCH) 50 mg/mL injection. ***Please note: A transition period will apply for the removal of all the aforementioned products and therefore, claims for these products will be honored for processing until April 1, 2005.***

In making their recommendation to remove these products from the *AHWDBL*, the Expert Committee indicated that these products no longer possess demonstrated therapeutic advantage compared to other presently accepted therapies or treatments for which they are indicated.

Additional Highlights

- **COMBIGAN** (brimonidine tartrate/timolol maleate) (ALL) 0.2%/0.5% ophthalmic solution has been added to the *AHWDBL* via special authorization, with the following criteria for coverage: "For patients who have had an inadequate response in lowering of intraocular pressure with a beta-blocking agent alone and are currently receiving the individual components (i.e. brimonidine and timolol) in combination. Special authorization may be granted for 12 months."

- **VALCYTE** (valganciclovir) (HLR) 450 mg tablet – An additional special authorization criterion was added in order to allow coverage "For the prevention of CMV disease in solid organ transplant patients at high risk (i.e. risk is defined as donor +ve/recipient -ve for CMV or recipient +ve post-active treatment of CMV disease with IV ganciclovir). Special authorization may be granted for 3 months."

the DBL report

Issue #33, October 2004

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The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCPC (Chair)
James L. Silvius, BA, MD, FRCPC (Vice Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Braden Manns, MD, MSc, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Glenn Monteith, MA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

- *New Products Added*
- *Products Not Added*

Pegetron Special Authorization Criteria Change

Products Removed from the AHWDBL

ABC 81171 (10/2004)

Highlights of New Products Added

■ **ATROVENT HFA** (ipratropium bromide) (BOE) 20 mcg/dose metered dose inhaler (MDI) has been added due to the impending removal of the current chlorofluorocarbon (CFC)-containing ATROVENT 20 mcg/dose MDI from the Canadian market. The transition from the CFC-containing ATROVENT to **ATROVENT HFA** is in keeping with the Environment Canada national transition strategy (as per the Montreal Protocol) to phase-out the use of ozone-depleting substances such as CFCs in MDIs.

In making their recommendation to add **ATROVENT HFA**, the Committee considered pharmacodynamic and clinical studies that demonstrated a 40 mcg dose (2 puffs of 20 mcg) delivered via the HFA MDI was therapeutically equivalent to a 40 mcg dose of the CFC MDI. Interestingly, pharmacokinetic studies included in the submission showed that the systemic bioavailability of ipratropium was significantly higher with the HFA MDI than with the CFC MDI ($p<0.05$); however, evidence of therapeutic equivalence of the above doses was provided in the clinical studies. It should be noted that **ATROVENT HFA** has not been designated as interchangeable with ATROVENT (CFC-containing) as no information was provided upon which the bioequivalence of the two formulations could be assessed.

■ **LESCOL XL** (fluvastatin sodium) (NOV) 80 mg extended release tablet is a line extension to the currently listed LESCOL product line, consisting of the 20 mg & 40 mg capsules. **LESCOL XL** 80 mg is dosed once daily, and is therefore an alternative for patients currently prescribed a dose of 40 mg twice daily. In addition, it was noted that this product provides a cost advantage, as the cost of one 80 mg XL tablet is less expensive than the cost of 2 x 40 mg capsules. Accordingly, the Committee recommended the addition of **LESCOL XL** 80 mg as it offers a therapeutic and/or cost advantage.

■ **APO-ALENDRONATE** (alendronate sodium) (APX) 10 mg tablet is a subsequent-entry generic product that has been deemed interchangeable with the innovator, FOSAMAX 10 mg tablet. This product was recommended for addition to the *AHWDBL* at parity with FOSAMAX and NOVO-ALENDRONATE 10 mg tablets, the current least cost alternative (LCA) product. **APO-ALENDRONATE** is priced equivalent to NOVO-ALENDRONATE, both offering a 30% savings over FOSAMAX. All three products are subject to coverage via special authorization. Please refer to the current *AHWDBL* for a full listing of special authorization criteria for these products.

Pegetron Special Authorization Criteria Change

■ **PEGETRON** (peginterferon alfa-2b/ ribavirin) (SCH) is currently available via special authorization on the *AHWDBL*. Following the Expert Committee's review of the new Canadian consensus guidelines on the management of viral Hepatitis, they recommended a change to the special authorization criteria for **PEGETRON**. Specifically, patients who are infected with genotype 1, and achieve a 2-log drop but who do not clear HCV RNA from serum at week 12, will be required to undergo repeat testing at 24 weeks to determine if they have cleared the virus. Please refer to the current *AHWDBL* for a full listing of special authorization criteria for **PEGETRON**.

Highlights of Products Not Added

■ **ALDARA** (imiquimod) (MMH) 5% topical cream was originally reviewed for potential addition to the *AHWDBL* in 1999. At that time, the Expert Committee gave due consideration to the information provided; however, it was concluded that there was insufficient evidence to support that **ALDARA** offered a significant therapeutic or cost advantage vis-à-vis other available therapies listed on the *AHWDBL*. Furthermore, it was noted that there appeared to be no head-to-head comparisons with other active therapies. The Committee recently reviewed a resubmission for this product for the indication of in the treatment of external genital warts, but noted that no new information was presented that would merit reconsideration of their previous decision. Accordingly, the Committee recommended that **ALDARA** not be added to the *AHWDBL*.

■ **NASONEX** (mometasone furoate) (SCH) 50 mcg/dose nasal metered dose spray is currently listed on the *AHWDBL* as a restricted benefit *for patients 3 to 12 years of age inclusive for the treatment of seasonal allergic rhinitis or perennial allergic rhinitis*. The Expert Committee considered a resubmission from the manufacturer requesting that the **NASONEX** be listed via special authorization for the treatment of acute sinusitis as adjunctive treatment to antibiotics. The Committee had reviewed a similar request in 2001; however, it was noted that the clinical data provided at that time did not appear to support a significant therapeutic advantage that would warrant a change in benefit status. The Committee gave due consideration to the information provided with the resubmission, but noted that no new information was provided that had not been previously reviewed. Accordingly, the Committee recommended that **NASONEX** maintain its current listing as a restricted benefit.

Products Removed from the AHWDBL

■ **642** (propoxyphene hydrochloride) (LIO) 65 mg tablet and **DARVON-N** (propoxyphene napsylate) (PAL) 100 mg capsule – A comprehensive review of the medical literature pertaining to propoxyphene containing products was conducted as a component of the Review of Benefit Status (ROBS) process. The Expert Committee gave due consideration to the information available and concluded that these products no longer possess a demonstrated therapeutic advantage compared to other presently accepted therapies or treatments of the disease entity for which they are indicated. In addition, the Committee noted ongoing concerns regarding the safety of this product. Accordingly, these products were recommended for removal from the *AHWDBL*, **effective October 1, 2004**. A 60-day transition period will apply to both products, and therefore claims will be honored for processing until December 1, 2004. More detailed information on the ROBS process, including ROBS criteria, can be found in the currently published *AHWDBL*.

the DBL report

Issue #32, July 2004

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EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Braden Manns, MD, MSc, FRCPC
James L. Silvius, BA, MD, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Glenn Monteith, MA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (07/2004)

Highlights of New Products Added

■ **APO-CIPROFLOX (APX), CO CIPROFLOXACIN (COB), GEN-CIPROFLOXACIN (GPM), NOVO-CIPROFLOXACIN (NOP), PMS-CIPROFLOXACIN (PMS), RATIO-CIPROFLOXACIN (RPM)** and **RHOXAL-CIPROFLOXACIN (RXP)** (ciprofloxacin hydrochloride) 250 mg, 500 mg & 750 mg tablets are first-entry generic products that have been deemed interchangeable with the innovator, CIPRO 250 mg, 500 mg & 750 mg tablets. The Committee recommended that these products be added to the *AHWDBL* as they offer 30% savings over the innovator products and anticipated savings of over $600,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Furthermore, as these products met criteria for FAST-TRACK addition, they were added to the *AHWDBL* **effective May 1, 2004**.

■ **DOM-PAROXETINE** (paroxetine hydrochloride) (DPC) 10 mg tablet is the first of this strength of paroxetine to be listed on the *AHWDBL*. Accordingly, it has been listed as a single source product. A dose of 10 mg is indicated in certain instances, as an initial starting dose for specific indications, as well as for the elderly and/or debilitated, or patients with hepatic or renal impairment. In addition, the availability of this strength may aid in dosage adjustments. The Committee recommended that **DOM-PAROXETINE 10 mg tablet** be added to the *AHWDBL* as it provides a therapeutic advantage.

■ **APO-CALCITONIN** (synthetic calcitonin salmon (salcatonin)) (APX) 200 iu/dose metered nasal spray is a first-entry generic product that was deemed interchangeable with the innovator, MIACALCIN nasal spray. This product is priced 26% less than the innovator, and therefore, the addition of this product to the *AHWDBL* could offer potential savings of over $150,000 in the first year of listing. The Committee recommended this product be listed in the *AHWDBL*, subject to the same special authorization criteria applied to MIACALCIN nasal spray (please refer to the current *AHWDBL* for a full listing of special authorization criteria for **APO-CALCITONIN** nasal spray).

■ **PMS-MIRTAZAPINE** (mirtazapine) (PMS) 30 mg tablet was deemed interchangeable with the innovator, REMERON 30 mg. The Committee recommended that this first-entry generic product be added to the *AHWDBL* as it offers 26% savings over REMERON and anticipated savings of approximately $118,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

Highlights of Products Not Added

■ **HUMATROPE** (somatropin) (LIL) – The 24 mg/cartridge injection is a line extension of **HUMATROPE** 6 mg and 12 mg cartridges, which are currently listed via special authorization. The Committee examined the utilization trends of the strengths of **HUMATROPE** used in the population covered by Alberta Health and Wellness, and concluded that there did not appear to be a clinical need for the 24 mg cartridge at this time. Accordingly, the Committee indicated that this product should not be added to the *AHWDBL* as it fails to offer a therapeutic advantage.

■ **REMERON RD** (mirtazapine) (ORG) – This new orally disintegrating tablet is available in 15 mg, 30 mg & 45 mg strengths, as line extensions to the currently listed REMERON 30 mg tablet. While the concept of quick dissolve drug delivery is a novel approach in antidepressant therapy, the Committee questioned the need for an orally disintegrating tablet in the treatment of depression. In addition, the Committee noted that while **REMERON RD** is priced less than REMERON, greater potential savings may be realized with the listing of the current first-entry interchangeable product. Therefore, the Committee recommended that this product not be added as it fails to offer a therapeutic and/or cost advantage.

Enbrel for Polyarticular Juvenile Rheumatoid Arthritis

■ **ENBREL** (etancercept) (AMG) 25 mg/vial injection has received approval from the Therapeutic Products Directorate of Health Canada for use in active polyarticular Juvenile Rheumatoid Arthritis (JRA). The Expert Committee reviewed a request from the manufacturer to have this indication added to the current special authorization criteria for **ENBREL**. The Committee recognized that there is a role for this product in the treatment of such a severe illness. As a result, following consultation with Alberta specialists in Pediatric Rheumatology, the Committee recommended that **ENBREL** be covered for the treatment of polyarticular JRA, for those patients meeting the published special authorization criteria. As **ENBREL** is also currently covered via special authorization for the treatment of severely active Rheumatoid Arthritis, please refer to the current *AHWDBL* for a full listing of special authorization criteria for **ENBREL** and the applicable special authorization form.

Changes to Special Authorization Coverage of Select Products for the Treatment of Hepatitis C

With recent and ongoing advances in the treatment of chronic hepatitis C, and the availability of newer and more effective therapies such as the pegylated interferons, the Expert Committee has recommended the following changes to the special authorization coverage of specific products on the *AHWDBL*.

■ **INTRON A** (interferon alfa-2b) (SCH) and **ROFERON-A** (interferon alfa-2a) (HLR) – The special authorization criteria for these products has been revised to read: "For the treatment of chronic active hepatitis B."

■ **REBETRON** (interferon alfa-2b/ribavirin) (SCH) – The Expert Committee has recommended that this product be removed from the *AHWDBL*.

An adequate transition period will be allowed in order to provide those patients currently receiving coverage of the above products, for the treatment of chronic hepatitis C, with ample opportunity to finish their current course of therapy or to request special authorization coverage for alternative therapy. New requests for special authorization coverage of these products for the treatment of chronic hepatitis C can no longer be considered **effective July 1, 2004**.

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EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Braden Manns, MD, MSc, FRCPC
James L. Silvius, BA, MD, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:
Marilyn P. Thornton, BSc (Pharm), MSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Rhonda Shkrobot, BSc (Pharm)
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

Changes to Special Authorization Criteria for:

The Rationale Behind Special Authorization (SA)

ABC 81171 (04/2004)

Highlights of New Products Added

■ **COVERSYL** (perindopril erbumine) (SEV) – This 8 mg tablet is a line-extension of the currently listed 2 mg and 4 mg tablets. The Expert Committee indicated that **COVERSYL 8 mg** may be more convenient for patients taking a dose of 8 mg daily (i.e., patients may take only one tablet rather than 2 x 4 mg). In addition, it was noted that the 8 mg tablet provides a cost advantage, as it is less expensive than the cost of 2 x 4 mg tablets. Accordingly, the Committee recommended that this product be added to the *AHWDBL,* as it possesses a therapeutic and/or cost advantage.

■ **KEPPRA** (levitiracetam) (VLH), a new anti-epileptic drug (AED) and member of the pyrrolidine class, is chemically unrelated to existing AEDs. **KEPPRA** is indicated as adjunctive therapy in the management of patients with epilepsy who are not satisfactorily controlled by conventional therapy. Due to its different mechanism of action, Committee members indicated that this product may have a place in therapy for select patients who are refractory. Accordingly, the Committee recommended that **KEPPRA** be added to the *AHWDBL*, via the following special authorization criteria:

"For use in combination with other anti-epileptic medication(s) in the treatment of partial seizures in patients who are refractory to adequate trials of three anti-epileptic medications used either as monotherapy or in combination. This drug must be prescribed in consultation with a specialist in Neurology. Special authorization may be granted for 24 months."

■ **MAVIK** (trandolapril) (ABB) 4 mg capsule is an extension of the currently listed **MAVIK** line of products. The Committee noted that the longer half-life of this angiotensin converting enzyme inhibitor (ACEI) may offer a therapeutic advantage. The Committee also indicated that the availability of **MAVIK 4mg** may be advantageous as it makes it more convenient for patients to obtain a higher dose of drug. In addition, it was noted that this product provides a cost advantage, as the cost of one 4 mg capsule is less expensive than the cost of 2 x 2 mg capsules. Accordingly, the Committee recommended addition of **MAVIK 4mg** as it offers a therapeutic and/or cost advantage.

■ **RISPERDAL M-TAB** (risperidone) (JOI) – This new formulation is a quick-dissolve tablet, produced using freeze-drying technology that results in highly porous tablets, which rapidly disintegrate upon contact with saliva. The Committee indicated this product may offer a therapeutic advantage in select patient populations, and recommended that it be added to the *AHWDBL*. **RISPERDAL M-TAB** 0.5 mg, 1 mg and 2 mg orally disintegrating tablets were listed **effective February 1, 2004**.

Changes to Special Authorization Criteria for Drugs used in Alzheimer's Disease

■ **ARICEPT, EXELON & REMINYL** – The Committee indicated that physicians who have completed the Care of the Elderly Six-Month/One-Year Fellowship Program will be added to those physicians already deemed designated prescribers, as defined within the current special authorization criteria for these products. Please refer to the appropriate section of the *AHWDBL* for further details.

Changes to Special Authorization Criteria for Pegetron

■ **PEGETRON** (peginterferon alfa-2b/ ribavirin) (SCH) – After extensive consultation with Alberta specialists in Hepatology and Infectious Diseases, the Expert Committee has recommended several changes to the special authorization criteria for **PEGETRON**. Effective April 1, 2004, these changes will include, for example, the availability of **PEGETRON** for use in a select group of patients who have previously not responded to, or relapsed following, interferon monotherapy; or who have relapsed following combination therapy with non-pegylated interferon and ribavirin. Please refer to the current *AHWDBL* for a full listing of special authorization criteria for **PEGETRON**, and the applicable special authorization form.

Highlights of Interchangeable Products Added

■ **GEN-CITALOPRAM** (citalopram hydrobromide) (GPM) is a first-entry interchangeable product. The 10 mg and 20 mg tablets were deemed interchangeable with the innovator, CELEXA 10 mg and 20 mg tablets, respectively. The Committee recommended that these products be added to the *AHWDBL* as they offer 30% savings over the innovator products and anticipated savings of over $1,000,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. Furthermore, as these products met criteria for FAST-TRACK addition, they were added to the *AHWDBL* **effective February 1, 2004**.

■ **NOVO-FOSINOPRIL** (fosinopril sodium) (NOP) 10 mg and 20 mg tablets were deemed interchangeable with MONOPRIL 10 mg and 20 mg tablets, respectively. NOVO-FOSINOPRIL was added to the *AHWDBL* **effective February 1, 2004**, as it met criteria for FAST-TRACK addition by offering 30% savings over the innovator product and anticipated savings of approximately $925,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

Highlights of Products Not Added

■ **ALPHAGAN P** (brimonidine tartrate) (ALL) 0.15% ophthalmic solution is a line-extension to ALPHAGAN 0.2% ophthalmic solution. **ALPHAGAN P** contains Purite®, a novel preservative. The Committee recommended that this product not be added as it fails to offer a therapeutic and/or cost advantage over other presently accepted therapies available on the *AHWDBL*.

■ **TRILEPTAL** (oxcarbazepine) (NOV) is indicated for use as monotherapy or adjunctive therapy in the treatment of partial seizures in adults with epilepsy and as adjunctive therapy in the treatment of partial seizures in children ages 6 years and over with epilepsy. The Committee noted that this agent is structurally related to carbamazepine and possesses pharmacokinetic properties that may offer an advantage with respect to fewer drug interactions; however, they expressed the opinion that these potential advantages do not merit the higher cost of the agent. In addition, the Committee asserted that **TRILEPTAL** has not demonstrated a clear therapeutic advantage over currently available products on the *AHWDBL*. Accordingly, the Committee recommended that this product not be added as it fails to offer a therapeutic and/or cost advantage.

The Rationale Behind Special Authorization (SA)

A version of the following article first appeared in* The DBL Report*, Issue #9, October 1997.

Physicians, pharmacists and patients often question the rationale behind limiting the coverage of a drug to SA. Limiting of coverage of a product to SA according to specific criteria is done when there is a concern that the potential for inappropriate use of a product is high, when the cost impact to the drug program of an unrestricted listing is prohibitive or when there are safety considerations. If there is evidence that a specific subgroup of patients will benefit from a product, SA is a means to ensure access for those patients. The criteria for SA coverage of products are developed by the Expert Committee through consultation with specialists and the review of clinical practice guidelines and pharmacoeconomic evaluations that aid to identify subgroups of patients in which a product is cost-effective. Information from the physician may be required regarding previous medications, patient's response to therapy and parameters that have been monitored in order to properly evaluate the SA request for certain products. The recommendation to limit coverage of a product to SA is not made lightly as the process is resource intensive and administratively costly. In addition, while SA is often criticized for being somewhat cumbersome and bureaucratic, it may serve as a means by which physicians can pause and consider the appropriate use of the cost-effective therapies that are available.

the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:

Norman R.C. Campbell, BMed Sc, MD, FRCPC (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCPC
Braden Manns, MD, MSc, FRCPC
James L. Silvius, BA, MD, FRCPC

ALBERTA HEALTH AND WELLNESS LIAISON:

David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC 81171 (01/2004)

Highlights of Products Added via Special Authorization

■ **EZETROL** (ezetimibe) (MFC) is a new class of lipid lowering compounds that selectively inhibit the intestinal absorption of cholesterol and related plant sterols. The Committee indicated that the clinical evidence reviewed supports that **EZETROL** may be of benefit to reduce cholesterol in select groups of high-risk patients. Accordingly, the Committee recommended that **EZETROL** be added to the *AHWDBL*, via the following special authorization criteria:

"For the treatment of hypercholesterolemia in patients who are intolerant to statins or in whom a statin is contraindicated and who are at high cardiovascular risk as defined by possessing one of the following: 1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or 2) Diabetes, or 3) Familial hypercholesterolemia, or 4) Three or more of the following risk factors: Family history of premature cardiovascular disease, Smoking, Hypertension, Obesity, Glucose Intolerance, Renal disease. Special authorization for these criteria may be granted for 24 months."

"For the treatment of hypercholesterolemia when used in combination with a statin in patients failing to achieve target LDL (<2.5mmol/L) with a statin at maximum tolerable dose or maximum recommended dose as per respective product monograph and who are at high cardiovascular risk as defined by possessing one of the following: 1) Pre-existing cardiovascular disease and/or cerebrovascular disease, or 2) Diabetes, or 3) Familial hypercholesterolemia, or 4) Three or more of the following risk factors: Family history of premature cardiovascular disease, Smoking, Hypertension, Obesity, Glucose Intolerance, Renal disease. Special authorization for these criteria may be granted for 24 months."

■ **SPIRIVA** (tiotropium bromide monohydrate) (BOE) is a long-acting, broncho-selective anticholinergic agent indicated for the long term, once daily, maintenance treatment of bronchospasm associated with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema. The Committee noted that **SPIRIVA** reduces the number of severe COPD exacerbations, and indicated that it may reduce hospitalizations. Hence, the Committee recommended that **SPIRIVA** be added via special authorization with the following criteria for coverage: "For the treatment of patients with moderate to severe chronic obstructive pulmonary disease (COPD) with a forced expiratory volume in one second (FEV_1) less than or equal to 65% of the normal predicted value and with a forced expiratory volume in one second to forced vital capacity ratio (FEV_1/FVC) of less than or equal to 70% and for whom breathlessness persists despite an adequate trial of a short-acting beta-2 agonist and inhaled ipratropium. Special authorization for these criteria may be granted for 24 months."

Novo-Alendronate 10 mg tablets

■ **NOVO-ALENDRONATE** (alendronate sodium) (NOP) 10 mg tablet is a first-entry generic product deemed interchangeable with the innovator, FOSAMAX 10 mg. The Committee recommended this product be listed in the *AHWDBL*, subject to the same special authorization criteria applied to FOSAMAX 10 mg. **NOVO-ALENDRONATE** was added to the *AHWDBL* effective November 1, 2003. This product offers a 30% savings over the innovator, and with the application of the least cost alternative (LCA) pricing policy beginning January 1, 2004, could result in anticipated savings of over $1,000,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing.

Changes to Special Authorization Criteria for Actos

■ **ACTOS** (pioglitazone hydrochloride) (LIL) – Effective October 1, 2003, the special authorization criteria for **ACTOS** 15 mg, 30 mg and 45 mg tablets were revised to read: "For the treatment of Type 2 diabetes mellitus in patients who are not adequately controlled by optimum doses or who are intolerant to metformin or sulfonylureas, or for whom these products are contraindicated. Special authorization may be granted for 24 months." Information is required regarding previous medications utilized and the patient's response to therapy. Information is also required regarding the requested Actos dose and dosing frequency. Coverage may be considered for once-daily dosing only.

Highlights of Products Added

■ **APO-CARVEDILOL** (carvedilol) (APO) and **PMS-CARVEDILOL** (carvedilol) (PMS) 3.125 mg, 6.25 mg, 12.5 mg & 25 mg tablets were deemed interchangeable with the respective strengths of COREG. The Committee recommended that these products be added to the *AHWDBL* as they offer 33% savings over the innovator product and anticipated savings of approximately $522,000 to the Alberta Health and Wellness-sponsored drug programs in the first year of listing. These products were listed effective November 1, 2003, as they met criteria for FAST-TRACK addition to the *AHWDBL*.

■ **CO-SIMVASTATIN** (simvastatin) (COB) 5 mg, 10 mg, 20 mg, 40 mg & 80 mg tablets are subsequent-entry interchangeable products. **CO-SIMVASTATIN** was added to the *AHWDBL* in an interchangeable grouping with APO-SIMVASTATIN, GEN-SIMVASTATIN and ZOCOR, effective November 1, 2003, as it met the criteria for FAST-TRACK addition by offering greater than $500,000 per year in additional savings to government-sponsored programs over the currently listed least cost alternative (LCA) price.

■ **METADOL** (methadone hydrochloride) (PMS) 1 mg, 5 mg, 10 mg and 25 mg tablets are line extensions of the Pharmascience methadone product line. The Committee noted that methadone capsules are currently compounded by pharmacists, and that commercially available methadone tablets might offer a therapeutic alternative for management of severe pain. Furthermore, the Committee commented that cost of **METADOL** tablets is less expensive to within the price range of other presently accepted therapies available for the treatment of pain. Accordingly, the Committee recommended this product be added to the *AHWDBL* as it offers a cost and/or therapeutic advantage.

Highlights of Products Not Added

■ **CONCERTA** (methylphenidate hydrochloride) (JOI) 18 mg, 36 mg & 54 mg tablets are extended-release formulations of methylphenidate hydrochloride, indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD). The Committee noted that the clinical evidence reviewed appeared to support that **CONCERTA** provides similar therapeutic benefit to methylphenidate IR tablets. However, given both the clinical and economic information provided, the Committee questioned whether the addition of this agent would merit the incremental costs that would be incurred. Accordingly, the Committee recommended that this product not be listed in the *AHWDBL* as it fails to offer a therapeutic and/or cost advantage over presently accepted therapies.

■ **PENNSAID** (diclofenac sodium) (DHC) is a 1.5% w/w topical solution of diclofenac sodium in 45.5% dimethylsulfoxide (DMSO). **PENNSAID** is indicated for treatment of the symptoms associated with osteoarthritis of the knee(s) only, for a treatment regimen of not more than three months duration, whether continuous or intermittent. The Committee noted that the financial impact of listing appears to be sensitive to the dose of medication used. Given the squeeze bottle format and the potential for the use of this product on greater than one knee or other areas of the body, the Committee indicated that the addition of this product would likely be cost additive. Accordingly, the Committee recommended that this product not be added as it fails to offer a therapeutic and/or cost advantage over other products currently listed on the *AHWDBL*.

the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCP(C) (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCP(C)
Braden Manns, MD, MSc, FRCP(C)
James L. Silvius, BA, MD, FRCP(C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC81171 (07/2003)

Highlights of New Products Added

❦ **CRESTOR** (rosuvastatin calcium) (AZC) – is a new lipid-lowering agent. The Committee indicated that **CRESTOR** appeared to be at least as efficacious as other presently accepted therapies on the *AHWDBL*, and may be cost saving when compared to select agents. Hence, the Committee recommended that **CRESTOR** be listed as it may offer a cost and/or therapeutic advantage.

❦ **BIPREL** (perindopril erbumine/indapamide) (SEV) – is indicated in the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate. The Committee noted that the price of **BIPREL** is equivalent to the price of each of its components and there is the potential to realize incremental savings of one dispensing fee (i.e., if patients receive one prescription for **BIPREL** versus individual prescriptions for each component). In addition, the Committee indicated that the availability of such a fixed-dose combination product may offer a therapeutic advantage by improving patient compliance. Accordingly, the Committee recommended that **BIPREL** be listed as it offers a cost and/or therapeutic advantage.

❦ **ESTRADOT** (estradiol-17β) (NOV) – This 25 mcg/day transdermal patch is a lower dose formulation of the **ESTRADOT** line of products already listed on the *AHWDBL*. Although the addition of this product represents the addition of another estrogen product to the *AHWDBL*, the Committee has expressed their concern regarding the emerging safety issues associated with the use of estrogen-containing products. Accordingly, the Committee indicated that it is their opinion that clinicians should carefully weigh the risks and benefits when prescribing estrogen-containing products.

❦ **ARIXTRA** (fondaparinux sodium) (OSS) – is indicated for the prophylaxis of venous thromboembolic events (VTE) in patients undergoing orthopedic surgeries of the lower limbs such as hip fracture, knee surgery or hip replacement surgery. **ARIXTRA** was deferred from the October 2002 meeting pending the receipt and review of additional information from the manufacturer. After reviewing additional materials, the Committee recommended **ARIXTRA** be listed. Accordingly, **ARIXTRA** will be added to the *AHWDBL* effective **June 1, 2003**.

❦ **PMS-ATENOLOL** (atenolol) (PMS) – The 25 mg tablet is a line extension of the Pharmascience atenolol product line. The Committee recognized that the practice of splitting of tablets may be an issue for patients requiring low doses of this agent. The Committee concluded that, in this instance, the availability of a lower strength of atenolol may offer a therapeutic advantage by facilitating dosing in a population that may require lower doses (e.g., geriatric patients). Accordingly, the Committee recommended that this product be added to the *AHWDBL*.

Products Designated as Interchangeable

APO-LITHIUM CARBONATE (lithium carbonate) (APX) – Following a review of information demonstrating the bioequivalence of **APO-LITHIUM CARBONATE** and Lithane, the Expert Committee recommended that **APO-LITHIUM CARBONATE** be deemed interchangeable with Lithane. The Committee noted that **APO-LITHIUM CARBONATE** and Carbolith had been designated as interchangeable previously; however, no evidence has been provided to indicate whether Carbolith and Lithane are interchangeable. Accordingly, the Committee recommended that two separate interchangeable categories for Lithane and Carbolith should be created within the *AHWDBL* with **APO-LITHIUM CARBONATE** designated as interchangeable with both Carbolith and Lithane.

Alberta Post-Marketing Study for Enbrel and Remicade

In recommending the coverage of Enbrel and Remicade for patients with severely active Rheumatoid Arthritis, and Remicade for severe, active and fistulizing Crohn's Disease, the Expert Committee expressed concern about the lack of data on long term safety and effectiveness for these new agents. As a result of these concerns and in consultation with specialists in the respective areas, a study is being launched, supported by Amgen and Schering, to monitor and measure the long-term effects of these drugs. Patients and their physicians are therefore required to provide consent to participate in this study, as a condition for receiving coverage.

Highlights of Additional Strengths and Formulations of Products Available via Special Authorization

❦ **ACTONEL** (risedronate sodium) (PGA) – The Committee recommended that **ACTONEL 35 mg**, a once-weekly dosing formulation, be added via special authorization with criteria for coverage at parity with that of ACTONEL 5 mg tablets as it offers both a cost and therapeutic advantage. In addition, it should be noted that those patients with current special authorization approval for ACTONEL for the treatment of osteoporosis will not be required to submit new special authorization requests to receive coverage of **ACTONEL 35 mg** (i.e., such patients may switch to **ACTONEL 35 mg**, depending on the patient or physician preference of dosing regimen).

❦ **ANDRODERM** (testosterone) (PAL) – The 5 mg/day strength is a line extension of ANDRODERM 2.5 mg/day transdermal delivery system currently available via special authorization on the *AHWDBL*. As the recommended dosage of ANDRODERM is 5 mg/day, the Committee noted that the use of **ANDRODERM 5 mg/day** may be more convenient than the use of ANDRODERM 2.5 mg/day (i.e., the use of one patch instead of two) and therefore, may offer a therapeutic advantage. Accordingly, this product has been added subject to the same special authorization criteria as ANDRODERM 2.5 mg/day: "For the treatment of congenital and acquired primary and secondary hypogonadism. Coverage cannot be considered when used for the treatment of androgen decline in the aging male (ADAM). Special authorization may be granted for 12 months."

❦ **EXELON** (rivastigmine hydrogen tartrate) (NOV) – The 2 mg/mL oral solution is a line extension of the EXELON capsules, indicated for the symptomatic treatment of patients with mild to moderate dementia of the Alzheimer's type. The Committee felt that the availability of an oral solution may offer a therapeutic advantage in a small population of patients. Accordingly, **EXELON 2 mg/mL oral solution** has been added to the *AHWDBL* subject to the same special authorization criteria as EXELON 1.5 mg, 3 mg, 4.5 mg and 6 mg capsules.

Highlights of Deferred Products

❦ **KINERET** (anakinra) (AMG) – is a recombinant, non-glycosylated antagonist of the human interleukin-1 (IL-1) receptor, indicated to reduce the signs and symptoms of active rheumatoid arthritis (RA) in patients 18 years of age or older. The review of **KINERET** has been deferred pending the receipt and review of information generated by an external consultation process.

Highlights of Products Not Added

❦ **BEXTRA** (valdecoxib) (PFI) – was not recommended for addition as the Expert Committee concluded that it does not offer a cost and/or therapeutic advantage vis-à-vis other presently accepted therapies on the *AHWDBL*. The Committee indicated that the clinical information in the submission did not provide convincing evidence that this product offered a therapeutic advantage over other COX-II inhibitors currently listed on the *AHWDBL*. In addition, the Committee voiced concern that the addition of BEXTRA may serve to grow the COX-II inhibitor market inappropriately.

the DBL report

Issue #28, April 2003

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

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EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCP(C) (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCP(C)
Braden Manns, MD, MSc, FRCP(C)
James L. Silvius, BA, MD, FRCP(C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (04/2003)

Highlights of New Products Added

❦ **FXT 40** (fluoxetine hydrochloride) (ORY) – is a capsule that delivers 40mg of fluoxetine hydrochloride. This product was reportedly introduced to meet the needs of patients requiring 40 mg of fluoxetine daily. The manufacturer indicated that the use of **FXT 40** would facilitate patient dosing and would represent potential cost savings as the cost of **FXT 40** is less than that of a patient taking 2 x 20 mg capsules of fluoxetine. Accordingly, the Committee recommended that this product be added as it offers a cost advantage.

❦ **LUMIGAN** (bimatoprost) (ALL) – 0.03% ophthalmic solution is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension who are intolerant or insufficiently responsive to another intraocular pressure lowering medication. In their resubmission, the manufacturer provided additional clinical and economic data that asserted that this product offers both a therapeutic and economic advantage. After reviewing the information provided, the Committee indicated that **LUMIGAN** appeared to offer a therapeutic advantage over select therapies available on the AHWDBL. Accordingly, the Committee recommended that this product be added.

❦ **UNIDET** (tolterodine L-tartrate) (PHD) – A resubmission for the 2 mg and 4 mg extended release capsules was provided by the manufacturer for the Committee's consideration. In their resubmission, the manufacturer requested that the Committee consider delisting DETROL and placing **UNIDET** on the AHWDBL in its place. The Committee indicated that **UNIDET** appears to possess similar efficacy as DETROL, but may offer a therapeutic advantage due to its once daily dosing regimen. Accordingly, the Committee recommended that DETROL be delisted. In addition, the Committee recommended that **UNIDET** be made available via special authorization with criteria that read: "For patients who are intolerant to oxybutynin. Special authorization is granted for 24 months."

❦ **ZYPREXA** (olanzapine) (LIL) – This 15 mg tablet is an extension of the Zyprexa line of products that offers a dosage form for patients requiring a higher dosage of olanzapine. The Committee indicated that the addition of this strength to the AHWDBL may facilitate patient compliance by decreasing potential confusion associated with using different strengths of Zyprexa tablets to obtain a 15 mg dose. In addition, there is a potential to realize incremental savings via the removal of one dispensing fee, as patients are no longer required to obtain multiple prescriptions to achieve the 15 mg dose (i.e., 1 x 5 mg tablet plus 1 x 10 mg tablet).

Changes to the Benefit Status of Detrol

Effective April 1, 2003, **DETROL** will no longer be eligible for special authorization. In its place, UNIDET (tolterodine L-tartrate) extended-release capsules will be available via special authorization on the AHWDBL. To facilitate transition to UNIDET, all patients with existing special authorization for **DETROL** will continue to receive coverage of **DETROL** until September 30, 2003. Effective October 1, 2003, **DETROL** will no longer be an eligible benefit and will not be eligible for consideration through special authorization.

In addition, to facilitate transition of existing **DETROL** patients to UNIDET, patients with existing special authorization for **DETROL** automatically receive special authorization for UNIDET as of April 1, 2003.

Changes to the Special Authorization Criteria for Evista

The Committee received a request from the manufacturer to expand special authorization criteria for **EVISTA**. After giving due consideration to the evidence provided, the Committee indicated that the special authorization criteria for Evista be revised to include: "For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures."

Highlights of Deferred Products

- **ZOMETA** (zoledronic acid) (NOV) – The manufacturer submitted a request to change the special authorization criteria for this product to include its newly granted indication of treatment of bone metastases due to prostate cancer. The Committee indicated that further information was required from both Alberta specialists and the manufacturer regarding this product. Accordingly, the Committee recommended that any changes to the special authorization criteria of **ZOMETA** be deferred pending receipt and review of the requested information.

Highlights of Products Not Added

- **AMARYL** (glimepiride) (AVE) – 1 mg, 2 mg and 4 mg tablets were resubmitted by the manufacturer. The Committee gave due consideration to the information provided; however, the Committee maintained that the evidence provided in the resubmission does not support a therapeutic advantage commensurate with the increase in cost over available sulfonylureas on the AHWDBL. Accordingly, the Committee recommended that this product not be added as it fails to offer a cost and/or therapeutic advantage.
- **BENZAMYCIN** (erythromycin/benzoyl peroxide) (DER) - 30 mg/g and 50 mg/g topical gel is indicated for the topical treatment of Grade II to III acne. The Committee noted that the data provided did not appear to support a therapeutic or economic advantage over available alternatives on the AHWDBL. Accordingly, the Committee recommended that **BENZAMYCIN** not be added.
- **TARKA** (trandolapril/verapamil hydrochloride) (ABB) - is indicated for the treatment of mild to moderate essential hypertension in patients for whom combination therapy is appropriate. Since, according to utilization data, it appears that trandolapril (MAVIK) is not being used by patients within the Alberta Health and Wellness sponsored drug program, the current clinical need for **TARKA** is questionable in this population. Accordingly, the Committee recommended that this product not be added as it fails to offer a cost and/or therapeutic advantage over currently listed products on the AHWBDL.
- **XALACOM** (latanoprost/timolol) (PHD) – ophthalmic solution is a product intended to decrease intraocular pressure. **XALACOM** was not added to the AHWDBL as it fails to offer a cost and/or therapeutic advantage. Specifically, the Committee indicated that there was a lack of evidence provided in the submission demonstrating therapeutic advantage over other products currently available on the AHWDBL. Furthermore, the Committee expressed concern that the addition of this agent may present a potential negative cost impact if the addition of this agent serves to expand the market inappropriately.

Changes to the Special Authorization Criteria for Nitoman

In Fall 2002, the Committee received several requests from clinicians requesting that the special authorization criteria for **NITOMAN** be broadened to other specialists, as well as specialists practicing outside of Movement Disorder Clinics. After a consultation process involving Alberta Neurologists, the Committee indicated that the special authorization criteria for **NITOMAN** be changed to read: " For the treatment of hyperkinetic movement disorders when prescribed by specialists in Neurology, Psychiatry or Geriatric Medicine."

the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

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EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCP(C) (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCP(C)
Braden Manns, MD, MSc, FRCP(C)
Stephen C. Newman, MSc, MD, CCFP
James L. Silvius, BA, MD, FRCP(C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

ABC 81171 (R2002/12)

Highlights of New Products Added

❦ **ANDRODERM** (testosterone) (PAL) –is a transdermal testosterone delivery system that has been demonstrated to provide more physiological plasma levels of testosterone as compared to IM testosterone. The Committee noted that although such levels were not shown to translate into improved clinical outcomes, the availability of a transdermal testosterone formulation may be more palatable for patients than other available products offering some therapeutic advantage. As a result, it was recommended that **ANDRODERM** be added to the AHWDBL via special authorization with the following criteria for coverage: "For the treatment of congenital and acquired primary and secondary hypogonadism. Coverage will not be considered when used for the treatment of male andropause."

❦ **FOSAMAX 70 mg** (alendronate sodium) (MSD) – The Committee considered additional information supplied by the manufacturer regarding improved compliance and preference for the once weekly vs. once daily dosing regimen. In addition, the Committee was advised that the price of this product had been reduced to $8.85/tablet, thereby providing a 28% savings over the cost of treating patients with FOSAMAX 10 mg tablets daily. Accordingly, the Committee recommended that **FOSAMAX 70 mg** be added via special authorization with criteria for coverage at parity with that of FOSAMAX 10 mg tablets as it offers both a cost and therapeutic advantage. In addition, it should be noted that those patients with current special authorization approval for FOSAMAX for the treatment of osteoporosis will not be required to submit new special authorization requests to receive coverage for **FOSAMAX 70 mg** (i.e., such patients may switch to **FOSAMAX 70 mg**, depending on their preference of dosing regimen).

❦ **NOVORAPID** (insulin aspart) (NNA) – The Committee considered clinical information supporting that **NOVORAPID** is at least as effective as HUMALOG in reducing HgbA1c and has a favorable impact on post-prandial hyperglycemia. In addition, the Committee considered economic information indicating **NOVORAPID** 100 U/mL vials and 100 U/mL penfill cartridges are slightly less expensive than HUMALOG vials and cartridges. Hence, the Committee recommended that **NOVORAPID** vials and penfill cartridges be added to the AHWDBL as they offer some cost advantage vis-à-vis HUMALOG.

Changes to the Benefit Status of Andriol

The Committee recommended that **ANDRIOL** (testosterone undecanoate) (ORG) change to a special authorization benefit with the following criteria for coverage: "For the treatment of congenital and acquired primary and secondary hypogonadism. Coverage will not be considered when used for the treatment of male andropause." To provide patients who are currently receiving treatment with **ANDRIOL** with ample opportunity to request special authorization coverage via the AHWDBL, a three-month transition period has been recommended. Accordingly, **ANDRIOL** will change to a special authorization benefit effective April 1, 2003.

Highlights of Interchangeable Products Added

❦ **APO-LAMOTRIGINE** (lamotrigine) (APX) – The 25 mg, 100 mg and 150 mg strengths were deemed interchangeable with LAMICTAL 25 mg, 100 mg and 150 mg tablets, respectively. The Committee recommended that these products be added to the AHWDBL as they offer 32% savings over the innovator products and anticipated savings of approximately $93,000 to the Alberta Health and Wellness sponsored drug programs in the first year of listing.

❦ **RATIO- IPRA SAL UDV** (ipratropium bromide/salbutamol sulfate) (RPH) – inhalation solution is a first-entry interchangeable product that is cross-licensed with the innovator product, COMBIVENT. **RATIO-IPRA SAL UDV** was added to the AHWDBL on November 1, 2002 as it met criteria for FAST-TRACK addition by offering 30% savings over the innovator product and anticipated savings of approximately $428,000 to the Alberta Health and Wellness sponsored drug programs in the first year of listing.

❦ **RATIO-BRIMONIDINE** (brimonidine tartrate) (RPH) – 0.2% ophthalmic drops is a first-entry interchangeable product that is cross-licensed with the innovator product, ALPHAGAN. The Committee recommended that this product be added to the AHWDBL as it offers a 37.5% savings over ALPHAGAN and anticipated savings of approximately $143,000 to the Alberta Health and Wellness sponsored drug programs in the first year of listing.

Highlights of Deferred Products

❦ **ARIXTRA** (fondaparinux sodium) (ORG) - is the first product in a new class of antithrombotic agents which is a selective, indirect inhibitor of factor Xa. During their review of the submission, the Committee noted that while **ARIXTRA** may be effective in the prophylaxis of asymptomatic deep vein thrombosis (DVT), it does not appear to be as effective for prophylaxis of symptomatic DVT and appears to have an increased bleeding risk. In addition, the Committee indicated that **ARIXTRA** is not economically attractive when compared to either FRAGMIN or INNOHEP, which appear to be the products predominantly used by AHWDBL beneficiaries. Accordingly, the Committee recommended that this product be deferred pending the receipt and review of additional information from the manufacturer pertaining to clinical and economic comparisons with agents commonly used in Alberta.

❦ **PEGETRON** (ribavirin/peginterferon alfa-2b) (SCH) – is indicated for the treatment of adult patients with histologically proven chronic hepatitis C who have elevated transaminases without liver decompensation and who are positive for HCV-RNA or anti-HCV. The Committee acknowledged that the once weekly dosing of **PEGETRON** may impact on patient compliance and, in turn, improve patient outcomes. However, the Committee questioned the dose equivalencies between **PEGETRON** and REBETRON and how these translate into the cost differences between agents. In addition, the Committee had several questions surrounding the potential use of **PEGETRON** in clinical practice. Hence, the Committee recommended that this product be deferred pending the receipt and review of additional information from the manufacturer and Alberta hepatologists.

Highlights of Products Not Added

❦ **THYROGEN** (thyrotropin alfa) (GZM) – is indicated as an adjunctive tool for serum thyroglobulin (Tg) testing with or without radioactive imaging in the follow-up of patients with well-differentiated thyroid cancer. The Committee noted that this agent is used as a component of diagnostic testing and diagnostic testing aids are generally not considered for potential funding on the AHWDBL. Furthermore, based on the clinical data provided and as per the **THYROGEN** product monograph, withdrawal of thyroid hormone therapy prior to Tg testing achieves superior results and thus, remains the standard of care. While the manufacturer asserted that the use of **THYROGEN** in place of withdrawal of thyroid therapy would result in a positive impact on patient quality of life, no data was provided to support this assertion. Therefore, the Committee recommended that this product not be added to the AHWDBL as it fails to offer a cost or therapeutic advantage.

❦ **XATRAL** (alfuzosin hydrochloride) (WIN) - The Committee considered a resubmission from the manufacturer for the coverage of the 10 mg tablets on the AHWDBL. The Committee advised that no additional information had been provided which would clearly delineate a therapeutic advantage of **XATRAL** over other currently available alternatives on the AHWDBL. Accordingly, the Committee elected to uphold their previous recommendation not to list **XATRAL** on the AHWDBL as it fails to offer a therapeutic advantage.

the DBL report

UPDATE

Issue #26, October 2002

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCP(C) (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCP(C)
Braden Manns, MD, MSc, FRCP(C)
Stephen C. Newman, MSc, MD, CCFP
James L. Silvius, BA, MD, FRCP(C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

ABC 81171 Update (R2002/10)

❦ **FLOVENT HFA** (fluticasone propionate) 125 mcg/dose and 250 mcg/dose MDIs were added to the AHWDBL as unrestricted benefits effective October 1, 2002. As well, **FLOVENT HFA** 50 mcg/dose was also made available via special authorization with the following criteria for coverage: "For the prophylactic management of steroid-responsive bronchial asthma in patients who are unable to use the Turbuhaler® form of budesonide." The transition from **FLOVENT** (CFC) MDIs to **FLOVENT HFA** MDIs, is in keeping with the Environment Canada national transition strategy (as per the Montreal Protocol) to phase-out the use of ozone-depleting substances such as CFCs in MDIs.

In making their recommendation to add **FLOVENT HFA** MDI to the AHWDBL, the Expert Committee considered a number of comparability studies assessing safety and efficacy of **FLOVENT** (CFC) vs. **FLOVENT HFA** MDIs. It should be noted that **FLOVENT HFA** MDIs have not been designated as interchangeable with **FLOVENT** (CFC) MDIs and the committee expressed concern that there is the potential for patients to experience differences in asthma control following a switch in products.

As a result, the Committee feels it is important that asthma control and adverse reactions be re-assessed by the physician when switching from **FLOVENT** (CFC) to **FLOVENT HFA** MDIs and is encouraging health care professionals to be advised of potential differences between the **FLOVENT** (CFC) and **FLOVENT HFA** formulations (as per the 'Dear Healthcare Professional' letter sent out by GlaxoSmithKline Inc).

the DBL report

Issue #25, October 2002

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCP(C) (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCP(C)
Braden Manns, MD, MSc, FRCP(C)
Stephen C. Newman, MSc, MD, CCFP
James L. Silvius, BA, MD, FRCP(C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of:

Devices Added to the AHWDBL as Restricted Benefits

Highlights of New Products Added

❦ **GLUCAGON** (glucagon rDNA origin) (LIL) – is a product intended to replace Glucagon (animal source) that was recently discontinued by the manufacturer. The Committee noted that the cost of recombinant **GLUCAGON** was significantly higher than that of the animal source product. However, with no alternative product currently available on the market for the emergency treatment of severe hypoglycemia, the Committee reluctantly agreed that the recombinant form of **GLUCAGON** be added to the AHWDBL despite the substantive cost disparity compared to animal-source Glucagon.

❦ **PARIET** (rabeprazole sodium) (JOI) – the 10mg and 20mg tablet formulations of this new proton pump inhibitor (PPI) were submitted for consideration. Following the Committee's review of the evidence provided, it was noted that there are no therapeutic advantages of **PARIET** vis-à-vis other PPIs currently listed on the AHWDBL; therefore, cost became the primary consideration in making a recommendation. As a result, the Committee recommended that only **PARIET 10 mg** should be added to the AHWDBL as it provided the most attractive cost savings. Specifically, **PARIET 10 mg** is priced at $0.65/tablet (or $1.30/2 x 10mg tablets), hence it is less expensive than Pariet 20mg priced at $1.90/tablet, as well as other PPIs currently listed on the AHWDBL.

❦ **VALCYTE** (valganciclovir HCl) (HLR) – 450mg tablets are indicated for the treatment of cytomegalovirus retinitis in patients with acquired immunodeficiency syndrome (AIDS). **VALCYTE** is a prodrug of ganciclovir, which is available on the AHWDBL as Cytovene in both an oral and IV formulation. Cytovene has a low oral bioavailability; therefore, the IV formulation is commonly used for both the induction and maintenance phases of treatment. Clinical studies showed that **VALCYTE** and Cytovene are comparable in terms of satisfactory patient responses. Therefore, the Committee recommended that **VALCYTE** be added via **Special Authorization** with the following criteria for coverage: "For the treatment of cytomegalovirus (CMV) retinitis in patients with acquired immunodeficiency syndrome (AIDS)."

Highlights of Deferred Products

❦ **DEXIRON** (iron dextran) (Luitpold) and **INFUFER** (iron dextran) (SAB) – are indicated for the treatment of iron deficiency in patients with documented iron deficiency in whom oral administration is unsatisfactory or impossible. The Committee acknowledged that these products are intended to replace the product, Jectofer, which has been discontinued by the manufacturer. The Committee expressed concern regarding the lack of data provided in iron deficient, but otherwise healthy individuals. In addition, it was noted that no pharmacokinetic data following intramuscular (IM) administration nor data to support IM use was provided in either of the submissions. Therefore, the Committee indicated that they required additional information prior to making a recommendation regarding the potential coverage of **DEXIRON** and **INFUFER** and recommended that these products be deferred pending the receipt and review of additional information from the respective manufacturers.

Devices Added to the AHWDBL as Restricted Benefits

- **PRIMEAIRE** (Methapharm) - is a portable, reusable, dual-valved holding device to be used with most metered dose inhalers. Evidence provided by the manufacturer indicates that drug delivery is improved when the spacing device is utilized as compared to the metered dose inhaler alone. The Committee noted that the price of this product is within the range of prices of spacing devices currently listed on the AWHDBL. Accordingly, the Committee recommended that **PRIMEAIRE** be granted a similar listing status. Hence, it was recommended that this product be made available as a **Restricted Benefit** with the following criteria for coverage: "Coverage is limited to one aerosol holding chamber per plan participant per year."

- **FACIAL MASKS FOR USE WITH PRIMEAIRE** (Methapharm) – There are four sizes of facial masks (pediatric, small, medium, large-adult) that are intended for use with the PrimeAire spacing device. As PrimeAire was recommended for addition to the AHWDBL, the **FACIAL MASKS** were recommended for addition as a **Restricted Benefit** with the following criteria for coverage: "Coverage is limited to one of each size (infant, pediatric, adult) aerosol holding chamber mask or chamber with mask per plan participant per year."

Highlights of Products Not Added

- **AMARYL** (glimepiride) (AVE) – 1 mg, 2 mg and 4 mg tablets were not recommended for addition to the AHWDBL, as they did not offer a cost and/or therapeutic advantage. Although **AMARYL** appeared unique in that it offered once daily dosing, the clinical evidence provided did not support a therapeutic advantage commensurate with the increased cost over sulfonylureas already available on the AHWDBL (e.g., glyburide, gliclazide).

- **ANDROGEL** (testosterone USP) (SLO) - 2.5 g/packet and 5 g/packet were not recommended for addition to the AHWDBL as they failed to offer a cost and/or therapeutic advantage. The Committee noted that there were no data provided to support effects on the symptoms of hypogonadism nor were there any data comparing **ANDROGEL** to Andriol or injectable testosterone. Furthermore, the Committee indicated that the cost of **ANDROGEL** was higher than that of Andriol and injectable testosterone. Hence, the Committee advised that insufficient evidence had been provided to support a therapeutic or economic benefit of **ANDROGEL** vis-à-vis other testosterone products currently listed on the AHWDBL.

- **DOVOBET** (calcipotriol & betamethasone dipropionate) (LEO) – the 50mcg/g & 0.5mg/g ointment was not recommended for addition as it does not offer a cost and/or therapeutic advantage. In making this recommendation, the Committee expressed concern that a fixed combination product such as **DOVOBET** does not allow for the titration of the steroid component. Specifically, the Committee noted that often patients with psoriasis use calcipotriol on a continuous basis and may alter their use of different steroids as needed (e.g., depending on severity, body area, etc). The use of **DOVOBET** may result in the continuous application of a potent steroid when it is not indicated. Furthermore, it was noted that the cost savings predicted by the manufacturer are largely based on the assumption that **DOVOBET** would be used once daily. Given that the individual components of this product are used twice daily, the Committee was skeptical that patients would alter their use of such agents to a once daily application.

- **LUMIGAN** (bimatoprost) (ALL) - 0.03% ophthalmic solution is indicated for the reduction of elevated intraocular pressure in patients with open angle glaucoma or ocular hypertension who are intolerant or insufficiently responsive to another intraocular pressure lowering medication. Due to discrepancies in the data reported within the submission that could not be explained, the Committee advised that it could not be determined whether **LUMIGAN** had any therapeutic advantages over products currently listed on the AHWDBL. In addition, the Committee noted **LUMIGAN** was priced similarly to Xalatan ($0.31/drop vs. $0.32/drop, respectively) but was more expensive than Travatan ($0.24/drop). Accordingly, the Committee recommended that **LUMIGAN** not be added to the AHWDBL, as it fails to offer a cost and/or therapeutic advantage.

- **STARLIX** (nateglinide) (NOV) – 60 mg, 120 mg and 180 mg tablets are short-acting insulin secretagogues indicated for monotherapy and in combination with metformin to lower blood sugar in patients with Type 2 diabetes mellitus. Based on the data provided, the Committee noted that **STARLIX** is comparable to Gluconorm (repaglinide). In addition, the Committee indicated that head to head studies comparing the two agents would have been useful to ascertain the clinical significance of the reported differences in pharmacokinetics between these two agents. Although the Committee found the pricing of **STARLIX** to be favorable (identical price for each tablet regardless of strength), they indicated that the addition of **STARLIX** would not merit the projected incremental costs that would be incurred. Hence, the Committee recommended that **STARLIX** not be added to the AHWDBL as it failed to offer a cost and/or therapeutic advantage.

the DBL report

Issue #24, July 2002

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
Norman R.C. Campbell, BMed Sc, MD, FRCP(C) (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCP(C)
Braden Manns, MD, MSc, FRCP(C)
Stephen C. Newman, MSc, MD, CCFP
James L. Silvius, BA, MD, FRCP(C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

ABC 81171 (R2002/07)

Highlights of New Products Added

❦ **PROTOPIC** (tacrolimus) (TBB) – is a topical immunomodulator approved for the treatment of atopic dermatitis when conventional agents (e.g. steroids) cannot be used. This product was recommended for addition via special authorization following consultation with Alberta Dermatologists. As a result, the following criteria for coverage apply for **PROTOPIC 0.03%** ointment:

- For use in patients 2 to 15 years of age inclusive with atopic dermatitis who are unable to tolerate or have failed topical steroid therapy.
- For use in patients 2 to 15 years of age with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids.
- For use in patients 16 years of age and older with atopic dermatitis affecting face and flexures who are unable to tolerate or have failed topical steroid therapy.
- For use in patients 16 years of age and older with atopic dermatitis who require ongoing use of potent (Class 3 or higher) topical steroids over greater than 30% of body surface area.

Please note that coverage for **PROTOPIC 0.1%** ointment will be made available only for adult patients meeting the last two criteria.

❦ **SYMBICORT** (budesonide/formoterol fumarate dihydrate) (AZC) – 100 mcg/6 mcg and 200 mcg/6 mcg Turbuhalers are CFC-free, dry powder combination products for use as maintenance therapy in asthmatic patients 12 years of age and older, and for whom such combination therapy is warranted. The Expert Committee is of the view that in the case of all combination products, patients should first be stabilized on the individual components administered separately. However, the Committee acknowledged that it may be appropriate, once patients are thus stabilized, to be administered a combination product such as **SYMBICORT** and so recommended that it be listed as a **Restricted Benefit** on the AHWDBL according to the following criteria: "For patients 12 years of age and older for the maintenance treatment of asthma where use of a combination product is appropriate".

Highlights of Deferred Products

❦ **FOSAMAX** (alendronate sodium) (MFC) – 70mg tablet is administered once weekly for the treatment and prevention of osteoporosis in postmenopausal women. The Committee expressed concern that a weekly dosage form may create compliance issues. For example, an elderly population may neglect to take an entire week's dose thereby resulting in a lack of efficacy. Alternatively, they may forget that they have taken a dose and cause an increase in toxicity. As a result, the Committee recommended that this product be deferred pending the receipt and review of information from the manufacturer that directly compares patient compliance with **FOSAMAX** 70mg once weekly and Fosamax 10mg daily.

UPDATE: Status of TNF-Antagonists

❦ RHEUMATOID ARTHRITIS – DEFERRED

ENBREL (etanercept) (WAY) and **REMICADE** (infliximab) (SCH) continue to be under review for coverage in the treatment of Rheumatoid Arthritis (RA). Prior to making a recommendation for coverage for this indication, the Expert Committee identified the need for an accurate assessment of the cost-effectiveness of TNF-antagonists for the treatment of RA. Therefore, further discussion has been deferred pending the availability of the Canadian Coordinating Office of Health Technology Assessment (CCOHTA) evaluation of these agents in the treatment of RA.

❦ CROHN'S DISEASE/ FISTULIZING CROHN'S DISEASE – NOT ADDED

The Expert Committee also deliberated on the use of **REMICADE** for the treatment of Crohn's Disease (CD) and Fistulizing CD. Information received from the manufacturer and following consultation with Alberta Gastroenterologists was reviewed as was the recently published CCOHTA evaluation of the use of **REMICADE** in CD and Fistulizing CD in detail. While the Expert Committee acknowledged that **REMICADE** may provide clinical benefit for treatment-resistant CD, the cost per quality-adjusted life year gained (QALY) is much higher than generally accepted therapies currently funded through the drug program. Hence, given the magnitude of the cost/QALY gained, continuing concerns relating to toxicity and lack of long-term outcome data, the Expert Committee has advised that the degree of clinical benefit expected from **REMICADE** for these indications does not justify the substantive expenditure of public funds required. As a result, it was recommended that **REMICADE** not be added to the AHWDBL for treatment of CD or Fistulizing CD.

Highlights of Products Not Added

❦ **DITROPAN XL** (oxybutynin chloride) (JOI) – 5 mg and 10 mg tablets were not recommended for addition to the AHWDBL, as they did not offer a therapeutic or cost advantage. In the resubmission, the manufacturer's position is that due to the unique drug delivery system, patients using **DITROPAN XL** experience less adverse events (e.g., dry mouth and cognitive impairment) than do patients using immediate release oxybutynin. The Committee advised that the incidence of adverse events associated with immediate release oxybutynin is likely related to the use of excessively high doses of oxybutynin that are used in the elderly and may be effectively dealt with by more comprehensive individualization of dosage in some elderly patients.

❦ **MERIDIA** (sibutramine hydrochloride monohydrate) (ABB) and **XENICAL** (orlistat) (HLR) were not recommended for addition to the AHWDBL. With regard to **MERIDIA**, the Committee referenced the March 2002 Health Canada Advisory that advised that a safety review of this product is currently being undertaken and that other countries have identified safety concerns which have led to suspension of sales of **MERIDIA** in one instance. The Committee advised that with evidence of benefit of only short-term weight loss, lack of cardiovascular outcome or morbidity/mortality data, and emerging safety concerns, the risk/benefit ratio of the drug should be re-examined.

Due to approval of a new indication for concomitant use with antidiabetic agents in overweight or obese Type 2 diabetics, **XENICAL** was resubmitted for the Expert Committee's consideration. While it was acknowledged that **XENICAL** appears to be efficacious in decreasing weight, which, in turn, may improve glycemic control, the Committee questioned the product's effectiveness and cost-effectiveness in comparison to alternative agents used in the management of Type 2 diabetes. When the magnitude of glycemic control induced with **XENICAL** was compared with that of other agents (i.e., thiazoledinediones) and the potential for use as add-on therapy considered, it was apparent that **XENICAL** could be cost additive without providing substantive clinical benefit over the long-term. Hence, **XENICAL** was not recommended for addition to the AHWDBL, as it does not offer a cost advantage and/or therapeutic advantage.

❦ **NEXIUM** (esomeprazole magnesium trihydrate) (AZC) 20 mg and 40 mg tablets were resubmitted for consideration. The Committee noted that while it has been shown that **NEXIUM** shows statistically significant advantages vis-à-vis omeprazole in some clinical trial endpoints, much of the data reported no clinically significant differences. In addition, the committee cautioned that such results must be considered in the context of the relative dose equivalencies of the two compounds. It is noteworthy to consider that in studies where 40 mg of **NEXIUM** are compared with 20 mg of omeprazole, it is expected that the results would indicate that **NEXIUM** is clinically superior given that patients receiving **NEXIUM** 40mg are essentially being administered a 2-fold higher dose of drug. Hence, the Committee recommended that **NEXIUM** not be added to the AHWDBL, as it fails to offer a cost and/or therapeutic advantage.

❦ **RENAGEL** (sevelamer hydrochloride) (GZM) – 400 mg and 800 mg tablets were not recommended for addition to the AHWDBL. The Committee's rationale for not recommending coverage was that there was no direct evidence provided substantiating a clear linkage between the progression of soft-tissue calcification and mortality and morbidity in patients with end-stage renal disease (ESRD). Despite the fact that patients with ESRD have a high propensity for cardiovascular disease, **RENAGEL** treatment has not been shown to have an effect on mortality and/or morbidity endpoints. If such data were available, then the high cost of the product, in comparison to treatment alternatives, could potentially be justified.

the AHWDBL report

Issue #23, April 2002

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:

Norman R.C. Campbell, BMed Sc, MD, FRCP(C) (Chair)
Judith M. Baker, BSc (Pharm), MSc, PhD
Erwin G. Friesen, BSc (Pharm), PharmD, FCSHP
Robert J. Herman, MD, FRCP(C)
Braden Manns, MD, MSc, FRCP(C)
Stephen C. Newman, MSc, MD, CCFP
James L. Silvius, BA, MD, FRCP(C)

ALBERTA HEALTH AND WELLNESS LIAISON:

David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:

Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume-Smith, BSc (Pharm), MSc, PhD

In this issue:

Highlights of New Products Added

■ **TRAVATAN** (travoprost) (ALC) – is a prostaglandin analogue indicated for the reduction of intraocular pressure in patients who are intolerant or insufficiently responsive to another intraocular pressure lowering medication. This product has the potential to be cost saving due to the lower cost/drop for TRAVATAN vs. **XALATAN**, another prostaglandin analogue listed on the AHWDBL. XALATAN must be refrigerated until dispensing and discarded 42 days after opening, whereas TRAVATAN does not have the same storage limitations. Accordingly, TRAVATAN may offer a convenient alternative for a patient that, depending on patient dosing, also offers additional cost savings.

■ **METADOL-D** (methadone hydrochloride) (PMS) – is indicated for the detoxification, treatment and maintenance of opioid addiction. The manufacturer has introduced METADOL-D in an effort to clearly differentiate between their methadone products when used for the indications of opioid dependence and analgesia. **METADOL**, an identical product that is intended for the analgesia indication, is currently a benefit on the AHWDBL. As a result, the ECDET recommended that METADOL-D be listed on AHWDBL in an interchangeable grouping with METADOL.

■ **ROSASOL** (metronidazole cream) (STI) – 1% cream has been added to the AHWDBL as an unrestricted listing. This product is indicated for the treatment of inflammatory lesions, erythema and telangectasia associated with rosacea. The addition of ROSASOL may present a slight cost advantage as it is priced equivalently or slightly less than other metronidazole topical preparations that are listed on the AHWDBL.

UPDATE: Removal of the LCA Policy from Methotrexate Sodium 25mg/mL Preserved and Unpreserved Injectable Products on the AHWDBL

Following the receipt of substantial input from health care providers and patients requesting that LCA not be applied to preserved and unpreserved injectable methotrexate products, the ECDET reconsidered their recommendation to reinstate LCA for these products. Concerns stemmed from the potential for increased product wastage and cost to the patient as a result of having to discard unused portions of the unpreserved product, which is the current LCA. After considering all input, the customary doses used in rheumatoid arthritis and the relative costs of each agent vis-à-vis anticipated program savings, the ECDET recommended that LCA be removed from the interchangeable grouping of methotrexate sodium 25mg/mL preserved and unpreserved injection products on the AHWDBL.

Highlights of Products Not Added

■ **FUCITHALMIC** (fusidic acid) (LEO) – 1% viscous eye drops (available with and without preservative) were not recommended for addition to the AHWDBL, as they did not offer a therapeutic or cost advantage. These ophthalmic preparations are indicated for the treatment of superficial eye infections caused by fusidic acid susceptible strains of bacteria. It was noted that conjunctivitis is usually a self-limiting condition; therefore, it is generally treated empirically and broad-spectrum antibiotics are often preferred. The ECDET expressed concern about the potential for treatment failure if a gram-negative organism is the causative agent. In addition, it was taken into consideration that there are several agents available on the AHWDBL that provide a broader spectrum of coverage than FUCITHALMIC**.**

■ **STARNOC** (zaleplon) (SEV) – is a non-benzodiazepine hypnotic that is intended for the short-term treatment and symptomatic relief of insomnia in patients who have difficulty falling asleep. This product was not recommended for addition to the AHWDBL as it failed to offer a cost or therapeutic advantage. Only a limited number of clinical studies were conducted in the elderly (>65 years); therefore, the results may not be generalizable to the population covered by the Alberta Health and Wellness seniors' drug program. Finally, given that STARNOC is considerably more expensive than other hypnotics, its addition to the AHWDBL would increase costs without providing significant therapeutic advantage.

Highlights of Changes to SA Criteria

■ **DOSTINEX** (cabergoline) (PHD) –The special authorization (SA) criteria for this product were revised to read: "For the treatment of hyperprolactinemia in patients who are intolerant to or who have failed bromocriptine." This change results in the removal of the restriction to physician specialty that could request coverage for DOSTINEX. The ECDET recommended this change in recognition of the fact that a variety of physicians treat individuals with hyperprolactinemia.

■ **RILUTEK** (riluzole) (AVE) –The SA criteria will now read: "For use in patients who have probable or definite Amyotrophic Lateral Sclerosis (ALS) as defined by the World Federation of Neurology (WFN) criteria, who have a vital capacity of >60% predicted and do not have a tracheostomy for invasive ventilation. This drug must be prescribed by a physician in the ALS Consortium." These changes result in differentiation between those patients who have a tracheostomy for the purpose of airway protection vs. those patients who require invasive ventilation. The clarification of SA criteria resulted from consultations with physicians in the ALS Consortium who advised that there was little data to support that patients received clinical benefit from RILUTEK once they required invasive ventilation.

Highlights of Deferred Products

■ **ENBREL** (etanercept) (WAY) and **REMICADE** (infliximab) (SCH) – continue to be considered in an ongoing review. As these products represent an unprecedented approach to the treatment of inflammatory disease, the ECDET has elected to conduct a class review that has entailed consultation with Alberta gastroenterologists and rheumatologists, the manufacturers, Health Canada and other provinces. The ECDET continues to deliberate and at the present time they are awaiting additional information requested through the consultation process.

■ **PROTOPIC** (tacrolimus) (TBB) – 0.03% and 0.1% ointments are indicated for short and long term intermittent treatment of patients with moderate to severe atopic dermatitis (AD) in whom conventional therapies are deemed inadvisable, or who are not adequately responsive to or intolerant of conventional therapies. Prior to making a recommendation, the ECDET deemed that consultation with Alberta Dermatologists would be prudent.

■ **RENAGEL** (sevelamer hydrochloride) (GZM) – 403 mg capsule is indicated for the control of hyperphosphatemia in patients with end stage renal disease on hemodialysis. The ECDET was advised that the manufacturer intends to replace the capsule formulation with a 400 mg and 800 mg tablet. As new clinical data will be presented by the manufacturer in the tablet submission, the ECDET opted to defer discussion pending the review of the new submission for the tablet formulation.

the DBL report

Issue #22, January 2002

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
Norman R.C. Campbell, BMed Sc, M.D., FRCP (C)
William F. Dryden, BSc (Pharm), PhD ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James L. Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume, BSc (Pharm), MSc

In this issue:

Highlights of the Review of SA Drugs Used in the Treatment of Osteoporosis

As part of its ongoing consideration of new evidence, the ECDET completed a comprehensive review of drugs available via special authorization (SA) that are used in the treatment of osteoporosis. The special authorization criteria for coverage of alendronate and risedronate for those patients who have experienced a fracture has been changed as follows:

> "For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. Special authorization for this criteria is granted for 24 months."

The change in criteria resulted from consideration of physician input and published clinical data that supports that treatment with alendronate over a 7-year period leads to a progressive increase in bone mineral density over and above that experienced in the first 12-months of therapy. In addition, the ECDET emphasized that **ACTONEL**, **EVISTA**, **FOSAMAX** and **MIACALCIN** are not indicated for use in combination and that such special authorization requests will be denied.

Highlights of New Products Added

■ **COMTAN** (entacapone) (NOV) is indicated as an adjunct to levodopa/carbidopa or levodopa/benserazide preparations to treat patients with idiopathic Parkinson's Disease who experience the signs and symptoms of end-of-dose "wearing-off." COMTAN is a specific, reversible inhibitor of catechol-o-methyltransferase (COMT) that does not appear to possess the hepatic toxicity associated with **TASMAR** (tolcapone), another medication within this class. In light of the availability of COMTAN, TASMAR will be delisted. As of April 1, 2002, patients currently on TASMAR will no longer be able to receive coverage for this drug.

■ **ZYVOXAM** (linezolid) (PHD) - the 600 mg oral tablet was recommended for coverage via SA with criteria that reads: "For the treatment of vancomycin resistant Enterococcus Infections. For the treatment of methacillin-resistant Staphylococcus aureus (MRSA)/methacillin-resistant Staphylococcus epidermidis (MRSE) infections in patients who are unresponsive to, or intolerant of, vancomycin. The SA criteria require that this drug be prescribed in consultation with a specialist in Infectious Diseases." The ECDET identified ZYVOXAM as a "high priority" drug and therefore, every attempt will be made to deal with requests for this medication via the SA process within one working day of the request being received by Alberta Blue Cross.

continued on reverse

Highlights of Products Not Added

■ **DIAMICRON MR** (gliclazide) (SEV) – the 30 mg modified release tablet was not recommended for addition to the AHWDBL. This modified release formulation mimics the circadian glycemic profile of patients with type 2 diabetes and requires once daily dosing. Despite these changes to the original formulation, clinical evidence showed no improvements in glycemic control compared to patients receiving regular-release (RR) gliclazide. Gliclazide RR is available as an unrestricted benefit on the AHWDBL.

■ **NEXIUM** (esomeprazole magnesium trihydrate) (AZC) – this product is the single S-enantiomer of **LOSEC** (omeprazole), which is a racemate or a 50:50 mixture of R- and S- enantiomers. The ECDET considered studies that compared 40 mg and 20 mg doses of esomeprazole with 20 mg doses of omeprazole. These studies failed to show any significant differences between **NEXIUM** and **LOSEC** on many measures of healing, resolution of symptoms and maintenance therapy of reflux esophagitis, acute and long-term treatment of GERD and the eradication of H. pylori infection when used in a regimen with clarithromycin and amoxicillin. The results are surprising given that patients in the **NEXIUM** arms of the trials received more active drug than those who received **LOSEC** (i.e., a higher dose of the S-enantiomer was used which also has greater bioavailability than the R-enantiomer)

Highlights of Changes to SA Criteria

■ **EPREX** (epoetin alfa) (JOI) – The SA criteria for this product were revised to facilitate the screening of SA requests. Specifically, the criteria have been changed to reflect the Therapeutic Products Directorate approved indication for EPREX. The SA criteria for coverage will now read: "For the treatment of anemia of nonmyeloid malignancies in patients with low hemoglobin (<100g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20g/L per month, the dose of EPREX should be reduced by about 25%. If hemoglobin exceeds 120g/L, therapy should be discontinued until hemoglobin falls below 100g/L, at which time EPREX should be reinstituted at a dose 25% below the previous dose." If the patient has iron overload the physician must state this in the request or alternatively, information is required regarding the patient's transferrin saturation, along with the results of liver function tests if applicable.

■ **RILUTEK** (riluzole) (AVE) – This product was added via SA effective October 1, 2001. At their October meeting, the ECDET recommended that the SA criteria be altered to remove the age restrictions and duration of illness in the original criteria in an effort to ensure that Albertans suffering from ALS have appropriate access to this drug. The criteria will now read: "For use in patients who have probable or definite Amyotrophic Lateral Sclerosis (ALS) as defined by the World Federation of Neurology (WFN) criteria, who have a vital capacity of >60% predicted and do not have a tracheostomy. This drug must be prescribed by a physician in the ALS Consortium." RILUTEK has received a conditional NOC from the Therapeutic Products Directorate; therefore, this product may only be prescribed by physicians of the ALS Consortium who are experienced in the diagnosis and management of ALS.

Highlights of Deferred Products

■ **RENAGEL** (sevalamer hydrochloride) (GZM) – 403 mg capsule is indicated for the control of hyperphosphatemia in patients with end stage renal disease on hemodialysis. The ECDET was advised that the manufacturer intends to replace the capsule formulation with a 400 mg and 800 mg tablet. In addition, new clinical data will be presented by the manufacturer in the tablet submission. Therefore, the ECDET elected to defer further discussion on this product pending the review of the new submission for the tablet formulation.

Interchangeability and application of LCA to Methotrexate Sodium 25mg/mL (base) Injection

Alberta Blue Cross has received a number of enquiries from pharmacies following the application of the LCA price policy to methotrexate sodium 25mg/mL (base) injection on the AHWDBL. It should be noted that unpreserved and preserved versions of these products have always been designated as interchangeable products on the AHWDBL, and that the LCA price policy was applied prior to 1997. Following a comprehensive review of the LCA pricing criteria for the AHWDBL, a decision was made to reinstate the LCA price policy to this interchangeable grouping of drugs. Concerns regarding wastage and discarding of unused drug if the unpreserved product is used have been raised; however, it is expected that the cost savings expected by the application of the LCA policy will outweigh the expense of the discarded product. Pharmacies will continue to be reimbursed by Alberta Blue Cross for the cost of the entire vial that is dispensed to a maximum of the LCA price per mL.

the DBL report
UPDATE

Update, December 2001

An Official Accompaniment to the Alberta Health Drug Benefit List (AHDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
Norman Campbell, BMed Sc, M.D., FRCP (C)
William F. Dryden, BSc (Pharm), PhD ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume, BSc (Pharm), MSc

Interchangeability of Warfarin Sodium Preparations

On December 01, 2001, the warfarin sodium preparation, **APO-WARFARIN**, will be designated as an interchangeable drug product with **Coumadin** and **Taro-Warfarin** on the Alberta Health and Wellness Drug Benefit List (AHWDBL).

In conducting its review of Apo-Warfarin, the Expert Committee followed up on its commitment to ensure that additional generic warfarin products would be reviewed as stringently as the first generic entrant, Taro-Warfarin. Due to concerns over generic to generic substitution, the Expert Committee and Alberta Health and Wellness sought assurance that Apo-Warfarin sold in Alberta would be manufactured to the same stringent manufacturing specifications (that exceed USP requirements) as Coumadin and Taro-Warfarin. Apotex Inc. has provided that assurance and consequently, Apo-Warfarin will be designated as interchangeable effective December 01, 2001.

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the DBL report

Issue #21, October 2001

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

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EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
Norman R.C. Campbell, BMed Sc, M.D., FRCP (C)
William F. Dryden, BSc (Pharm), PhD ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James L. Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume, BSc (Pharm), MSc

In this issue:

Highlights of New Products Added

■ **DDAVP** (desmopressin acetate) (FEI) 0.1 and 0.2 mg tablets—the ECDET recommended DDAVP tablets be added after taking into consideration additional clinical information and a new budget impact analysis provided by the manufacturer. The new formulation will provide therapeutic advantage compared to the traditional nasal formulation particularly in patients with diabetes insipidus.

■ **REMERON** (mirtazapine) (ORG) is indicated for the symptomatic relief of depressive illness. This product has shown efficacy comparable to that of amitriptyline and has a favorable safety and side effect profile compared to other antidepressants already listed in the AHWDBL.

■ **SINGULAIR** (montelukast sodium) (MFC)—as the indication for SINGULAIR was expanded to include children 2 to 5 years of age, the 4 mg chewable tablet has been added to the AHWDBL to facilitate administration of SINGULAIR to this age group. This new formulation will be available as a "**Restricted Benefit**" for patients 2 to 18 years of age. *Please note that even though this strength is primarily designed for children 2 to 5 years of age, there may be a small number of children over 5 who are still managed on lower doses; therefore, the 4 mg chewable tablet shall be made available for patients 2 to 18 years of age to enable access to lower doses where appropriate*.

■ **TEVETEN** (eprosartan mesylate) (SLO)—this product appears to provide similar therapeutic benefits compared to other agents already listed at an apparent slightly lower price.

■ **ZYPREXA ZYDIS** (olanzapine) (LIL)—this new formulation may be advantageous when compliance or difficulty in swallowing is an issue. This product has been added to the AHWDBL because it offers cost and therapeutic advantage for the treatment of patients who cannot/will not swallow traditional oral tablets or for the treatment of patients where an injectable is either contraindicated or cannot be tolerated.

continued on reverse

Highlights of Products Not Added

■ **TAMIFLU (**oseltamivir phosphate) (HLR)—this product was re-reviewed by the ECDET as requested by the manufacturer. The recommendation was not to add this product to the AHWDBL since the clinical data presented failed to show a therapeutic benefit for the population covered by the AHW drug programs.

■ **XENICAL** (orlistat) (HLR)—this product was re-reviewed by the ECDET as requested by the manufacturer. The ECDET maintains that the clinical evidence supporting the impact of XENICAL on morbidity and mortality endpoints remains weak therefore the recommendation was not to add this product to the AHWDBL.

Suggest a Topic

Requests for topics or information on reviewed drug products to appear in The DBL Report are welcome and can be forwarded to:

Scientific and Research Services
Clinical Drug Services and Evaluation
Alberta Blue Cross
10009 - 108 St.
Edmonton, AB T5J 3C5
Fax (780) 498-8384

ABC 81278 2001/08

Highlights of Products Added via Special Authorization (SA)

■ **PEG-INTRON** (peginterferon alfa-2b) (SCH) is indicated as monotherapy in case of intolerance or contraindication to ribavarin, for the treatment of adult patients with chronic hepatitis C without liver decompensation. Coverage of PEG-INTRON will be provided according to the following criteria: "For the treatment of chronic hepatitis C in patients with evidence of active liver disease who are 18 years of age or older with documented evidence of intolerance or contraindication to ribavirin." Confirmation of the diagnosis of chronic hepatitis C with active liver disease is required. Information must include the patient's pre-treatment anti-HCV and serum HCV RNA (by PCR) status. Information is also required regarding whether liver enzymes (ALT/AST) are elevated, or the results of a liver biopsy. Specific information is required regarding why ribavirin cannot be used.

■ **RILUTEK** (riluzole) (AVE), the first agent indicated for use in amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease), has been added via SA for patients 18 to 75 years of age who have probable or definite ALS as defined by World Federation of Neurology (WFN) criteria with onset within 5 years, who have a vital capacity of >60% predicted and do not have a tracheostomy. This drug must be prescribed by a physician in the ALS consortium. Patients who previously received RILUTEK and were not eligible for the Phase IV study can be considered for coverage if they meet the SA criteria. This listing is transitional pending RILUTEK receiving a full NOC from Health Canada.

SA Criteria for Antiplatelet Agents

■ **AGGRENOX** (dipyridamole/ASA) (BOE)—published clinical data have shown that the combination of dipyridamole and ASA significantly decreases the incidence of strokes in patients that have already experienced a cerebrovascular event. As a consequence, AGGRENOX has been made available to patients in Alberta, via SA, effective August 1, 2001.

With the addition of AGGRENOX to the AHWDBL, the ECDET has also recommended that the SA criteria for PLAVIX (clopidogrel bisulfate) (BMS) be revised to reflect the most appropriate use of these agents in the treatment of cerebrovascular and non-cerebrovascular ischemic events, respectively. As a result, the SA criteria are as follows:

AGGRENOX (dipyridamole/ASA) (BOE)

- "For use in patients who have experienced a cerebrovascular ischemic event (e.g. stroke, TIA)."

PLAVIX (clopidogrel bisulfate) (BMS)

- "For the prevention of thrombosis, for one month, when prescribed following intravascular stent placement."
- "For the prevention of cerebrovascular (e.g. stroke, TIA) and non-cerebrovascular ischemic events in patients who have a contraindication to ASA."
- "For use in patients who have experienced a non-cerebrovascular ischemic event while on ASA."
- "For use in patients who have experienced a cerebrovascular ischemic event (e.g. stroke, TIA) while on dipyridamole/ASA (AGGRENOX) or for whom dipyridamole/ASA (AGGRENOX) is contraindicated."

the DBL report

Issue #20, August 1, 2001

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

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EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
Norman R.C. Campbell, BMed Sc, M.D., FRCP (C)
William F. Dryden, BSc (Pharm), PhD ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James L. Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume, BSc (Pharm), MSc

In this issue:

Highlights of Products Added via Special Authorization (SA)

■ **IMITREX** (sumatriptan) (GLA) - the 50 mg strength has been added via SA to accomodate patients who are unable to tolerate the 100 mg tablets. Please refer to the appropriate section of the AHWDBL for details.

■ **LOSEC** (omeprazole magnesium) (AZC)- the 10 mg sustained-release tablet has been added via SA to meet the needs of patients unable to tolerate the 20 mg tablets.

■ **ZOMETA** (zolendronic acid) (NOV) has been added via SA according to the following criteria: "For the treatment of tumor-induced hypercalcemia in patients with documented evidence of intolerance or lack of response to clodronate or pamidronate." Following consultation with experts, zoledronic acid appears to be a third line agent, most appropriately reserved for use in patients resistant to clodronate and pamidronate.

Changes in SA Criteria

■ **ACTOS** (pioglitazone) (LIL) - the SA criteria have been re-reviewed by the ECDET at the request of the manufacturer. Although data supporting safety and efficacy exist for pioglitazone in combination with sulfonylureas and metformin, to date, an indication for combination therapy has not been approved by the TPD (Therapeutic Products Directorate). As a consequence, the ECDET recommended that ACTOS continue to be reimbursed for monotherapy only and this is reflected in the SA criteria. Therefore, the criteria for coverage read as follows: "For the treatment of Type 2 diabetes mellitus in patients who are not adequately controlled by optimum doses or who are intolerant to metformin or sulfonylureas, or for whom these products are contraindicated. ACTOS will be considered for coverage only when used as monotherapy."

■ **EPREX** (epoetin alfa) (ORT) – the SA criteria for this product have been expanded to include coverage: "For the treatment of anemia of cancer in patients with low hemoglobin (<100 g/L) in whom blood transfusions are not possible due to transfusion reactions, cross-matching difficulties or iron overload. If hemoglobin is rising by more than 20 g/L per month, the dose of EPREX should be reduced by about 25%. If hemoglobin exceeds 120 g/L, therapy should be discontinued until hemoglobin falls below 100 g/L, at which time EPREX should be re-instituted at a dose 25% below the previous dose." It is the view of the ECDET that transfusion remains a less expensive option and affords patients the immediate benefits of treatment.
Please note that renewal requests may be considered if the patient's hemoglobin is <120 g/L while on EPREX.

continued on reverse

Highlights of Products Not Added

■ **ANDRODERM** (testosterone) (PAL) has not been added to the AHWDBL since clinical data failed to show a significant therapeutic benefit compared to other testosterone products currently listed. Even though ANDRODERM may produce more physiologic levels of testosterone, no difference in reducing symptoms of hypogonadism and sexual dysfunction was demonstrated when compared to IM testosterone enanthate.

FLUOROQUINOLONES

■ **AVELOX** (moxifloxacin hydrochloride) (YNO) and

■ **TEQUIN** (gatifloxacin) (BMS) - following consultation with Alberta Infectious Disease specialists, the ECDET agrees that there is a significant concern regarding non-judicious use of broad-spectrum fluoroquinolones. As a result, it was recommended that these agents not be added since no therapeutic or cost advantage was seen in listing these products.

Suggest a Topic

Requests for topics or information on reviewed drug products to appear in The DBL Report are welcome and can be forwarded to:

Scientific and Research Services
Clinical Drug Services and Evaluation
Alberta Blue Cross
10009 - 108 St.
Edmonton, AB T5J 3C5
Fax (780) 498-8384

New LCA Products Added

New interchangeable groupings have been established with the addition of the following first entry generic products:

Drug	Generic Brand	Innovator Brand	Date Added
Cimetidine (oral solution)	Apo-Cimetidine	Tagamet (oral liquid)*	August 1, 2001
Hydrocortisone valerate (cream and ointment)	Tarocort	Westcort	August 1, 2001
Gabapentin	Pms-Gabapentin	Neurontin	July 1, 2001**
Lisinopril (10 mg tablet)	Apo-Lisinopril	Prinivil, Zestril	August 1, 2001
Nefazodone hydrochloride	Apo-Nefazodone, Lin-Nefazodone	Serzone	July 1, 2001**
Zopiclone (5 mg tablet)	Pms-Zopiclone	Imovane	August 1, 2001

* Recently discontinued.

** Please note that the products Pms-Gabapentin, Apo-Nefazodone and Lin-Nefazodone were fast-tracked because of the substantial savings they will bring to the government-sponsored programs.

Highlights of Deferred Products

■ **ENBREL** (etanercept) (WAY) is the first of a new class of genetically engineered biologic response modifiers (TNF antagonists). At the present time ENBREL is indicated for use in rheumatoid arthritis (RA), however, a large number of clinical trials are on-going or have been completed for many different indications. The ECDET has deferred a recommendation on this product pending consultation with the rheumatology community and other stakeholders.

■ **RENAGEL** (sevelamer hydrochloride) (GZM) is an non-absorbed phosphate binder indicated for the control of hyperphosphatemia in end-stage renal disease patients on hemodialysis. Therapeutic advantage is anticipated for patients who cannot tolerate traditional calcium-containing phosphate binders or who cannot control their hyperphosphatemia. In addition to reducing serum phosphate and parathyroid hormone levels, beneficial effects on LDL cholesterol have been demonstrated. Consultations with nephrologists in Alberta are on-going to determine the exact place in therapy for RENAGEL.

■ **RILUTEK** (riluzole) (AVE) is the first agent indicated for use in amyotrophic lateral sclerosis (ALS or Lou Gehrig's disease). Clinical data have shown that RILUTEK may extend survival and/or time to tracheotomy; however, functional status and symptoms are not affected by treatment. Because of a lack of data in terms of HRQOL (Health Related Quality Of Life), the ECDET has deferred a recommendation on this product pending consultation with specialists.

ABC 81228 2001/07

the DBL report

Issue #19, April 2001

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

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EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
Norman R.C. Campbell, BMed Sc, M.D., FRCP (C)
William F. Dryden, BSc (Pharm), PhD ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James L. Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume, BSc (Pharm), MSc

In this issue:

Highlights of New Products Added

■ **LIPIDIL SUPRA** (fenofibrate, microcoated formulation) (AOO) will provide an improved formulation of fenofibrate at no extra cost compared to the currently listed products. Fibrates have been confirmed to be the most appropriate therapy for certain dyslipidemic patients and their use is endorsed in the recently published "New Canadian Recommendations for the Management and Treatment of Dyslipidemia".

■ **OXY-IR** (oxycodone hydrochloride) (PFR) has been added to the AHWDBL to provide a 20 mg strength immediate-release (IR) formulation and a less expensive 10 mg IR tablet of oxycodone.

■ **PREMPLUS** (conjugated estrogen/medroxyprogesterone acetate) (WAY) provides one tablet of conjugated estrogen and one tablet of medroxyprogesterone in one package and is expected to impact on compliance and convenience for post-menopausal women on continuous estogen-progestin therapy.

Changes in Special Authorization (SA)

■ **ACTONEL** (risendronate) (PGA)—the SA criteria have been expanded to include coverage: "For the treatment of osteoporosis in patients who have documented hip, vertebral or other fractures. SA is granted to a maximum of 12 months. The patient would go on to etidronate/calcium at the beginning of the second year."

■ **ARAVA** (leflunomide) (AVE)—coverage by SA will now be considered when requested by specialists in Internal Medicine in addition to specialists in Rheumatology. This change was prompted by the fact that some patients in remote geographic areas experience difficulties in gaining access to a rheumatologist.

■ **NEUPOGEN** (filgrastim) (AMG)—the SA criteria for this product have been expanded to include coverage: "For the reduction in the duration of neutropenia, fever, antibiotic use and hospitalization following induction and consolidation treatment for acute myeloid leukemia (AML)." This drug must be prescribed by the Directors of Alberta Cancer Board Centres (or their designates). Data have shown that the original theoretical concern that NEUPOGEN would act as a growth factor for AML is unfounded.

■ **SOTALOL** 80 mg tablets—all brands of sotalol 80 mg tablets previously available by SA will now be listed as unrestricted benefits. As a result, SA will not be required effective April 1, 2001.

continued on reverse

Highlights of Products Not Added

■ **MOBICOX** (meloxicam) (BOE) has not been added as it does not offer therapeutic advantage vis-à-vis other products currently listed. The clincial trial data demonstrated that, at lower doses, a larger number of patients discontinued treatment due to lack of efficacy and when the dose was increased, there were significantly greater GI adverse events reported.

■ **TEVETEN** (eprosartan mesylate) (SLO) has not been added due to its lack of therapeutic advantage. It appears that there would be little incentive for patients to be switched to this new angiotensin II receptor antagonist (ARB). Data supporting its efficacy appear unremarkable and data comparing eprosartan with other ARBs are not available.

Suggest a Topic

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Scientific and Research Services
Clinical Drug Services and Evaluation
Alberta Blue Cross
10009 - 108 St.
Edmonton, AB T5J 3C5
Fax (780) 498-8384

Expert Committee Profiles: Dr. Norman R. C. Campbell

Dr. Norman R. C. Campbell joined the Expert Committee in July 2000. He obtained his B. Med. Sc. and M.D. from Memorial University of Newfoundland (NF) and received his M.D. from the same university. Dr. Campbell completed his residency in Clinical Pharmacology and Internal Medicine at the Mayo Foundation and the Memorial University of NF, respectively. Dr. Campbell is a diplomat of the American Board in Internal Medicine and a specialist in Clinical Hypertension (The American Society of Hypertension). He has served on numerous scientific advisory committees and has been President of the Canadian Hypertension Society and the Canadian Coalition for High Blood Pressure Prevention and Control. He is currently chairing the Steering Committee for the Canadian Hypertension Recommendations and the Research Committee of the Canadian Society for Internal Medicine. Dr. Campbell is a full professor in the Departments of Medicine and of Pharmacology and Therapeutics at the University of Calgary, and his research interests include studies of drug interactions, assessment of cardiovascular risk factors and evaluation of antihypertensive drugs. His clinical interests are in the fields of general medicine, hypertension, clinical pharmacology and the application of evidence-based knowledge into practice.

Dr. Campbell's vision of the Alberta government-sponsored drug programs is that they should provide new therapies that have been proven effective thus assisting physicians with a more systematic approach to pharmacotherapy.

Changes in SA Renewal Policy for Selected Products

■ In the April 1, 2001 AHWDBL you will note that SA approvals will be extended to 24 months for selected products where approval has been based on a failure to respond or intolerance to other standard therapy (or where other standard therapy is contraindicated). Products affected are:

ACCOLATE	DETROL	IMITREX
ACTONEL	DOSTINEX	MAXALT
ACTOS	DURAGESIC patches	MIACALCIN
AMATINE	EFFEXOR tablets	NEORAL
AMERGE	EVISTA	PLAVIX
ARAVA	FENTANYL injection	SINGULAIR
AVANDIA	FLOVENT 50 mcg	ZANAFLEX
CARDIZEM SR	FOSAMAX	ZOMIG
COUMADIN injection		

Please consult the SA section of the April 1, 2001 AHWDBL for additional details.

■ SA approvals of **BEROTEC U.D.V.**, **ATROVENT U.D.V.** (and generics), **DUOVENT U.D.V.** and **VENTOLIN Nebules P.F.** 2 mg/mL (and generics) will also be extended to 24 months for patients who cannot prepare a dose using the multidose nebulizer solution. Similarly, **SINGULAIR** and **ACCOLATE** renewals will be extended to
24 months also for patients who cannot operate inhalers.

■ **PROSCAR** approvals will be provided until the patient turns 65 years of age, in cases where the patient is considered a poor surgical risk.

the DBL report

Issue #18, January 2001

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
Norman Campbell, BMed Sc, M.D., FRCP (C)
William F. Dryden, BSc (Pharm), PhD ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume, BSc (Pharm), MSc

In this issue:

Products for Osteoporosis Added via Special Authorization

Physicians are now provided with new coverage options for their patients with osteoporosis who are unable to be effectively treated with etidronate (DIDROCAL) because of intolerance or unresponsiveness. The following products for the treatment of osteoporosis have been made available via Special Authorization: **ACTONEL 5 mg** (risedronate sodium) (PGA), **EVISTA** (raloxifene hydrochloride) (LIL), **MIACALCIN** (salmon calcitonin, nasal spray) (NOV). These products have shown significant increases in bone mineral density and reductions in the incidence of vertebral fractures in post-menopausal women. The

SA criteria for coverage read the same for all products: *For the treatment of osteoporosis in patients with documented evidence of intolerance or lack of response to etidronate (i.e. demonstrated as a >2% loss in bone mineral density in one year).*

Products for Type 2 Diabetes Mellitus Added via Special Authorization

Two agents of the new class of antidiabetic drugs known as “glitazones”, **AVANDIA** (rosiglitazone maleate) (BMJ) and **ACTOS** (pioglitazone hydrochloride) (LIL) have been added to the AHWDBL effective December 1, 2000.

These products have been shown to be effective in improving glycemic parameters in Type 2 diabetic patients by reducing insulin resistance, the underlying condition of NIDDM (Non-Insulin Dependent Diabetes Mellitus). Glycemic control is obtained without an increase in circulating insulin or insulin precursors levels and because these agents exert their activity only in the presence of insulin, they are not indicated in the treatment of Type 1 diabetes (IDDM, Insulin-Dependent Diabetes Mellitus). It would appear that patients who are not adequately controlled by conventional therapy with oral hypoglycemic agents (metformin and sulfonylureas), would benefit the most from treatment with AVANDIA or ACTOS. As a result, the SA criteria are as follows: *For the treatment of Type 2 diabetes mellitus in patients who are not adequately controlled by optimum doses or who are intolerant to metformin or sulfonylureas or for whom these products are contraindicated*. Please note that while AVANDIA is indicated for combination therapy, at the current time, ACTOS has obtained approval from the TPP only for use as monotherapy.

continued on reverse

Highlights of New Products Added

■ **ESTALIS** (norethindrone acetate/ estradiol-17b) (NOV) is the first combination estrogen/progestin transdermal patch developed for use in a continuous-wear dosage regimen. It offers an alternative to the sequential-wear (2 weeks of estrogen alone + 2 weeks of estrogen/progestin) transdermal patches for post-menopausal women. It has shown efficacy in relieving menopausal and post-menopausal symptoms with suppression of endometrial hyperplasia and uterine bleedings.

■ **NASONEX** (mometasone furoate) (SCH) is the only nasal corticosteroid now indicated for use in children as young as 3 years of age. Data have shown no evidence of growth suppression in children treated with NASONEX. This product has been added as a restricted benefit *for patients 3 to 12 years of age inclusive for the treatment of seasonal allergic rhinitis or perennial allergic rhinitis*. Less expensive alternatives (e.g. budesonide, beclomethasone, flunisolide) are available as unrestricted benefits on the AHWDBL for patients in whom the risk of growth suppression is not a concern.

Suggest a Topic

Requests for topics or information on reviewed drug products to appear in The DBL Report are welcome and can be forwarded to:

Scientific and Research Services
Clinical Drug Services and Evaluation
Alberta Blue Cross
10009 - 108 St.
Edmonton, AB T5J 3C5
Fax (780) 498-8384

Additional Products Added via Special Authorization

■ **ARAVA** (leflunomide) (AVE) has been added to the AHWDBL effective November 1, 2000 for the treatment of refractory rheumatoid arthritis (RA).

Leflunomide is the first of a new class of DMARDs (Disease-Modifying Anti-Rheumatic Drugs) that has been shown to be effective in slowing the rate of progression of joint damage in patients with RA. Clinical response is obtained in about 40 to 65% of patients with active disease. Since the efficacy of leflunomide appears to be superior to that of sulfasalazine but comparable to that of metho-trexate, ARAVA represents a therapeutic alternative for patients with refractory disease unresponsive to methotrexate or for patients who are intolerant to methotrexate or in whom methotrexate is contraindicated.

SA criteria are the following: *For the treatment of refractory rheumatoid arthritis in patients who have failed an adequate trial of methotrexate. For patients who are unable to tolerate or with a contraindication to methotrexate. This drug product must be prescribed by a specialist in Rheumatology. Initial SA is granted for a maximum of 4 months. Renewal requests may be granted for a period of 12 months.*

■ **DOSTINEX** (cabergoline) (PHD) is a new agent used for the treatment of hyperprolactinemia. Cabergoline is well tolerated and is administered according to a convenient weekly dosing regimen. It has been added via SA according to the following criteria: *For the treatment of hyperprolactinemia in patients who are intolerant to or who have failed bromocriptine. This drug product must be prescribed by a specialist in Internal Medicine or Endocrinology*.

■ **ZANAFLEX** (tizanidine hydrochloride) (DAX) is an antispasticity agent that has been shown to be as efficacious as diazepam and baclofen in the treatment of severe spasticity associated with multiple sclerosis and spinal cord injury. Tizanidine has a good tolerability profile and represents an alternative for patients not able to tolerate baclofen or diazepam at antispasticity dosages. SA criteria are as follows: *For the treatment of spasticity in patients with documented evidence of intolerance or lack of response to diazepam or baclofen.*

Highlights of Products Not Added

■ **TAMIFLU** (oseltamivir phosphate) (HLR) is indicated for the treatment of uncomplicated acute illness due to influenza virus. This product was re-reviewed at the request of the manufacturer. While new data have shown a reduction in secondary illness treated with antibiotics in the elderly population receiving TAMIFLU, the duration of illness was not significantly different in patients treated with TAMIFLU compared to those treated with placebo. There remains a lack of data to show a significant impact on major complications arising from influenza or on morbidity and mortality endpoints. In conclusion, there is insufficient benefit to justify the magnitude of expenditure the listing of this drug would entail.

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the DBL report
UPDATE

Update, December 2000

An Official Accompaniment to the Alberta Health Drug Benefit List (AHDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
Norman Campbell, BMed Sc, M.D., FRCP (C)
William F. Dryden, BSc (Pharm), PhD ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume, BSc (Pharm), MSc

Interchangeability of Warfarin Sodium Preparations

On December 1, 2000, the warfarin sodium preparations, COUMADIN and TARO-WARFARIN will be designated as interchangeable drug products on the Alberta Health and Wellness Drug Benefit List (AHWDBL).

The designation of interchangeability of these warfarin sodium preparations follows a long and comprehensive review by the Expert Committee on Drug Evaluation and Therapeutics. In their review, the Expert Committee considered comparative bioavailability data provided by rigorous bioequivalence studies, manufacturing and quality control specifications, and prior decisions by federal regulatory bodies such as the Canadian Therapeutic Products Programme (TPP) and the US Food and Drug Administration (FDA). They also reviewed information from Dupont Pharma Inc. and Taro Pharmaceuticals Inc. provided as a result of a challenge by Dupont Pharma Inc. to the potential interchangeability of these products.

The products TARO-WARFARIN and COUMADIN are bioequivalent. Bioequivalence study design requirements and standards for narrow therapeutic range drugs, in accordance with the TPP Directive *'Standards for Comparative Bioavailability Studies Involving Drugs with a Narrow Therapeutic Range - Oral Dosage Forms',* were met in all instances. TARO-WARFARIN and COUMADIN are manufactured according to the same stringent manufacturing specifications that exceed USP requirements. It should be noted that both the TPP and FDA have declared equivalence between TARO-WARFARIN and COUMADIN.

In the determination of bioequivalence and interchangeability of drug products, consideration is given to differences in formulations and how such differences may affect the absorption of a drug. Care must be taken not to inappropriately transfer therapeutic concerns about the characteristics of a drug to the determination of bioequivalence if there are no significant absorption or formulation differences detected. Warfarin sodium is a highly permeable, soluble drug which has idiosyncratic elimination profiles, but does not have any documented absorption problems. Furthermore, it is available in the simple formulation of an uncomplicated, regular release tablet.

Statements in the COUMADIN product monograph and labeling that recommend additional INR testing or monitoring should occur if generic warfarin is substituted for COUMADIN were made at a time when there were warfarin

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ABC 80103 / 40359 2000/11

(continued from page 1)

products in the marketplace that were not bioequivalent or therapeutically equivalent to COUMADIN (e.g. warfarin potassium).

At the conclusion of their review, the Expert Committee expressed confidence that TARO-WARFARIN can be substituted for COUMADIN with the full expectation that it will produce the same clinical effect and safety profile. The Expert Committee felt that additional INR testing over and above that normally required for routine patient monitoring is not warranted when TARO-WARFARIN is substituted for COUMADIN.

In the future, additional generic warfarin products may become available in the marketplace. Each of these products will be reviewed as stringently as TARO-WARFARIN has been. Theoretic concerns about the therapeutic risks of new generic products being compared to the innovator, and not to other generics, will be dealt with as each new product is reviewed.

the DBL report

Issue #17, October 2000

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
Norman Campbell, BMed Sc, M.D., FRCP (C)
William F. Dryden, BSc (Pharm), PhD ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE SUPPORT:
Larry Shipka, BSc (Pharm)
Eugenia Palylyk-Colwell, BSc (Pharm), PhD
Carlyn Volume, BSc (Pharm), MSc

In this issue:

Changes in Special Authorization Criteria

■ Special Authorization criteria for **ACCOLATE** (zafirlukast) (AZC) and **SINGULAIR** (montelukast) (MFC) have been revised. These products will now be available "for the prophylaxis and chronic treatment of asthma in patients over the age of 18 who meet one of the following criteria: a) when used as adjunctive therapy in patients who do not respond adequately to high doses of inhaled glucocortico-steroids and long-acting β_2-agonists. Patients must be unable to use long-acting β_2-agonists or have demonstrated persistent symptoms while on long-acting β_2-agonists, OR b) cannot operate inhaler devices. For the prophylaxis of exercise-induced bronchoconstriction in patients over the age of 18 where tachyphylaxis exists for long acting β_2-agonists." SINGULAIR remains an unrestricted benefit for patients 6 to 18 years of age whereas ACCOLATE is unrestricted for patients 12 to 18 years of age.

■ Special Authorization criteria regarding the use of **NEORAL** (cyclosporine) (NOV) for the treatment of rheumatoid arthritis have also been modified: cyclosporine will now be available "for the treatment of severe rheumatoid arthritis in patients who are unable to tolerate or have failed an adequate trial of methotrexate. This drug product must be prescribed by a specialist in Rheumatology".

Special Authorization for Cerezyme

■ **CEREZYME** (imiglucerase) (GZM) was added to the AHWDBL effective May 1, 2000, by Special Authorization for the management of Gaucher Disease. Gaucher Disease is a rare genetic disorder that requires enzyme replacement therapy. Physicians who have patients who may benefit from imiglucerase are required to submit medical information to Alberta Blue Cross. The information will be reviewed for eligibility according to established guidelines.

Highlights of New Products Added

■ **Fixed-dose Combination Antihypertensive Agents -** the therapeutic value of fixed-dose combination products (e.g. ACE inhibitor/diuretic and ARB/diuretic) for the treatment of hypertension has been recently recognized in several reports (e.g. 1999 WHO International Society of Hypertension Guidelines and Adherence to Management of High Blood Pressure: Recommendations of the Canadian Coalition for High Blood Pressure Prevention and Control - 1998). While these products are not indicated for initial therapy and should be used only in patients already titrated to the optimal dose of the two components, the

continued on reverse

Highlights of Deferred Products

■ **AVANDIA** (rosiglitazone maleate) (SMJ) is the first "glitazone" to be brought to market in Canada and is the first agent to be indicated for the treatment of insulin resistance. Efficacy of AVANDIA, alone or in combination with metformin or sulphonylurea drugs, has been demonstrated in Type II diabetic patients not controlled by diet and exercise. Significant reductions in glycemic parameters were accompanied by a decrease in levels of insulin and insulin precursors; however, the long term impact on hard clinical endpoints remains unclear. Because of the high cost of this drug, further discussions are in progress to determine the appropriate use of AVANDIA and to define the population of patients that would be expected to benefit the most from treatment with this product.

■ **VISUDYNE** (verteporfin) (CBV) is a drug used for age-related macular degeneration (AMD) in "Visudyne Therapy," a two-stage process requiring intravenous administration of verteporfin and irradiation of the macula with non-thermal laser red light. Results of the clinical investigation in patients with predominantly classic subfoveal choroidal neovascularization show significant efficacy in preventing degeneration of visual acuity parameters; however, it appears that patients will likely require multiple treatments and the long term benefit in terms of prevention of blindness remains to be clarified. Discussions with expert retinal ophthalmologists in the province and the manufacturer are necessary to gather further information regarding the incidence of AMD in Alberta and the expected long-term benefit of this high cost treatment.

continued from reverse

appropriate use of these agents provides therapeutic benefit over concomitant therapy in terms of improved compliance, particularly in the elderly. The following products have been added to the AHWDBL effective October 1, 2000: **AVALIDE** (irbesartan/hydrochlorothiazide) (WIN), **DIOVAN HCT** (valsartan/hydrochlorothiazide) (NOV), **HYZAAR DS** (losartan/hydrochlorothiazide) (MFC), **INHIBACE PLUS** (cilazapril/hydrochlorothiazide) (HLR), **PRINZIDE** (lisinopril/hydrochlorothiazide) (MFC), **ZESTORETIC** (lisinopril/hydrochlorothiazide) (AZC).

Please note that although Prinivil and Zestril have been designated as interchangeable, no data to support the interchangeability of Prinzide and Zestoretic have been reviewed, therefore these products are considered non-interchangeable.

■ **QVAR** (beclomethasone dipropionate) (MMH) is a CFC-free MDI that uses hydrofluoroalkane-13a (HFA) as a propellant. Lung deposition of beclomethasone is enhanced and oropharyngeal deposition is reduced due to smaller particle size when delivered via QVAR compared to the CFC-containing formulation of beclomethasone. Clinical trials have shown that approximately 2.6 times the dose of CFC-beclomethasone is required to produce the same effect on lung function as QVAR.

Expert Committee Profiles: Dr. Stephen C. Newman

Dr. Stephen C. Newman joined the Expert Committee in May 1999. He obtained his BSc (mathematics) and M.A. (mathematics) from Dalhousie University (Halifax, NS), and received his M.D. and MSc (epidemiology) from the University of Toronto. Dr. Newman is a professor in the Department of Psychiatry at the University of Alberta and holds a cross-appointment with the Department of Public Health Sciences and the Department of Family Medicine. He has been the recipient of the Alberta Heritage Foundation for Medical Research (AHFMR) Scholar Award and has served on numerous scientific advisory committees, most recently on the Scientific Review Committee for the Alberta Mental Health Research Fund, the Alberta Health Collaboration Advisory Committee for the Health Research Fund (Alberta Health and AHFMR) and the Research Ethics Board at the Faculty of Medicine (U of A). Dr. Newman is a member of various professional associations including the Canadian Society of Epidemiology and Biostatistics, the Society for Epidemiologic Research and the American Psychopathological Association. Furthermore, he teaches in the areas of statistics, epidemiology and critical appraisal of medical literature; his research interests include the study of prevalence of psychiatric disorders, in particular, geriatric depression and the incidence of suicide attempts.

Dr. Newman's vision of the Alberta government-sponsored drug programs is that they should ensure that Albertans have access to the best drug therapies available that are consistent with scientifically demonstrated efficacy.

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the DBL report

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An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
William F. Dryden, BSc (Pharm), PhD. ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD.
Stephen C. Newman, MSc., M.D., CCFP
James Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE SUPPORT:
Larry Shipka, BSc Pharm
Eugenia Palylyk-Colwell, BSc Pharm, PhD

In this issue:

Change in Benefit Status

■ **EFFEXOR-XR** (venlafaxine HCl) (extended-release capsules) (WAY), available on the AHWDBL via Special Authorization (SA) since October 1998, will now be covered as an unrestricted benefit. A new goal in the treatment of depression would be to have patients achieve remission (absence of symptoms) as opposed to only eliciting a response. Data show that a dose of 150 mg/day of venlafaxine is necessary to promote remission in most patients. The XR formulation can provide the appropriate dose with a once-a-day administration at a lower cost compared to the use of two immediate-release (IR) tablets.

Please Note: **EFFEXOR** tablets (IR formulation), available since April 1996, will continue to be covered by SA according to the following criteria: "Consideration may be given on an exception basis, to those patients who experience clinically significant difficulties with the extended-release (XR) formulation of venlafaxine". This six month extension of coverage will facilitate physicians' transition of patients from EFFEXOR tablets to the XR formulation where appropriate; or will allow physicians to re-apply for SA for those patients unable to tolerate the XR formulation. Requests for new patients for EFFEXOR tablets (IR) will be subject to the new SA criteria starting July 1, 2000.

Highlights of New Products Added

■ **GLUCONORM** (repaglinide) (NNA) was added to the AWHDBL effective May 1, 2000. Repaglinide is a short-acting insulin secretagogue which is chemically unrelated to traditional sulphonylureas. It is absorbed rapidly from the GI tract and has a very short half-life. As a prandial glucose regulator, GLUCONORM has been shown to carry a lower risk of hypoglycemia particularly in patients with flexible life-styles.

■ **FLOVENT** (fluticasone propionate) **50 mcg MDI** (metered dose inhaler) (GLA) has been made available via SA according to the following criteria: "For the prophylactic management of steroid-responsive bronchial asthma in patients who are unable to use the Turbuhaler® dosage form of budesonide". Low dose fluticasone has been shown to have efficacy comparable to that of budesonide, which is available at a lower cost. However, patients who do not have sufficient inspiratory capacity to use the Turbuhaler® device needed for the administration of budesonide, will benefit from the availability of the MDI.

Please note: 1) **FLOVENT DISKUS 50 mcg and 100 mcg MDPI** (multi-dose powder inhaler) were not added due to cost considerations. 2) **FLOVENT 25 mcg MDI** was not added since the recommended dose for children >4 yrs of 2 inhalations BID can be delivered by 1 inhalation BID of the 50 mcg strength.

continued on reverse

Highlights of Products Not Added

■ **XENICAL** (orlistat) (HRL) is indicated in conjunction with hypocaloric diet for obesity management. Consultations with clinicians in Alberta regarding the place of XENICAL in the management of diabetes resulted in the conclusion that this drug is not of significant benefit. It is unlikely that the prescription of XENICAL for one year would affect the natural history of diabetes which is a progressive condition with a tendency for requiring increasing pharmacological therapy. No guidelines are available on when it is appropriate to discontinue treatment with XENICAL.

Highlights of Deferred Products

■ **EVISTA** (raloxifene HCl) (LIL) remains deferred pending further review by the ECDET. Data to support a protective effect of raloxifene on breast and uterine tissue as well as a significant effect on cardiovascular endpoints are encouraging, yet remain inconclusive. As a consequence, recommendations and decisions regarding reimbursement must be done only in the context of osteoporosis therapy. From the osteoporosis data, the effect of raloxifene on vertebral fractures is comparable to that of other agents already available. The ECDET wishes to wait for the results of the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) evaluation of raloxifene that will encompass both primary and secondary prevention as well as the treatment of osteoporosis.

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■ **BAYCOL** 0.4 mg (cerivastatin sodium) (YNO) has shown efficacy comparable to that of pravastatin 40 mg at a lower cost.

■ **MONOCOR** (bisoprolol fumarate) (CRY) which is currently indicated for the control of hypertension, is priced comparably to the LCA price of other β-blockers listed. Data have shown slight therapeutic benefit and better tolerability, particularly in the elderly.

■ **OXEZE TURBUHALER®** (formoterol fumarate dihydrate) 6 mcg (AZE) will offer flexibility for dosing in children.

■ **PMS-TERBINAFINE** (PMS), fast-tracked for May 1, 2000, will bring significant savings to the program.

Expert Committee Profiles: Dr. Judith Baker

Dr. Judith Baker joined the Expert Committee in May 1999. She obtained her BSP (Pharmacy), M.Sc. (Pharmaceutics) and Ph.D. in Biological Psychiatry from the University of Saskatchewan. Dr. Baker is a member of numerous professional associations including the Alberta Pharmaceutical Association (APhA) of which she was President in 1990, the Canadian Pharmaceutical Association (CPhA), the Canadian College of Clinical Pharmacy, the Capital Health Region (CHR) Pharmacists Association and the Canadian College of Neuropsychopharmacology. Dr. Baker has been a member of and has chaired many committees including the APhA Regulatory Affairs Committee and the APhA Drug Schedules Committee. Dr. Baker has also held teaching appointments at the University of Alberta and the University of Aston (UK). In addition to practicing as a part-time community pharmacist, Dr. Baker is currently involved in many projects related to pharmacy practice through her consulting roles for the Alberta Wellnet Pharmaceutical Information Network, APhA, Alberta Medical Association (AMA), CPhA, Health Outcome Pharmacies, and Capital Health Authority. Dr. Baker currently chairs the APhA Practice Review Committee and is a member of the AMA Cognitive Impairment Clinical Practice Working Group and a member of the Alberta Wellnet Pharmaceutical Information Network Working Group. Dr. Baker's vision of the Alberta government-sponsored drug programs is that they should be comprehensive in terms of the range of drug therapies offered but must be administered in a fiscally responsible manner. Solutions will have to be found to the questions such as "Who will benefit most from treatment?" and "How can we afford to pay for the drug treatment?" that are posed by the new and extremely expensive "biotechnology" drugs.

Products Removed from the AHWDBL

■ Products containing pseudoephedrine have been removed from the AHWDBL as they are available as over-the-counter medications. They are: **BALMINAL DECONGESTANT** (oral syrup), **DRIXORAL N.D.** (sustained-release tablets), **ELTOR-120** (sustained-released tablets) and **ROBIDRINE** (tablets).

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the DBL report

Issue #15, April 2000

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
William F. Dryden, BSc (Pharm), PhD. ARCST
Erwin G. Friesen, BSc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD.
Stephen C. Newman, MSc., M.D., CCFP
James Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE SUPPORT:
Larry Shipka, BSc Pharm
Eugenia Palylyk-Colwell, BSc Pharm, PhD

In this issue:

Highlights of New Products Added

■ **ACCOLATE** (zafirlukast) (ZEN) and **SINGULAIR** (montelukast sodium) (MSD) have been added via Special Authorization (SA) for individuals > 18 years for the prophylaxis and chronic treatment of asthma as an alternative to increased doses of inhaled glucocorticosteroids. Patients must be unable to use long-acting β_2 agonists or have demonstrated persistent symptoms despite use of long-acting β_2 agonists. These criteria are based upon the recently published Canadian Asthma Consensus Report [CMAJ 1999; 161 (11 Suppl)]. There is Level I evidence for use of long-acting β_2 agonists as add-on therapy to moderate or higher doses of inhaled glucocorticosteroids, whereas the use of Leukotriene-Receptor Antagonists (LTRAs) as add-on therapy is supported only by Level II evidence. As a result, long-acting β_2 agonists should be the primary treatment choice.

■ **ADVAIR** (combination of salmeterol and fluticasone) (GLA), which is indicated only for patients with reversible obstructive airways disease >12 years of age, was added as an unrestricted benefit. Advair has been shown to be superior to monotherapy with the single agents. According to the 1999 Canadian Asthma Consensus Report, inhaled long-acting β_2 agonists should be used as add-on therapy to moderate or higher doses of inhaled glucocorticosteroids to achieve control of persistent asthma symptoms (Level I).

■ **ALERTEC** (modafinil) (DAX) is the only drug approved in Canada, to date, specifically for the treatment of narcolepsy. This condition is estimated to affect approximately 1,500 Albertans. Alertec will be available to patients via SA according to the following: "For the treatment of documented narcolepsy when initially prescribed by a sleep specialist affiliated with a recognized level 1 lab or a general neurologist or a psychiatrist."

■ **MONUROL** (fosfomycin tromethamine) (PFR) is a single dose treatment for uncomplicated urinary tract infections (UTI). It has been shown to be comparable in efficacy to 7-10 days of fluoroquinolone therapy. Monurol is more costly than treatment of UTI with older agents or 3-day fluoroquinolone regimens; however, it is cost-effective when compared with 7-10 days of fluoroquinolones. Patient compliance is likely to improve with the single dose treatment.

■ **PLAVIX** (clopidogrel bisulfate) (WIN) has been available on the AHWDBL via SA since January 15, 2000 for the prevention of thrombosis post intravascular stent placement. SA criteria have now been broadened and Plavix will be covered for the prevention of cardiovascular events according to the following: "For those patients who are not able to take ASA either due to a contraindication to ASA or have recurrent events while on ASA."

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Clarification on Aricept Special Authorization (SA) Criteria

ARICEPT (donepezil hydrochloride) (PFI) was added to the AHWDBL via SA on December 1, 1999. The SA criteria for **ARICEPT** were developed and refined on the basis of "best practice" principles in order to provide reimbursement for patients with a MMSE (Mini-Mental State Examination) score between 10 to 26. As a point of clarification, SA reimbursement will be considered and continuously provided for those patients whose MMSE score rises above 26 while on **ARICEPT,** providing that their MMSE score at the time of starting **ARICEPT** was <26.

Products removed from the AHWDBL

Following a review of vaccines covered on the AHWDBL, the Alberta Health and Wellness Disease Control and Prevention Branch has recommended that Hepatitis B Immune Globulin (**BAYHEP**) and Tetanus Immune Globulin (**BAYTET)** be removed from the AHWDBL effective April 1, 2000. These products are recommended in post-exposure situations only on the advice of the Medical Officer of Health and will be supplied free of charge through regional public health. In addition, Influenza Virus Vaccine (**FLUVIRAL)** and Pneumococcal Vaccine (Polyvalent) (**PNEUMOVAX 23)** have also been removed and will be provided free of charge to individuals at risk. Additional information on availability can be obtained from regional public health.

Highlights of Deferred Products

■ **INHIBACE PLUS** (cilazapril and hydrochlorothiazide) (HLR) is deferred pending further review and discussion by the Expert Committee on the clinical value and cost-effectiveness of combination antihypertensive products in light of the recently published International Society of Hypertension Guidelines for the Management of Hypertension.

■ **XENICAL** (orlistat) (HLR) has been shown to have significant effects on weight loss, weight regain and improvement in metabolic profile of obese individuals. These outcomes, including an effect on glycemic control, may be of particular benefit to Type II diabetics; however, this must be explored further. As a result, Xenical has been deferred for further review to allow consultation with the manufacturer and Alberta diabetologists regarding these benefits and impact upon long-term health outcomes. Furthermore, additional information is required regarding guidance on when patients should discontinue Xenical.

Highlights of Products Not Added

■ **ALDARA** (imiquimod) (MMH), which is indicated for the treatment of external genital and perianal warts/condyloma acuminata in adults, was not added. A less expensive alternate therapy, WARTEC (podophyllotoxin) (PMS), is available on the AHWDBL and is also a patient-applied therapy.

■ **RELENZA** (zanamivir) (GLA) is indicated for the treatment of uncomplicated acute illness due to influenza virus in patients 12 years and older who have been symptomatic for no more than 2 days. The primary endpoint in clinical trials was the median time to alleviation of major signs and symptoms of influenza. Results showed a statistically significant reduction of 1 day in this endpoint; however, no data have been provided which show a significant impact of Relenza on major complications of influenza or on mortality and morbidity endpoints. Furthermore, there is insufficient evidence for efficacy in high risk patients (e.g. elderly or patients with underlying respiratory disease).

■ **TOBI** (tobramycin sulfate) (PGC), a preservative-free formulation of tobramycin sulfate for inhalation, was not added to the AHWDBL. Consultations with infectious diseases and cystic fibrosis specialists indicated that the theoretical risk of lung damage due to the preservative has not been seen clinically. It appears that the compounding of preservative-free tobramycin solution for inhalation can be done relatively easily and at lower cost. Therefore there is no incentive for adding this expensive formulation to the AHWDBL

■ **VIAGRA** (sildenafil citrate) (PFI), which is indicated for the treatment of erectile dysfunction (ED), has not been added. Following consultation with Alberta experts, there was no strong support for addition of this product to the AHWDBL. Products for the treatment of ED have historically not been covered on Alberta government-sponsored drug programs.

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the DBL report

Issue #14, January 2000

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSc (Pharm), MSc., PhD
William F. Dryden, BSc (Pharm), PhD. ARCST
Erwin G. Friesen, Bsc (Pharm), Pharm. D., FCSHP
Fakhreddin Jamali, Pharm. D., PhD.
Stephen C. Newman, MSc., M.D., CCFP
James Silvius, BA, M.D., FRCP (C)

ALBERTA HEALTH AND WELLNESS LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE SUPPORT:
Larry Shipka, BSc Pharm
Eugenia Palylyk-Colwell, BSc Pharm, PhD

In this issue:

Note:

A reduced version of the DBL report will accompany each issue of the updates to the AHWDBL. This publication provides an opportunity for communication between the Expert Committee and Alberta physicians and pharmacists. Questions and suggestions on issues of interest are welcome.

Highlights of New Products Added

■ **ACCURETIC (quinapril hydrochloride/hydrochlorothiazide**) (PDA) the Expert Committee has revisited the issue of fixed-ratio combination products in the treatment of hypertension and has come to the conclusion that after the patient is titrated to the appropriate dose with the single agents, the use of the combination product can be of therapeutic value, particularly for the management of seniors with hypertension already on multidrug regimens. The two available strengths of Accuretic allow the dose of quinapril to be increased while the hydrochlorothiazide dose remains constant.

■ **ARICEPT (donepezil hydrochloride)** (PFI) has become available via Special Authorization (SA) effective December 1, 1999. SA criteria for Aricept have been developed and refined on the basis of "best practice" principles following review of the literature and consultation with specialists. Existing patients with a MMSE (Mini-Mental State Examination) score of 10 to 26 are eligible for coverage and any prescriber in Alberta may submit SA requests for such patients. All physicians can initiate therapy with Aricept for new patients with a MMSE score of 14 to 26. Only physicians with recognized expertise in the management of dementia disorders can initiate therapy in new patients with a MMSE score of 10 to 13. Once initiated, therapy with Aricept can be continuously reimbursed for all patients with a score of 10 to 26.

■ **COSOPT (dorzolamide hydrochloride and timolol maleate)** (MSD) this combination product for the control of ocular hypertension and open-angle glaucoma was added, since it provides cost savings compared to the administration of single agents and can potentially improve compliance in the treatment of conditions that often require combination therapy.

■ **HUMATROPE (somatropin)** (LIL) is now available via SA for the replacement of endogenous growth hormone (GH) in adults with severe GH deficiency. Information is required regarding the results of a diagnostic insulin tolerance test. GH values < 3 mcg/L during hypoglycemia are indicative of severe GH deficiency.

Highlights of Deferred Products

■ **GLUCONORM (repaglinide)** (NNA) is a short-acting insulin secretagogue that offers a short onset of action, a short half-life, and less risk of hypoglycemia if a patient misses a meal. Since it is more expensive than the listed Least Cost Alternative (LCA) products, glyburide and gliclazide, further discussion is required to determine if it is cost-effective.

■ **TOBI (tobramycin sulfate)** (PGC) this preservative-free formulation of tobramycin sulfate for inhalation received "Priority Review" by the Therapeu-

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Why are drug products under review not eligible for special authorization or made available on an exception basis?

Physicians and Pharmacists often ask why drug products under review are not eligible for special authorization, or made available on an exception basis?

The Expert Committee on Drug Evaluation and Therapeutics was established by the Minister of Health and Wellness to consider the scientific, therapeutic, clinical, and socio-economic merits of drug products. This was done to ensure therapeutic advantage and cost-effectiveness of new drug products added to the *Alberta Health & Wellness Drug Benefit List (AHWDBL).* If a drug product were made available before it was actually reviewed by the Committee, this would circumvent the purpose of the drug review process and the mandate of the Expert Committee.

In addition, it would be unethical to provide coverage for a drug product prior to the review being completed, in the event that the outcome of the review is a decision not to add the drug product to the *AHWDBL*. Please note that the Minister of Health and Wellness makes final decisions after reviewing the recommendations of the Expert Committee and Alberta Health and Wellness.

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tic Products Programme (TPP) of Health Canada. Data showed efficacy versus placebo; however, therapeutic advantage over the use of the parenteral solution as inhalation therapy has not been shown in clinical trials. Tobi is significantly more expensive than the parenteral solution. Consultations with infectious diseases and cystic fibrosis specialists are on-going.

Expert Committee profiles: Dr. James Silvius

Dr. James Silvius joined the Expert Committee in May 1999. Prior to this, he obtained his MD degree from the University of Alberta and has undertaken clinical training in internal medicine and geriatrics in Edmonton and Halifax. Dr. Silvius obtained the Royal College Certificate of Special Competence in Geriatric Medicine in 1990. He is currently Clinical Associate Professor in the Division of Geriatric Medicine at the University of Calgary (U of C) and Deputy Chief of the Regional Division of Geriatric Medicine, U of C. His research interests are in the management of dementia. Dr. Silvius is a member of both the Canadian and Alberta Medical Associations, the Canadian Society of Geriatric Medicine and the AMA-APhA Joint Communications Advisory Committee for Drug Use in the Elderly. He is a consultant geriatrician for the David Thompson Health Region and the Site Leader for Seniors' Health (Acute Care) at the Peter Lougheed Centre in Calgary. Dr. Silvius chairs the Pharmacy and Therapeutics Committee (Continuing Care) of the Calgary Regional Health Authority.

Dr Silvius sees the programs sponsored by AH&W as having a vital role to play in medical management of patients in Alberta. As new therapies become available for conditions where there have not been therapies or where they provide decided advantages over traditional agents, a mechanism must be in place to allow these new products to be affordable for those who would most benefit from them. In Dr. Silvius' opinion, the Expert Committee assists with recommendations on these therapies. Questions continually arise as to appropriate roles for new agents. Unrestricted and potentially inappropriate use, with costs borne by society, is not in the best interest of society. Failure to recommend agents for appropriate coverage is not in the best interest of the patient. According to Dr. Silvius, the role of the Committee increasingly is to attempt to make recommendations that balance the competing demands of the need for agents to be made expeditiously available, with an awareness of societal costs associated with their use. "It is a difficult task, and not an exact science!"

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the DBL report

Issue #13, October 1999

An Official Accompaniment to the Alberta Health and Wellness Drug Benefit List (AHWDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, M.D., FRCP (C), FACP (Chair)
Judith M. Baker, BSP, MSc., PhD
William F. Dryden, BSc Pharm, PhD, ARCST
Erwin G. Friesen, BSc Pharm, Pharm. D. , FCSHP
Fakhreddin Jamali, Pharm. D., PhD
Stephen C. Newman, MSc., M.D., CCFP
James Silvius, BA, M.D., FRCP(C)

ALBERTA HEALTH LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE SUPPORT:
Larry Shipka, BSc Pharm
Eugenia Palylyk-Colwell, BSc Pharm, PhD

In this issue:

Note

We would like to bring to your attention the similarity in brand names between the new anti-inflammatory **CELEBREX** (celecoxib) and the antidepressant **CELEXA** (citalopram hydrobromide).

Highlights of New Products 'Fast-Tracked'

A number of products met Alberta Health and Wellness (AHW) criteria for fast-track and were added either July 1 or August 1, 1999:

■ **CELEBREX** (celecoxib) (SEA) is the first of a new category of NSAIDS — the COX-II inhibitors. At therapeutic doses COX-II inhibitors affect proinflammatory prostaglandins but not COX-I mediated prostaglandins which are responsible for homeostatic effects. Data have shown that the GI safety profile of Celebrex is superior to that of other NSAIDs. It does not inhibit platelet aggregation and does appear to cause clinically important renal changes in patients with normal renal function; potential effects in patients with severe renal insufficiency have yet to be determined. This product had received "Priority Review" status by the Therapeutic Products Programme (TPP) of Health Canada and was listed as an unrestricted benefit effective August 1, 1999.

■ **REBETRON** (ribavirin/ interferon alfa-2b) (SCH) for the treatment of hepatitis C received "Priority Review" status by TPP and was made available by Special Authorization effective August 1, 1999 to allow patients that were receiving ribavirin through the TPP Special Access Program (SAP) to complete 48 weeks of treatment. The SAP program was discontinued for ribavirin on April 30, 1999. Further review is necessary to determine coverage for the use of this combination therapy in the general hepatitis C population.

■ **SANDOSTATIN LAR** (ocreotide acetate) (NOV) received "Priority Review" status by TPP and has been added to the AHWDBL effective July 1, 1999 "for the treatment of acromegaly". The new indications of diarrhea associated with carcinoid tumours and VIP-omas are currently under reveiw. This product is administered by intramuscular injection once a month whereas Sandostatin SC is administered subcutaneously three times a day. The impact of the "LAR" formulation on patient acceptability and compliance will be substantial.

Highlights of New Products Added

■ **ACCOLATE** (zafirlukast) (ZEN) was added as an unrestricted benefit for individuals 12 to 18 years of age ONLY. Leukotriene receptor antagonists (LTRA) offer therapeutic advantage for children due to the potential to reduce dosage of steroids which may impact on bone development. Coverage of LTRA for the management of adult asthma remains under review.

■ **ATACAND** (candesartan cilexetil) (AST) and **AVAPRO** (irbesartan) (BMS) were added. These new Angiotensin II AT_1 Receptor Blockers (ARBs) at $1.08 day offer therapeutic advantage compared to **COZAAR** (losartan at $1.10-2.20/day)

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Highlights of New Products Added

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in terms of pharmacokinetic profile and 24 hour blood pressure control. It appears that antihypertensive control is satisfactorily obtained with QD administration while at times, BID administration of losartan is required. **DIOVAN** (valsartan) at $1.05/day is also covered. It should be noted that clinical data comparing the new ARBs to losartan are available; however, only pharmacodynamic studies have directly compared the new ARBs.

■ **CELEXA** (citalopram hydrobromide) (VLH) is a highly selective and potent SSRI with minimal effects on norepinephrine and dopamine reuptake. Citalopram exhibits weak or no inhibition of the isozymes of the cytochrome P450; as a consequence it has a low potential for drug interactions. It is less expensive than the current market leader antidepressants (i.e. **ZOLOFT** and **PAXIL**).

■ **HEPTOVIR** (lamivudine) (GLA) has expanded criteria for coverage via Special Authorization which are "To prevent hepatitis B re-infection in post-liver transplant patients".

Change in Benefit Status

Effective October 1, 1999, Special Authorization will no longer be required for **FORADIL** (formoterol fumarate) 12 mcg/dose inhalation capsule, **OXEZE** (formoterol fumarate dihydrate) 12 mcg/dose aerosol and **SEREVENT** (salmeterol xinafoate) 25 mcg/dose aerosol, 50 mcg/dose inhalation disk and 50 mcg/dose metered inhalation powder. These products are now unrestricted benefits.

New LCA Products Added

New interchangeable groupings have been established with the inclusion of additional first entry generic products on July 1, August 1 and October 1, 1999. Some products were fast-tracked because of the substantial savings they will bring to the government-sponsored programs.

Drug	Generic Brand	Innovator Brand	Date Added
Amiodarone	Alti-Amiodarone	Cordarone	August 1, 1999
Divalproex sodium	Apo-Divalproex, Novo-Divalproex, Nu-Divalproex	Epival	July 1, 1999
Enalapril maleate	Nu-Enalapril	Vasotec	July 1, 1999
Fenofibrate	Apo-Feno-Micro, PMS-Fenofibrate	Lipidil Micro	July 1, 1999
Fenofibrate	Gen-Fenofibrate	Lipidil Micro	August 1, 1999
Gentamicin (ophthalmic ointment)	Gentamicin Ophthalmic Ointment	Garamycin	October 1, 1999
Ipratropium (nasal spray)	PMS-Ipratropium	Atrovent	October 1, 1999
Tobramycin (ophthalmic solution)	Tomycine PMS-Tobramycin	Tobrex	October 1, 1999

Note: a 60-day transition period will apply to all new LCA categories.

Highlights of Products Not Added

■ **ARICEPT** (donepezil hydrochloride) (PFI) remains *deferred* as discussions with the manufacturer are on-going in order to define a way of making the drug available to an appropriate population of patients that would benefit from this treatment.

■ **INHIBACE PLUS** (cilaprazil/hydrochlorothiazide) (HLR) is a 'fixed combination' product. The recommendation not to add this product to the AHWDBL is consistent with the fact that fixed ratio/poly pharmacy dosage forms do not offer the flexibility of dose titration necessary for optimal treatment of hypertension and are not the agents of choice in clinical practice.

■ **EVISTA** (raloxifene hydrochloride) (LIL) remains *deferred* for further discussion since no new data have been provided to support efficacy in terms of a significant impact on hip fractures, cardiovascular and breast/uterine cancer outcomes.

■ **PLAVIX** (clopidogrel bisulfate) (WIN) which is indicated for the secondary prevention of vascular ischemic events in patients with a history of symptomatic atherosclerotic disease, remains a *deferred* product. AHW and the manufacturer are working towards ensuring appropriate use of clopidogrel if it is covered on the government sponsored drug programs. Additional information has been requested pertaining to the use of clopidogrel 'post-stent'.

ABC 80103 / 40359 99/08

the DBL report
UPDATE

Update, April 1999

An Official Accompaniment to the Alberta Health Drug Benefit List (AHDBL)

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

produced by Alberta Blue Cross

EXPERT COMMITTEE MEMBERS:
D. Neil Graham, MD, FRCP (C), FACP (Chair)
William F. Dryden, BSc Pharm, PhD, ARCST
Erwin G. Friesen, BSc Pharm, PharmD, FCSHP
Fakhreddin Jamali, PharmD, PhD, FCP

ALBERTA HEALTH LIAISON:
David Bougher, BSP, MHSA

ADMINISTRATIVE SUPPORT:
Larry Shipka, BSc Pharm
Eugenia Palylyk-Colwell, BSc Pharm, PhD

Interchangeability of Levothyroxine Sodium Preparations

The levothyroxine sodium preparations, SYNTHROID and ELTROXIN have been designated as interchangeable since the first interchangeability designations in the AHDBL effective October 1, 1993. This was based on a recommendation by the Expert Committee on Drug Quality and Therapeutics following a review of data supplied by the manufacturers of SYNTHROID at that time (Boots Pharmaceuticals Ltd.) and ELTROXIN (Glaxo Canada Inc.) and consideration of similar decisions taken in other provinces.

In the April 1, 1999 AHDBL, the product LEVOTEC has also been designated as interchangeable with SYNTHROID and ELTROXIN; however, the product LEVO-T remains not interchangeable.

In reviewing the interchangeability of LEVOTEC, the Expert Committee considered new and comprehensive bioequivalence data comparing LEVOTEC and SYNTHROID, information provided by Knoll Pharma Inc. (current manufacturer of SYNTHROID) and information provided by Technilab Inc. (manufacturer of LEVOTEC).

The products LEVOTEC and SYNTHROID are bioequivalent. Bioequivalence study design requirements and standards for Narrow Therapeutic Range drugs as per the *Therapeutic Products Directorate Report C* and Directive *'Standards for Comparative Bioavailability Studies Involving Drugs with a Narrow Therapeutic Range - Oral Dosage Forms'* were met in all instances.

The active ingredient and absorbed moiety in levothyroxine sodium preparations is levothyroxine (T_4). In the determination of bioequivalence and interchangeability of drug products, consideration is given to differences in formulations and how differences in formulations affect absorption of the active ingredient.

Pharmacodynamic endpoints or clinical studies are used as surrogate measures of bioequivalence and interchangeability only if measurement of the absorbed moiety in plasma or urine cannot be made with sufficient accuracy and sensitivity. Although TSH measurement is recommended to determine if levothyroxine dosage is optimal *(Thyroid Testing Guidelines for Alberta Physicians),* it is not an appropriate parameter to measure differences between formulations as it is also a function of patient and disease factors and not solely formulation factors.

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the DBL report

Issue #109, July 2019

An Official Accompaniment to the Alberta Drug Benefit List (ADBL) produced by Alberta Blue Cross

The Expert Committee on Drug Evaluation and Therapeutics (ECDET)

EXPERT COMMITTEE MEMBERS:
Scott Klarenbach, MD, MSc (Health Econ), FRCPC, (Chair)
Fiona Clement, PhD, (Vice-Chair)
Caitlin A. Clarke, BScPhm, PharmD
Margaret Gray, BSP, FCSHP
Mike Kolber, BSc, MD, CCFP, MSc
Naeem Ladhani, BScPharm
Tony Nickonchuk, BScPharm
Glen J. Pearson, BScPhm, PharmD, FCSHP, FCCS
Jeremy Slobodan, BSP
Donna Woloschuk, BSP, PharmD, M.Ed. FCSHP

ALBERTA HEALTH LIAISON:
Chad Mitchell, BSc Pharm, MSc

ADMINISTRATIVE AND SCIENTIFIC SUPPORT:
Julia Chan, BSc (Pharm)
Amanda Chung, BSc (Pharm)
Sherry Dieleman, BSc (Pharm), MSc
Connie Lussier, BSP, MA

In this issue:

Brief Summary of Drug Review Activities

The Expert Committee on Drug Evaluation and Therapeutics met on May 13, 2019. The Committee reviewed Manufacturer submissions for twelve (12) 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 four (4) Drug Products.

In addition to Drug Products reviewed by the Expert Committee, three (3) Drug Products underwent Expedited Review for listing on the *ADBL* effective July 1, 2019.

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 Product was reviewed by CDR and the Expert Committee and added to the *ADBL* effective July 1, 2019:

- **PROBUPHINE* 80 mg subdermal implant** (buprenorphine hydrochloride) (KTI) via Special Authorization (SA)

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 (07/2019)

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 July 1, 2019:

- **MAR-FEBUXOSTAT* 80 mg tablet** (febuxostat) (MAR) via Special Authorization

Highlights of Line Extension Drug Products Reviewed for the ADBL

Addition of the following Drug Products to the *ADBL* effective July 1, 2019:

- **AA-CLOZAPINE 50 mg & 200 mg tablets** (clozapine) (AAP)

Special Authorization Criteria Changes

The Special Authorization criteria for coverage for the following Drug Product has been revised effective June 17, 2019:

- **SPINRAZA* 2.4 mg/mL injection** (nusinersen sodium) (BIO)

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 (06/2019)