BC PharmaCare Newsletter

Edition 19-001
March 28, 2019

In this edition

PHARMACARE NEWSLETTER SERVICE RESUMES

After a brief hiatus, the PharmaCare Newsletter will resume periodic publishing, detailing formulary changes, policy changes, new or updated procedures and contacts, guidance during drug shortages, and other information important to the health sector in B.C.

This edition includes formulary changes implemented since October 30, 2018.

BRITISH COLUMBIA

The PharmaCare Newsletter is published by the Pharmaceutical Services Division to provide information to British Columbia's health care providers.

CHANGES TO GENERIC DRUG PRICING

Effective April 1, 2019, B.C. is amending the Drug Price Regulation to increase patient choice and access to generic drugs. The amendment was introduced as part of British Columbia's commitment to the 5-year initiative announced by the pan-Canadian Pharmaceutical Alliance and the Canadian Generic Pharmaceutical Association in January 2018.

The amendment introduces the following changes:

- **Removing exclusivity**
  To increase patient choice of generics in an LCA category, the opportunity for manufacturers to submit exclusive generic drug listings will be removed.
- **Increasing Maximum Accepted List Price (MALP) for oral solids**
  To better align with other provinces, and to provide opportunity for more products to fall at or below MALP (and therefore be included in the PharmaCare formulary), the MALP for oral solids will increase to 25% from 20%. The MALP remains at 35% for all other generic drugs.
- **Adopting brand name reference prices from other jurisdictions**
  B.C. will align with other provinces and more often use the same brand name reference price (used to calculate the MALP) as other jurisdictions. This change supports a streamlined submission process for generic drugs.

For more information, refer to additional resources on the 2019 Amendments to the B.C. Drug Price Regulation and Drug Submissions for Generic Drug Products.

Reimbursement limits for LCA and RDP drugs are detailed in the Low Cost Alternative and Reference Drug Program data files. Annual price increases effective April 1 can be found in the LCA/RDP data files in the Upcoming Changes section.

YOUR VOICE: PATIENT INPUT NEEDED FOR COPD REVIEW

The feedback and experiences of patients, caregivers, and patient groups is integral to B.C.'s drug review process.

The Ministry depends on pharmacies and practitioners to help connect patients and their caregivers with opportunities to provide input. If you have a patient who is currently taking one of the drugs under review or who has COPD, please encourage them to visit **www.gov.bc.ca/BCyourvoice**.

THERAPEUTIC REVIEW OF TREATMENTS FOR CHRONIC OBSTRUCTIVE PULMONARY DISEASE		
DRUGS INCLUDED IN THE REVIEW	• Aclidinium bromide (TUDORZA® GENUAIR®) • Aclidinium bromide-formoterol fumarate (DUAKLIR® GENUAIR®) • Beclomethasone dipropionate (QVAR™) • Budesonide (PULMICORT® TURBUHALER®) • Budesonide-formoterol fumarate (SYMBICORT® TURBUHALER®)	• Formoterol fumarate (FORADIL and OXEZE® TURBUHALER®) • Glycopyrronium bromide (SEEBRI® BREEZHALER®) • Indacaterol maleate (ONBREZ® BREEZHALER®) • Indacaterol-glycopyrronium (ULTIBRO® BREEZHALER®) • Mometasone furoate (ASMANEX® TWISTHALER®)

	• Ciclesonide (ALVESCO®) • Fluticasone furoate (ARNUITY ELLIPTA) • Fluticasone furoate-vilanterol (BREO ELLIPTA) • Fluticasone furoate-umeclidinium-vilanterol (TRELEGY ELLIPTA) • Fluticasone propionate (FLOVENT HFA and FLOVENT DISKUS, and AERMONY RESPICLICK™) • Fluticasone propionate-salmeterol (ADVAIR, ADVAIR DISKUS and ARBESDA RESPICLICK™)	• Mometasone furoate-formoterol (ZENHALE®) • Salmeterol xinafoate (SEREVENT® DISKHALER® and SEREVENT® DISKUS®) • Tiotropium (SPIRIVA® and SPIRIVA® RESPIMAT®) • Tiotropium-olodaterol (INSPIOLTO™ RESPIMAT®) • Umeclidinium (INCRUSE ELLIPTA) • Umeclidinium-vilanterol (ANORO ELLIPTA)
INPUT WINDOW	February 27–April 24, 2019	

LIMITED COVERAGE DRUGS

The following drugs have been added as Limited Coverage Drugs under Fair PharmaCare and Plans B, C, F, and W.

COVERAGE EFFECTIVE	February 26, 2019		
DRUG NAME	**abobotulinumtoxinA** (Dysport Therapeutic™)		
INDICATION	cervical dystonia (spasmodic torticollis) and focal spasticity		
DIN	02460203	STRENGTH AND FORM	300 units/vial sterile lyophilized powder for solution for injection
	02456117		500 units/vial sterile lyophilized powder for solution for injection
PLAN G BENEFIT	No	PLAN P BENEFIT	No

COVERAGE EFFECTIVE	December 18, 2018		
DRUG NAME	**evolocumab** (Repatha®)		
INDICATION	Heterozygous Familial Hypercholesterolemia		
DIN	02446057	STRENGTH AND FORM	140 mg/mL prefilled autoinjector
	02459779		120 mg/mL in 3.5mL auto mini-doser
PLAN G BENEFIT	No	PLAN P BENEFIT	No

COVERAGE EFFECTIVE	December 18, 2018		
DRUG NAME	**ezetimibe**		
INDICATION	Hypercholesterolemia		
DIN	02354101	STRENGTH AND FORM	Teva-ezetimibe 10 mg tablet
	02416409		Pms-ezetimibe 10 mg tablet
	02416778		Sandoz ezetimibe 10 mg tablet
	02419548		Ran-ezetimibe 10 mg tablet
	02422662		Mar-ezetimibe 10 mg tablet
	02423235		Jamp-ezetimibe 10 mg tablet
	02423243		Mint-ezetimibe 10 mg tablet
	02425610		Ach-ezetimibe 10 mg tablet
	02427826		Apo-ezetimibe 10 mg tablet
	02429659		ezetimibe 10 mg tablet (Sivem Pharmaceuticals)
	02431300		ezetimibe 10 mg tablet (Sanis Health)
	02469286		Auro-ezetimibe 10 mg tablet
PLAN G BENEFIT	No	PLAN P BENEFIT	No
Ezetimibe is a regular benefit for recipients of Plan W (First Nations Health Benefits) coverage.			

COVERAGE EFFECTIVE	November 27, 2018		
DRUG NAME	**glatiramer acetate** (Glatect™)		
INDICATION	Relapsing-remitting multiple sclerosis		
DIN	02460661	STRENGTH AND FORM	20mg/mL pre-filled syringe
PLAN G BENEFIT	No	PLAN P BENEFIT	No

COVERAGE EFFECTIVE	November 13, 2018		
DRUG NAME	**mepolizumab** (Nucala)		
INDICATION	Severe eosinophilic asthma		
DIN	02449781	STRENGTH AND FORM	100 mg/mL vial of lyophilized powder for subcutaneous injection
PLAN G BENEFIT	No	PLAN P BENEFIT	No

COVERAGE EFFECTIVE	March 26, 2019		
DRUG NAME	**Methadone hydrochloride** (Metadol-D®)		
INDICATION	Opioid use disorder		
DIN	02244290	STRENGTH AND FORM	10 mg/mL oral concentrate (unflavoured)
PHARMACARE PINs	67000005	DISPENSE TYPE	Dispensed with witnessed ingestion
	67000006		Dispensed without witnessed ingestion
	67000007		Delivery with witnessed ingestion
	67000008		Delivery without witnessed ingestion
PLAN G BENEFIT	Yes	PLAN P BENEFIT	No
More information about opioid agonist treatments covered by PharmaCare are detailed on the OAT PINs and DINs page.			

COVERAGE EFFECTIVE	February 26, 2019		
DRUG NAME	**onabotulinumtoxinA** (Botox®)		
INDICATION	overactive bladder onabobotulinumtoxinA is also a Limited Coverage benefit for the treatment of spasmodic torticollis, blepharospasm, strabismus, equinus foot deformity, focal spasticity, and urinary incontinence associated with multiple sclerosis or subcervical spinal cord injury.		
DIN	01981501	STRENGTH AND FORM	50, 100, or 200 units/vial concentrate power for solution for injection
PLAN G BENEFIT	No	PLAN P BENEFIT	No

COVERAGE EFFECTIVE	January 29, 2019		
DRUG NAME	**propranolol hydrochloride** (Hemangiol®)		
INDICATION	proliferating infantile hemangioma		
DIN	02457857	STRENGTH AND FORM	3.75 mg/mL oral solution
PLAN G BENEFIT	No	PLAN P BENEFIT	No

COVERAGE EFFECTIVE	November 27, 2018		
DRUG NAME	**rituximab** (Rituxan®)		
INDICATION	Relapsing-remitting multiple sclerosis Rituximab is already covered as a Limited Coverage drug for the treatment of rheumatoid arthritis and granulomatosis with polyangiitis or microscopic polyangiitis		
DIN	02241927	STRENGTH AND FORM	10 mg/mL vial for intravenous infusion
PLAN G BENEFIT	No	PLAN P BENEFIT	No

COVERAGE EFFECTIVE	November 13, 2018		
DRUG NAME	**rotigotine** (Neupro®)		
INDICATION	advanced stage Parkinson's disease		
DIN	02403900	STRENGTH AND FORM	2 mg/24 hour transdermal patch
	02403927		4 mg/24 hour transdermal patch
	02403935		6 mg/24 hour transdermal patch
	02403943		8 mg/24 hour transdermal patch
PLAN G BENEFIT	No	PLAN P BENEFIT	Yes

COVERAGE EFFECTIVE	March 12, 2019		
DRUG NAME	**tocilizumab** (Actemra®)		
INDICATION	Giant cell arteritis Tocilizumab is already covered as a Limited Coverage drug for the treatment of polyarticular juvenile idiopathic arthritis, systemic juvenile idiopathic arthritis, and rheumatoid arthritis.		
DIN	02424770	STRENGTH AND FORM	162 mg/0.9 mL pre-filled syringes
PLAN G BENEFIT	No	PLAN P BENEFIT	No

Hepatitis C Coverage Expansion

Since January 29, 2019, glepcaprevir-pibrentasvir (Maviret™) has been covered as a Limited Coverage Drug for the treatment of Chronic Hepatitis C in patients affected by severe renal impairment or end stage renal disease requiring hemodialysis.

As of March 21, 2019, this coverage has been expanded to remove the renal criteria. Coverage of glecaprevir-pibrentasvir is now available under Fair PharmaCare and Plans B, C, F, and W for patients who meet the updated criteria.

COVERAGE EFFECTIVE	Initial January 29, 2019, expanded March 21, 2019		
DRUG NAME	**glecaprevir-pibrentasvir** (Maviret™)		
INDICATION	Chronic Hepatitis C		
DIN	02467550	STRENGTH AND FORM	100 mg-40 mg tablet
PLAN G BENEFIT	No	PLAN P BENEFIT	No

Duloxetine Coverage Expansion

As of November 27, 2018, generic duloxetine, which is a Plan P regular benefit, is now also a Limited Coverage Drug under Fair PharmaCare and Plans B, C, F, and W.

COVERAGE EFFECTIVE	November 27, 2018
DRUG NAME	**duloxetine**
INDICATION	For the treatment of neuropathic pain
DIN	STRENGTH AND FORM
02429446	Pms-Duloxetine 30 mg delayed release capsule
02429454	Pms-Duloxetine 60 mg delayed release capsule
02436647	Auro-Duloxetine 30 mg delayed release capsule
02436655	Auro-Duloxetine 60 mg delayed release capsule
02437082	Duloxetine 30 mg delayed release capsule (Teva Canada Ltd.)
02437090	Duloxetine 60 mg delayed release capsule (Teva Canada Ltd.)
02438259	Ran-Duloxetine 30 mg delayed release capsule
02438267	Ran-Duloxetine 60 mg delayed release capsule
02438984	Mint-Duloxetine 30 mg delayed release capsule
02438992	Mint-Duloxetine 60 mg delayed release capsule
02439948	Sandoz Duloxetine 30 mg delayed release capsule
02439956	Sandoz Duloxetine 60 mg delayed release capsule
02440423	Apo-Duloxetine 30 mg delayed release capsule
02440431	Apo-Duloxetine 60 mg delayed release capsule
02446081	Mar-Duloxetine 30 mg delayed release capsule

02446103	Mar-Duloxetine 60 mg delayed release capsule
02451913	Jamp-Duloxetine 30 mg delayed release capsule
02451921	Jamp-Duloxetine 60 mg delayed release capsule
02453630	Duloxetine 30 mg delayed release capsule (Sivem Pharmaceuticals)
02453649	Duloxetine 60 mg delayed release capsule (Sivem Pharmaceuticals)
02426633	Mylan-Duloxetine 30 mg delayed release capsule
02426641	Mylan-Duloxetine 60 mg delayed release capsule

Vancomycin Limited Coverage Criteria Change

As of December 18, 2018, PharmaCare has updated Limited Coverage Criteria for vancomycin for the treatment of *Clostridium difficile* infection.

To improve access to treatment, coverage criteria were amended to include patients who were initiated on oral vancomycin as an inpatient in a hospital, nursing home, or long-term care facility, as well as to remove the requirement that the drug be prescribed by an infectious disease or gastrointestinal specialist.

Urgent Special Authority requests for vancomycin can be made by prescribers and pharmacists.

- Monday to Friday, 8:00 a.m. to 4:00 p.m., prescribers can submit requests via the usual Special Authority process and indicate the request is urgent. A coverage decision should be provided within 24 hours.
- After hours, if a patient meets criteria, a prescriber or pharmacist can contact the PharmaNet HelpDesk to request urgent Special Authority for vancomycin.
- The HelpDesk is available 24 hours per day, 7 days per week.

Glatiramer Coverage Transitioning from Copaxone to Glatect

PharmaCare is changing coverage of glatiramer products. Multiple sclerosis patients currently using Copaxone® brand glatiramer must transition to Glatect™ (in consultation with their prescriber) to maintain PharmaCare coverage.

As of November 27, 2018, all Special Authority (SA) requests and renewals for glatiramer acetate for multiple sclerosis patients will be approved for Glatect brand only.

Patients with existing SA approval for glatiramer will have coverage for both brands during the transition period beginning November 27, 2018 until May 28, 2019, when Copaxone coverage ends.

To maintain patients' coverage, prescribers must write a new prescription, indicating the transition to Glatect. The patient's existing glatiramer SA remains in effect until the next renewal date.

Glatect is now also included in the Collaborative Prescribing Agreement available to MS neurologists practicing in designated MS clinics in B.C.

Natalizumab Limited Coverage Criteria Change

As of March 26, 2019, PharmaCare has updated the Limited Coverage criteria for natalizumab (Tysabri®), to reflect its change in the formulary from a third-line treatment to a second-line treatment for relapsing remitting multiple sclerosis.

Plan W Gliclazide Coverage

Gliclazide (Diamicron® and generic) 80 mg tablet and gliclazide modified release 30 mg and 60 mg tablets (Diamicron® MR and generics) are currently Limited Coverage benefits, subject to the Low Cost Alternative policy.

As of November 27, 2018, gliclazide is a regular benefit for Plan W beneficiaries and remains a Limited Coverage drug for other eligible PharmaCare plans.

Changes to Coverage for Chronic Hepatitis B Treatments and Delisting of Adefovir

The Ministry of Health has completed a review of tenofovir, entecavir and adefovir for the treatment of chronic hepatitis B. Based on the results of this review, PharmaCare is changing coverage of and criteria for drugs used in the treatment of chronic Hepatitis B.

PharmaCare is discontinuing coverage of adefovir (Hepsera® and Apo-adefovir) 10 mg tablet. Effective November 27, 2018, no new Special Authority (SA) requests for adefovir will be approved. Patients with existing SA approval for adefovir will be automatically granted approval for tenofovir disoproxil fumarate (300 mg tablets, Viread® and generics).

Patients with existing Special Authority approval for adefovir will have 6 months to meet with their prescriber and discuss transition to an alternative treatment. Their coverage of adefovir will end on May 29, 2019.

Also effective November 27, 2018, coverage of tenofovir disoproxil fumarate and entecavir is expanding:

- Tenofovir disoproxil fumarate is now covered as a first-line option for treatment-naïve patients with or without compensated cirrhosis, as well as for treatment-experienced, medication-compliant patients who demonstrate lamivudine resistance or who have previously used adefovir and have persistent viremia.
- Entecavir is now covered as a first-line option for treatment-naïve patients with or without compensated cirrhosis.

For more information, refer to the PharmaCare Coverage of Chronic Hepatitis B Treatments information sheet.

HIGH COST DRUGS

The following products have been added to the list of designated high cost drugs.

DIN	DRUG	ALLOWABLE MARKUP	EFFECTIVE DATE
02467550	glecaprevir-pibrentasvir (Maviret™) 100mg-40 mg tablet	2%	March 21, 2019
02470373	infliximab (Renflexis™) 100 mg vial	5%	November 3, 2018
02449781	mepolizumab (Nucala) 100 mg/mL vial	5%	November 13, 2018
02463121	obeticholic acid (Ocaliva) 5 mg tablet	5%	October 30, 2018

02463148	obeticholic acid (Ocaliva) 10 mg tablet	5%	October 30, 2018
02451158	selexipag (Uptravi®) 200 mcg tablet	5%	October 30, 2018
02451166	selexipag (Uptravi®) 400 mcg tablet	5%	October 30, 2018
02451174	selexipag (Uptravi®) 600 mcg tablet	5%	October 30, 2018
02451182	selexipag (Uptravi®) 800 mcg tablet	5%	October 30, 2018
02451190	selexipag (Uptravi®) 1000 mcg tablet	5%	October 30, 2018
02451204	selexipag (Uptravi®) 1200 mcg tablet	5%	October 30, 2018
02451212	selexipag (Uptravi®) 1400 mcg tablet	5%	October 30, 2018
02451220	selexipag (Uptravi®) 1600 mcg tablet	5%	October 30, 2018

NON-BENEFITS

The following drugs have been reviewed and will not be added as PharmaCare benefits.

DIN	DRUG
02473623	brodalumab (Siliq™) 140 mg/mL solution for injection
02363445	dexamethasone (Ozurdex®) 0.7 mg intravitreal implant
02470365	dupilumab (Dupixent™) 150 mg/mL pre-filled syringe
02458640	edoxaban (Lixiana®) 15 mg tablet
02458659	edoxaban (Lixiana®) 30 mg tablet
02458667	edoxaban (Lixiana®) 60 mg tablet
02474018	mesalazine (Mezera™) 1 g suppository
02474026	mesalazine (Mezera™) 1g/actuation foam enema
02464241	tenofovir alafenamide (Vemlidy™) 25 mg tablet

Etidronate Delisting Reminder

As announced August 21, 2018, and effective February 19, 2019, PharmaCare no longer provides coverage of etidronate for the prevention of fractures due to osteoporosis, based on product availability and current practice guidelines.

All patients who were taking etidronate as of August 2018 were automatically granted Special Authority coverage for both alendronate and risedronate. Any patients who have not transitioned off etidronate should speak with their prescriber about treatment options.