

# PEI Pharmacare Bulletin

Issue (2023-1 )

January 9, 2023

**NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY**  
**(EFFECTIVE DATE: (JANUARY 23, 2023))**

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Cyclosporine	Verkazia	0.1%	Oph emulsion	02484137	SNN
Criteria	<p>For the treatment of pediatric patients between the age of 4 and 18 years of age with severe vernal keratoconjunctivitis (VKC) who meet the following criteria:</p> <ul style="list-style-type: none"> <li>Grade 3 (severe) or 4 (very severe) on the Bonini scale, <i>OR</i></li> <li>Grade 4 (marked) or 5 (severe) on the modified Oxford scale.</li> </ul> <p>Discontinuation Criteria:</p> <ul style="list-style-type: none"> <li>Treatment should be discontinued if no improvement in signs and symptoms of VKC is observed, <i>OR</i></li> <li>Treatment should be discontinued if signs and symptoms of VKC have resolved.</li> </ul> <p>Clinical Note:</p> <ul style="list-style-type: none"> <li>Documentation of the severity of signs and symptoms of VKC at treatment initiation and renewal must be provided.</li> </ul> <p>Claim Notes:</p> <ul style="list-style-type: none"> <li>The patient must be under the care of a physician experienced in the diagnosis and treatment of VKC.</li> <li>Initial approval period: 6 months.</li> <li>Renewal approval period: 1 year</li> </ul>				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Catastrophic Drug Program				

Darolutamide	Nubeqa	300 mg	Tablet	02496348	BAY
Criteria	<p>In combination with androgen deprivation therapy (ADT) for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) who are at high risk of developing metastases<sup>1</sup>.</p> <ul style="list-style-type: none"> <li>Patients should have a good performance status. Treatment should continue until unacceptable toxicity or radiographic disease progression.</li> </ul> <p>Clinical Notes:</p> <ul style="list-style-type: none"> <li>Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart, with the last PSA &gt; 2 ng/mL.</li> <li>Patients should have no detectable distant metastases by either CT, MRI or technetium-99m bone scan.</li> <li>Castrate levels of testosterone must be maintained.</li> </ul>				

	<ul style="list-style-type: none"> <li>Patients with N1 disease, pelvic lymph nodes &lt; 2cm in short axis located below the aortic bifurcation are eligible for darolutamide.</li> <li>Darolutamide will not be funded for patients who experience disease progression on apalutamide or enzalutamide.</li> <li>Patients receiving darolutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on darolutamide.</li> <li>Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued darolutamide in the non-metastatic setting due to intolerance without disease progression.</li> </ul> <p><sup>1</sup>High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10 months during continuous ADT.</p>
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Fenofibrate	AA-Fenofibrate	67 mg	Capsule	02243180	AAA
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Hydrocortisone/ pramoxine/zinc	Proctodan-HC	0.5%-1%-0.5%	Ointment	02234466	ODN
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Hydrocortisone/ pramoxine/zinc	Proctodan-HC	10 mg-20 mg- 10 mg	Suppository	02240851	ODN
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Isavuconazole	Cresemba	100 mg	Capsule	02483971	AVI
Criteria	<p>For the treatment of adult patients with invasive aspergillosis who have a contraindication, intolerance or have failed to respond to oral voriconazole and caspofungin.</p> <p>For the treatment of adult patients with invasive mucormycosis.</p> <p>Claim Notes:</p> <ul style="list-style-type: none"> <li>Must be prescribed by a hematologist or specialist in infectious diseases or medical microbiology.</li> <li>Initial requests will be approved for a maximum of 3 months.</li> </ul>				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Lidocaine	Lidodan	5 %	Ointment	02083795	ODN
Criteria	Open benefit				
Program Eligibility	Financial Assistance Drug Program, Nursing Home Drug Program				

Potassium chloride	Odan-K 20	20 mmol	Extended release tablet	80004415	ODN
Criteria	Open benefit				
Program Eligibility	Financial Assistance Drug Program, Nursing Home Drug Program				

Macitentan	Opsumit	10 mg	Tablet	02415690	JAN
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Criteria	For the treatment of patients with Group 1 pulmonary arterial hypertension (PAH) with a World Health Organization (WHO) functional class of at least II. Clinical Note: <ul style="list-style-type: none"> <li>The diagnosis of PAH should be confirmed by right heart catheterization.</li> </ul> Claim Notes: <ul style="list-style-type: none"> <li>Must be prescribed by, or in consultation with, a physician experienced in the treatment of PAH.</li> <li>Combined use of more than one endothelin receptor antagonists will not be reimbursed.</li> <li>The maximum dose of macitentan that will be reimbursed is 10mg daily.</li> </ul>
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Raloxifene	ACT-Raloxifene	60 mg	Tablet	02358840	ACT
Criteria	For the treatment of postmenopausal osteoporosis associated with documented fragility fracture when bisphosphonates are not tolerated or are contraindicated.  For the treatment of postmenopausal osteoporosis without documented fractures when patient is at high 10 year fracture risk (using fracture risk tables) and bisphosphonates are not tolerated or are contraindicated.				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Regorafenib	Stivarga	40 mg	Tablet	02403390	BAY
Criteria	For patients with metastatic and/or unresectable gastrointestinal stromal tumors (GIST) who have had disease progression on, or intolerance to, imatinib and sunitinib; AND has ECOG $\leq$ 1.  For the treatment of patients with unresectable hepatocellular carcinoma (HCC) who have experienced disease progression on sorafenib or lenvatinib and meet all of the following criteria: <ul style="list-style-type: none"> <li>Child-Pugh class status of A.</li> <li>ECOG performance status of 0 or 1.</li> </ul> Clinical Notes: <ul style="list-style-type: none"> <li>Treatment should continue until disease progression or unacceptable toxicity.</li> <li>Patients with disease progression on sorafenib must have tolerated a minimum dose of 400 mg per day for at least 20 of the last 28 days of treatment.</li> </ul>				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Sulfamethoxazole/ trimethoprim	Sulfatrim Pediatric	100 mg/20 mg	Tablet	00445266	AAA
Criteria	Open benefit				
Program Eligibility	Cystic Fibrosis Drug Program, Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, HIV Drug Program, Nursing Home Drug Program, Seniors Drug Program, Tuberculosis Drug Program, Catastrophic Drug Program				

Trifluridine/ tipiracil	Lonsurf	15 mg/6.14 mg 20 mg/8.19 mg	Tablet Tablet	02472104 02472112	TAI
Criteria	For the treatment of adult patients with metastatic gastric cancer or adenocarcinoma of the gastroesophageal junction who meet the following criteria: <ul style="list-style-type: none"> <li>Previously treated with at least two prior lines of chemotherapy including a fluoropyrimidine, a platinum, and either a taxane or irinotecan and if appropriate, with HER2-targeted therapy.</li> <li>Patients should have a good performance status.</li> </ul> Clinical notes: <ul style="list-style-type: none"> <li>Trifluridine/tipiracil should be used in combination with best supportive care</li> </ul>				

	<ul style="list-style-type: none"> <li>Treatment should be discontinued upon disease progression or unacceptable toxicity</li> <li>Requests will be considered for patients who have an intolerance or contraindication to platinum-based therapy</li> </ul>
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Vandetanib	Caprelsa	100 mg 300 mg	Tablet Tablet	02378582 02378590	GZY
Criteria	For the treatment of symptomatic and/or progressive medullary thyroid cancer (MTC) in patients with unresectable locally advanced or metastatic disease. Treatment should be for patients with a good performance status and should continue until disease progression or unacceptable toxicity.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

**CRITERIA UPDATE/ PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY**  
**(EFFECTIVE IMMEDIATELY)**

Cabergoline	Apo-Cabergoline	0.5 mg	Tablet	02455897	APX
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Cabozantinib	Cabometyx	20 mg 40 mg 60 mg	Tablet Tablet Tablet	02480824 02480832 02480840	IPS
Criteria	<p>The current criteria has been expanded to include: For the second-line treatment of adult patients with unresectable hepatocellular carcinoma who meet all of the following criteria:</p> <ul style="list-style-type: none"> <li>Disease progression on sorafenib or lenvatinib</li> <li>Child-Pugh class status of A</li> <li>ECOG performance status of 0 or 1</li> </ul> <p>Clinical Note:</p> <ul style="list-style-type: none"> <li>Treatment should continue until the patient no longer experiences clinical benefit or experiences unacceptable toxicity.</li> </ul> <p>Claim Notes:</p> <ul style="list-style-type: none"> <li>Requests for cabozantinib will not be considered for patients who experience disease progression on regorafenib or atezolizumab in combination with bevacizumab.</li> <li>Approval period: 6 months</li> </ul>				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Crizotinib	Xalkori	200 mg 250 mg	Capsule	02384256 02384264	PFI
Criteria	<p>The current criteria has been expanded to include: For the first-line treatment of patients with ROS-1 positive non-small cell lung cancer (NSCLC).</p> <p>Clinical Notes:</p> <ul style="list-style-type: none"> <li>Eligible patients should be previously untreated and have a good performance status.</li> <li>Treatment may continue until disease progression or unacceptable toxicity.</li> <li>Patients with ROS-1 positive NSCLC who are currently receiving first-line chemotherapy or have been previously treated with chemotherapy or immunotherapy will be eligible for treatment with crizotinib.</li> </ul>				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				