

## P.E.I. Pharmacare Bulletin

Issue (2018-4)

July 11, 2018

### CRITERIA CHANGES/NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY

Effective July 23, 2018:

Product (Generic Name)	Product (Brand Name)	Strength	Dosage Form	DIN	MFR
Atomoxetine	<u>Strattera and various generics</u>	10 mg	Capsule	Various	LIL & various generics
		18 mg	Capsule		
		25 mg	Capsule		
		40 mg	Capsule		
		60 mg	Capsule		
		80 mg	Capsule		
		100 mg	Capsule		
	Criteria	Open benefit			
	Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Program, Generic Drug Program, Catastrophic Drug Program			
Ketotifen	<u>Zaditor</u>	0.025 %	Ophthalmic Drops	02242324	LAB
	Criteria	Open benefit			
	Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Program, Seniors Drug Program, Nursing Home Program, Catastrophic Drug Program			
Mesalazine	<u>Salofalk</u>	1 gm	Suppository Retention Enema	02242146 02112795	APT
		2 gm/60 gm			
	Criteria	Open benefit			
	Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Program, Seniors Drug Program, Nursing Home Program, Catastrophic Drug Program			
Olopatadine	<u>Patanol and various generics</u> <u>Pataday and various generics</u>	0.1 %	Ophthalmic Drops	Various	NVR & various generics
		0.2 %	Ophthalmic Drops		
	Criteria	Open benefit			
	Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Program, Seniors Drug Program, Nursing Home Program, Catastrophic Drug Program			
Triamcinolone acetonide	<u>Kenalog-10</u> <u>Kenalog-40</u>	10 mg/ml	Vial (Injection)	01999761 01999869	BMS
		40 mg/ml	Vial (Injection)		
		<u>Triamcinolone Acetonide</u>	40 mg/ml	Injection	01977563
	Criteria	Open benefit			
	Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Program, Seniors Drug Program, Nursing Home Program, Catastrophic Drug Program			

**Effective August 1, 2018:**

Product (Generic Name)	Product (Brand Name)	Strength	Dosage Form	DIN	MFR
Ranibizumab	<u>Lucentis</u>	2.3mg/0.23mL 0.5mg/0.5mL	Vial (Injection) Prefilled Syringe	02296810 02425629	NVR NVR
	Criteria	Coverage has expanded to include the following conditions: diabetic macular edema (DME), retinal vein occlusion (RVO), choroidal neovascularization (CNV) Restriction of treatment to the better seeing eye for wAMD has been removed. Please see the PEI Pharmacare Formulary on August 1, 2018 for full treatment criteria.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Aflibercept	<u>Eylea</u>	2mg/0.5mL	Vial (Injection)	02415992	BAY
	Criteria	Coverage has expanded to include the following conditions: diabetic macular edema (DME), retinal vein occlusion (RVO) Restriction of treatment to the better seeing eye for wAMD has been removed. Please see the PEI Pharmacare Formulary on August 1, 2018 for full treatment criteria.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Axitinib	<u>Inlyta</u>	1 mg 5 mg	Tablet Tablet	02389630 02389649	PFI
	Criteria	For the second line treatment of metastatic clear cell renal carcinoma for patients who are unable to tolerate ongoing use of an effective dose of everolimus or who have a contraindication to everolimus.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Aztreonam	<u>Cayston</u>	75 mg/ml	Vial (Inhalation)	02329840	GIL
	Criteria	For the treatment of chronic pulmonary Pseudomonas aeruginosa infections, when used as a cyclic treatment, in patients with moderate to severe cystic fibrosis and deteriorating clinical condition despite treatment with inhaled tobramycin.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Cobimetinib	<u>Cotellic</u>	20 mg	Tablet	02452340	HLR
	Criteria	In combination with vemurafenib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or stage IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms. Approvals are for a maximum daily dose of 60 mg during 21 consecutive days per 28 day cycle.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Crizotinib	<u>Xalkori</u>	200 mg 250 mg	Capsule Capsule	02384256 02384264	PFI
	Criteria	Existing coverage is expanded to include first-line therapy for patients with an ALK-positive NSCLC with an ECOG performance status of 0-2.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Dornase alfa	<u>Pulmozyme</u>	1 mg/ml	Amp (Inhalation)	02046733	HLR
	Criteria	For cystic fibrosis patients with a FEV1<70% predicted with clinically significant decline in FEV1 not responsive to usual treatment.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			

Product (Generic Name)	Product (Brand Name)	Strength	Dosage Form	DIN	MFR
Ibrutinib	<b>Imbruvica</b>	140 mg	Capsule	02434407	JAN
	Criteria	For patients with chronic lymphocytic leukemia (CLL)/small lymphocytic lymphoma (SLL) who have received at least one prior therapy and are considered inappropriate for treatment or re-treatment with a fludarabine-based regimen.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Ivacaftor	<b>Kalydeco</b>	150 mg	Tablet	02397412	VER
	Criteria	<p>For the treatment of cystic fibrosis in patients who meet the following criteria:</p> <ul style="list-style-type: none"> <li>• Age 6 years and older; AND</li> <li>• Patient has documented G551D mutation in the Cystic Fibrosis Transmembrane Conductance Regulator (CFTR) gene.</li> </ul> <p>Initial renewal criteria: Renewals will be considered in patients with documented response to treatment (after at least 6 months of therapy), as evidenced by the following: In cases where the patient's sweat chloride levels prior to commencing therapy were above 60 mmol/litre: i. the patient's sweat chloride level fell below 60 mmol/litre; OR ii. the patient's sweat chloride level is 30% lower than the level reported in a previous test; In cases where the patient's sweat chloride levels prior to commencing therapy were below 60 mmol/litre: i. the patient's sweat chloride level is 30% lower than the level reported in a previous test; OR ii. the patient demonstrates a sustained absolute improvement in FEV1 of at least 5% when compared to the FEV1 test conducted prior to the commencement of therapy. If the expected reduction does not occur, a sweat chloride test should be performed again one week later. If the criteria are not met, funding will be discontinued. Subsequent renewal criteria after the patient has met the initial renewal criteria: The patient is continuing to benefit from therapy with Kalydeco. The patient's sweat chloride level and FEV1 must be provided with each request.</p>			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Rifaximin	<b>Zaxine</b>	550 mg	Tablet	02410702	LUP
	Criteria	<p>For reducing the risk of overt hepatic encephalopathy (HE) recurrence (i.e., 2 or more episodes), if the following clinical criteria are met: Clinical Criteria:</p> <ul style="list-style-type: none"> <li>• Patients are unable to achieve adequate control of HE recurrence with maximal tolerated dose of lactulose alone.</li> <li>• Must be used in combination with maximal tolerated doses of lactulose.</li> <li>• For patients not maintained on lactulose, information is required regarding the nature of the patient's intolerance to lactulose.</li> </ul>			
	Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Program, Seniors Drug Program, Nursing Home Program, Catastrophic Drug Program			
Riociguat	<b>Adempas</b>	0.5 mg 1 mg 1.5 mg 2 mg 2.5 mg	Tablet Tablet Tablet Tablet Tablet	02412764 02412772 02412799 02412802 02412810	BAY
	Criteria	For the treatment of inoperable chronic thromboembolic pulmonary hypertension (CTEPH, World Health Organization [WHO] Group 4) or persistent or recurrent CTEPH after surgical treatment in adult patients (>18 years of age) with WHO Functional Class (FC) II or III pulmonary hypertension (PH). Should be prescribed by a clinician with experience in the diagnosis and treatment of CTEPH.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			

Product (Generic Name)	Product (Brand Name)	Strength	Dosage Form	DIN	MFR
Stiripentol	<b><u>Diacomit</u></b>	250 mg 500 mg 250 mg 500 mg	Capsules Capsules Powder for Susp Powder for Susp	02398958 02398966 02398974 02398982	BIO
	Criteria	For use in combination with clobazam and valproate as adjunctive therapy of refractory generalized tonic-clonic seizures in patients with severe myoclonic epilepsy in infancy (Dravet syndrome), whose seizures are not adequately controlled with clobazam and valproate alone. The patient must be under the care of a neurologist or a pediatrician.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Vemfuranib	<b><u>Zelboraf</u></b>	240 mg	Tablet	02380242	HLR
	Criteria	Existing coverage is expanded to include use in combination with cobimetinib, for the treatment of patients with previously untreated BRAF V600 mutation-positive unresectable stage III or stage IV melanoma who have a good performance status. Treatment should continue until unacceptable toxicity or disease progression. If brain metastases are present, patients should be asymptomatic or have stable symptoms.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			
Adalimumab Infliximab Infliximab Vedolizumab	<b><u>Humira</u></b> <b><u>Inflectra</u></b> <b><u>Remicade</u></b> <b><u>Entyvio</u></b>	40 mg/0.8 ml 100 mg 100 mg 300 mg	Prefilled Syringe Vial (Injection) Vial (Injection) Vial (Injection)	02258595 02419475 02244016 02436841	ABV PFI JAN TAK
	Criteria	For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are: - refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks, and prednisone ≥ 40mg daily for two weeks or IV equivalent for one week); or -corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year). •Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically: -a decrease in the partial Mayo score ≥ 2 from baseline, and -a decrease in the rectal bleeding subscore ≥ 1. Please see the PEI Pharmacare Formulary on August 1, 2018 for full treatment criteria.			
	Program Eligibility	High Cost Drug Program, Catastrophic Drug Program			

### **IMPORTANT NOTICES**

#### **Change in Methadone Oral Solution Coverage:**

Effective September 4, 2018, PEI Pharmacare will no longer reimburse for Methadose oral solution. Metadol-D 10mg/mL oral solution (DIN 02244290) will continue to be covered. This will align with changes being made by NIHB effective the same date.

#### **Removal of Upper Limit Age Restriction:**

Effective immediately, the age restriction of ages 6-25 years for coverage of Concerta (and generics), Biphentin, and Vyvanse will be updated to remove the upper age limit of 25 years. If a pharmacy comes across a scenario where a claim will no longer process due to a end-date in place for clients turning 25, they may call Help Desk to have the end-date removed.