Updates to the Alberta Drug Benefit List

Effective March 1, 2020

Alberta Government

Inquiries should be directed to:

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Website: https://www.alberta.ca/drug-benefit-list-and-drug-review-process.aspx

Administered by Alberta Blue Cross
on behalf of Alberta Health.

The Drug Benefit List (DBL) is a list of drugs for which coverage may be provided to program participants. The DBL is not intended to be, and must not be used as a diagnostic or prescribing tool. Inclusion of a drug on the DBL does not mean or imply that the drug is fit or effective for any specific purpose. Prescribing professionals must always use their professional judgment and should refer to product monographs and any applicable practice guidelines when prescribing drugs. The product monograph contains information that may be required for the safe and effective use of the product.

Copies of the *Alberta Drug Benefit List* are available from Pharmacy Services, Alberta Blue Cross at the address shown above.

Binder and contents: **$42.00** ($40.00 + $2.00 G.S.T.)
Contents only: **$36.75** ($35.00 + $1.75 G.S.T.)

A cheque or money order must accompany the request for copies.

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Special Authorization

The following drug product(s) will be considered for coverage by Special Authorization for patients covered under Alberta government-sponsored drug programs.

New Drug Product(s) Available by Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
FULPHILA 6 MG/0.6 ML INJECTION SYRINGE	PEGFILGRASTIM	00002484153	BGP

Additional Brand(s) and/or Strength(s) of Drug Product(s) Available by Special Authorization

Trade Name / Strength / Form	Generic Description	DIN	MFR
APO-FINGOLIMOD 0.5 MG CAPSULE	FINGOLIMOD HYDROCHLORIDE	00002469936	APX
JAMP FINGOLIMOD 0.5 MG CAPSULE	FINGOLIMOD HYDROCHLORIDE	00002487772	JPC
MAR-FINGOLIMOD 0.5 MG CAPSULE	FINGOLIMOD HYDROCHLORIDE	00002474743	MAR
ODAN LEVOCARNITINE 100 MG / ML ORAL SOLUTION	LEVOCARNITINE	00002492105	ODN
TARO-FINGOLIMOD 0.5 MG CAPSULE	FINGOLIMOD HYDROCHLORIDE	00002469618	TAR

Drug Product(s) with Changes to Criteria for Coverage

Trade Name / Strength / Form	Generic Description	DIN	MFR
KALYDECO 150 MG TABLET	IVACAFTOR	00002397412	VER

Added Product(s)

Trade Name / Strength / Form	Generic Description	DIN	MFR
ACT VENLAFAXINE XR 75 MG EXTENDED-RELEASE CAPSULE	VENLAFAXINE HCL	00002304325	TEV
JAMP DORZOLAMIDE-TIMOLOL 0.5 % OPHTHALMIC SOLUTION	TIMOLOL MALEATE/ DORZOLAMIDE HCL	00002457539	JPC
JAMP-DORZOLAMIDE 2 % OPHTHALMIC SOLUTION	DORZOLAMIDE HCL	00002453347	JPC
VYZULTA 0.024 % OPHTHALMIC SOLUTION	LATANOPROSTENE BUNOD	00002484218	VCL

New Established Interchangeable (IC) Grouping(s)

The following IC Grouping(s) have been established and LCA pricing will be applied effective April 1, 2020.

Generic Description	Strength / Form	New LCA Price
LEVOCARNITINE	100 MG / ML ORAL SOLUTION	0.4854

Least Cost Alternative (LCA) Price Change(s)

The following established IC Grouping(s) are affected and a revised LCA price has been established. Groupings affected by a price change, will be effective April 1, 2020.

Please review the online Alberta Drug Benefit List at https://www.ab.bluecross.ca/dbl/idbl_main1.php for further information.

Generic Description	Strength / Form	New LCA Price
DORZOLAMIDE HCL	2 % OPHTHALMIC SOLUTION	2.1081

Product(s) with a Price Change

The following product(s) had a Price Change. The previous higher price will be recognized until March 31, 2020. For products within an established IC Grouping, the LCA price may apply.

Trade Name / Strength / Form	Generic Description	DIN	MFR
SANDOZ DORZOLAMIDE 2 % OPHTHALMIC SOLUTION	DORZOLAMIDE HCL	00002316307	SDZ

PART 2

Drug Additions

DORZOLAMIDE HCL

2 % (BASE) OPHTHALMIC SOLUTION

	00002453347	**JAMP-DORZOLAMIDE**	**JPC**	$	**2.1081**
	00002316307	**SANDOZ DORZOLAMIDE**	**SDZ**	$	**2.1081**
	00002216205	TRUSOPT	PUR	$	4.2840
☒	00002269090	TRUSOPT (PRESERVATIVE-FREE)	PUR	$	4.2900

DORZOLAMIDE HCL/ TIMOLOL MALEATE

2 % (BASE) * 0.5 % (BASE) OPHTHALMIC SOLUTION

	00002299615	**APO-DORZO-TIMOP**	**APX**	$	**1.9887**
	00002457539	**JAMP DORZOLAMIDE-TIMOLOL**	**JPC**	$	**1.9887**
	00002437686	**MED-DORZOLAMIDE-TIMOLOL**	**GMP**	$	**1.9887**
	00002344351	**SANDOZ DORZOLAMIDE/ TIMOLOL**	**SDZ**	$	**1.9887**
☒	00002258692	COSOPT PRESERVATIVE-FREE	PUR	$	2.6250
	00002240113	COSOPT	PUR	$	6.4900

LATANOPROSTENE BUNOD

0.024 % OPHTHALMIC SOLUTION

	00002484218	VYZULTA	VCL	$	5.2500

VENLAFAXINE HCL

75 MG (BASE) ORAL EXTENDED-RELEASE CAPSULE

	00002304325	**ACT VENLAFAXINE XR**	**TEV**	$	**0.1825**
	00002331691	**APO-VENLAFAXINE XR**	**APX**	$	**0.1825**
	00002452847	**AURO-VENLAFAXINE XR**	**AUR**	$	**0.1825**
	00002278553	**PMS-VENLAFAXINE XR**	**PMS**	$	**0.1825**
	00002380080	**RAN-VENLAFAXINE XR**	**RAN**	$	**0.1825**
	00002310325	**SANDOZ VENLAFAXINE XR**	**SDZ**	$	**0.1825**
	00002275031	**TEVA-VENLAFAXINE XR**	**TEV**	$	**0.1825**
	00002354721	**VENLAFAXINE XR**	**SNS**	$	**0.1825**
	00002385937	**VENLAFAXINE XR**	**SIV**	$	**0.1825**
	00002237280	EFFEXOR XR	PFI	$	2.0010

PART 3

Special Authorization

FINGOLIMOD HYDROCHLORIDE

Relapsing Remitting Multiple Sclerosis (RRMS):

Special authorization coverage may be provided for the treatment of relapsing remitting multiple sclerosis (RRMS) to reduce the frequency of clinical relapses and to delay the progression of physical disability in adult patients (18 years of age or older) who are refractory or intolerant to at least ONE of the following:
- interferon beta
- glatiramer acetate
- dimethyl fumarate
- teriflunomide
- peginterferon beta.

Definition of 'intolerant'

Demonstrating serious adverse effects or contraindications to treatments as defined in the product monograph, or a persisting adverse event that is unresponsive to recommended management techniques and which is incompatible with further use of that class of MS disease modifying therapy (DMT).

Definition of 'refractory'
-Development of neutralizing antibodies to interferon beta.

-When the above MS DMTs are taken at the recommended doses for a full and adequate course of treatment, within a consecutive 12-month period while the patient was on the MS DMT, the patient has:

1) Been adherent to the MS DMT (greater than 80% of approved doses have been administered);

2) Experienced at least two relapses* of MS confirmed by the presence of neurologic deficits on examination.
i. The first qualifying clinical relapse must have begun at least one month after treatment initiation.
ii. Both qualifying relapses must be classified with a relapse severity of moderate, severe or very severe**.

* A relapse is defined as the appearance of new symptoms or worsening of old symptoms, lasting at least 48 hours in the absence of fever, not associated with withdrawal from steroids. Onset of clinical relapses must be separated by a period of at least one month. At least one definite gadolinium-enhancing T1 MRI lesion (not questionable faint enhancement) obtained at least 90 days after initiation of the DMT and at least 90 days before or after a relapse may substitute for one clinical relapse.

**Relapse Severity: with moderate relapses modification or more time is required to carry out activities of daily living; with severe relapses there is inability to carry out some activities of daily living; with very severe relapses activities of daily living must be completed by others.

Coverage

For coverage, this drug must be prescribed by a registered MS Neurologist. A current assessment must be completed by a registered MS Neurologist at every request.

To register to become an MS Neurologist please complete the Registration for MS Neurologist Status Form (ABC 60002).

Initial Coverage

1) The registered MS Neurologist must confirm a diagnosis of RRMS;

2) The patient must have active disease which is defined as at least two relapses* of MS during

FINGOLIMOD HYDROCHLORIDE

the previous two years or in the two years prior to starting an MS DMT. In most cases this will be satisfied by the refractory to treatment criterion but if a patient failed an MS DMT more than one year earlier, ongoing active disease must be confirmed.

3) The patient must be ambulatory with or without aid (The registered MS Neurologist must provide a current updated Expanded Disability Status Scale (EDSS) score less than or equal to 6.5).

Coverage will not be approved when any MS DMT or other immunosuppressive therapy is to be used in combination with fingolimod.

Coverage of fingolimod will not be approved if the patient was deemed to be refractory to fingolimod in the past, i.e., has not met the 'responder' criteria below in 'Continued Coverage'.

Following assessment of the request, coverage may be approved for up to 12 months. Patients will be limited to receiving a one-month supply of fingolimod per prescription at their pharmacy for the first 12 months of coverage.

Continued Coverage

For continued coverage beyond the initial coverage period, the patient must meet the following criteria:

1) The patient must be assessed by a registered MS Neurologist;

2) The registered MS Neurologist must confirm a diagnosis of RRMS;

3) The registered MS Neurologist must provide a current updated EDSS score. The patient must not have an EDSS score of 7.0 or above sustained for one year or more;

Coverage of this drug may be considered in a patient with a sustained EDSS score of 7.0 or above in exceptional circumstances. For MS DMT coverage to be considered, details of the exceptional circumstance must be provided in a letter from the registered MS Neurologist and accompany the Special Authorization Request Form.

4) The registered MS Neurologist must confirm in writing that the patient is a 'responder' who has experienced no more than one inflammatory event in the last year (defined as either a clinical relapse or gadolinium-enhancing lesion). In instances where a patient has had four or more clinical relapses in the year prior to starting treatment, there must be at least a 50% reduction in relapse rate over the entire treatment period.

Following assessment of the request, continued coverage may be approved for maintenance therapy for up to 12 months. Patients may receive up to 100 days' supply of fingolimod per prescription at their pharmacy.

Restarting After an Interruption in Therapy Greater Than 12 Months

In order to be eligible for coverage, after an interruption of therapy greater than 12 months, the patient must meet the following criteria:

1) At least one relapse* per 12 month period; or
2) At least two relapses* during the previous 24 month period.

All requests (including renewal requests) for fingolimod must be completed using the Alemtuzumab/Fingolimod/Natalizumab For Multiple Sclerosis Special Authorization Request Form (ABC 60000).

0.5 MG (BASE) ORAL CAPSULE

00002469936	**APO-FINGOLIMOD**	**APX**	$	**21.7381**
00002487772	**JAMP FINGOLIMOD**	**JPC**	$	**21.7381**

FINGOLIMOD HYDROCHLORIDE

00002474743	**MAR-FINGOLIMOD**	**MAR**	$	**21.7381**
00002469715	**MYLAN-FINGOLIMOD**	**MYP**	$	**21.7381**
00002469782	**PMS-FINGOLIMOD**	**PMS**	$	**21.7381**
00002482606	**SANDOZ FINGOLIMOD**	**SDZ**	$	**21.7381**
00002469618	**TARO-FINGOLIMOD**	**TAR**	$	**21.7381**
00002469561	**TEVA-FINGOLIMOD**	**TEV**	$	**21.7381**
00002365480	GILENYA	NOV	$	86.9525

IVACAFTOR

"For the treatment of cystic fibrosis (CF) in patients age six (6) years and older who have one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R; and

For the treatment of cystic fibrosis (CF) in patients aged 18 and older with an R117H mutation in the CFTR gene.

For coverage, this drug must be prescribed by a prescriber affiliated with one of the following Alberta Cystic Fibrosis Clinics:
- Cystic Fibrosis Clinic, Adult: Kaye Edmonton Clinic
- Cystic Fibrosis Services - Adult Outpatient: Foothills Medical Centre
- Cystic Fibrosis Clinic, Pediatric: Stollery Children's Hospital
- Pediatric Cystic Fibrosis Clinic: Alberta Children's Hospital

Initial coverage may be approved for up to 150 mg every 12 hours for 6 months. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

Renewal Criteria

The sweat chloride test will be repeated at the next routine review appointment after starting ivacaftor to determine whether sweat chloride levels are reducing and to check compliance with the drug regimen. The sweat chloride level will then be re-checked 6 months after starting treatment to determine whether the full reduction (as detailed below) has been achieved. Thereafter sweat chloride levels will be checked annually.

For continued coverage of up to 150mg every 12 hours beyond the initial 6-month authorization, the patient will be considered to have responded to treatment if either:

a) The patient's sweat chloride test falls below 60mmoL/L; OR
b) The patient's sweat chloride test falls by at least 30%

In cases where the baseline sweat chloride test is already below 60mmoL/L, the patient will be considered to have responded to treatment if either:

c) The patient's sweat chloride test falls by at least 30%; OR
d) The patient demonstrates a sustained absolute improvement in FEV1 of at least 5%. In this instance FEV1 will be compared with the baseline pre-treatment level one month and three months after starting treatment.

Following this assessment, continued coverage of up to 150 mg every 12 hours may be approved for a period of 12 months. Patients will be limited to receiving a one-month supply per prescription at their pharmacy.

If the expected reduction in sweat chloride does not occur, the patient's CF clinician will first explore any challenges in following the recommended dosing schedule for ivacaftor. The patient's sweat chloride will then be retested around one week later and funding discontinued if the patient does not meet the above criteria."

All requests (including renewal requests) for ivacaftor must be completed using the Ivacaftor Special Authorization Request Form (ABC 60004).

150 MG ORAL TABLET

00002397412	KALYDECO	VER	$	420.0000

LEVOCARNITINE

"For the treatment of primary carnitine deficiency. Information is required regarding the total plasma carnitine levels."

"For the treatment of patients with an inborn error of metabolism that results in secondary carnitine deficiency. Information is required regarding the patient's diagnosis."

"Special authorization may be granted for 6 months."

In order to comply with the first criteria: Information is required regarding pre-treatment total plasma carnitine levels.

The following product(s) are eligible for auto-renewal.

100 MG / ML ORAL SOLUTION

00002492105	**ODAN LEVOCARNITINE**	**ODN**	$	**0.4854**
00002144336	CARNITOR	SGM	$	0.5711

PEGFILGRASTIM

Effective March 1, 2020, all Special Authorization requests for pegfilgrastim will be assessed for coverage with Fulphila or Lapelga. Neulasta will not be approved for new pegfilgrastim starts or repeat treatments (e.g., new course of chemotherapy).

"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/Plerixafor Special Authorization Request Form (ABC 60013).

Please note: Coverage cannot be considered for palliative patients.

6 MG / SYR INJECTION SYRINGE

☒ 00002484153	FULPHILA	BGP	$	1600.0000
☒ 00002474565	LAPELGA (0.6 ML SYRINGE)	APX	$	1878.7300
☒ 00002249790	NEULASTA (0.6 ML SYRINGE)	AMG	$	2504.9700