A

Health PEI
One Island Health System

PEI Pharmacare
P.O. Box 2000
Charlottetown, PE
C1A 7N8
www.healthpei.ca

Santé Î.-P.-É.
Un système de santé unique

Programmes provinciaux de medicaments
C.P. 2000
Charlottetown, PE
C1A 7N8
www.healthpei.ca

PEI Pharmacare Bulletin

Issue (2021 - 10) **December 6, 2021**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: (DECEMBER 20, 2021)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN/PDIN	MFR
Adalimumab	**Amgevita**	**40 mg/0.8 ml**	**Prefilled Pen Prefilled Syringe**	**02459302 02459299**	**AMG**
Criteria	For the treatment of ankylosing spondylitis, Crohn's disease, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, or ulcerative colitis, as per clinical criteria for currently listed Adalimumab outlined in the PEI Pharmacare online Formulary. For Adalimumab naïve patients, approved requests will be for a biosimilar product.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Alectinib	**Alecensaro**	**150 mg**	**Capsule**	**02458136 00904400***	**HLR**
Criteria	For the treatment of patients with anaplastic lymphoma kinase (ALK)-positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer when used: • as first-line therapy, or • following disease progression on, or intolerance to, crizotinib. Renewal Criteria • Confirmation that the patient is responding to treatment. Claim Notes: • Requests for alectinib will not be considered for patients who experience disease progression on any ALK inhibitor other than crizotinib. • No further ALK inhibitor will be reimbursed following disease progression on alectinib. • Initial approval period: 1 year. • Renewal approval period: 1 year *Claims that exceed the maximum claim amount of $9999.99 must be divided as separate transactions, using DIN first and PDIN* second.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Cabozantinib	Cabometyx	20 mg 40 mg 60 mg	Tablet Tablet Tablet	02480824 02480832 02480840	IPS
Criteria	For the treatment of patients with advanced or metastatic renal cell carcinoma who have received at least one prior vascular endothelial growth factor receptor (VEGFR) tyrosine kinase inhibitor (TKI) therapy when used as: • second-line therapy following disease progression on sunitinib, pazopanib or pembrolizumab in combination with axitinib; or • third-line therapy following disease progression on immunotherapy and VEGFR TKI (i.e., sunitinib or pazopanib), used in any sequence. Renewal Criteria: • Written confirmation that the patient has responded to treatment and there is no evidence of clinically meaningful disease progression. Clinical Note: • Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity. Claim Notes: • Requests for cabozantinib will not be considered for patients who experience disease progression on everolimus or axitinib monotherapy. • Initial approval period: 1 year. • Renewal approval period: 1 year				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Letermovir	Prevymis Prevymis	240 mg 480 mg	Tablet Tablet	02469375 02469383	MER
Criteria	For the prevention of cytomegalovirus (CMV) infection in adult CMV-seropositive recipients [R+] of an allogeneic hematopoietic stem cell transplant (HSCT) who have undetectable CMV viremia at baseline and meet one of the following criteria: • umbilical cord blood as a stem cell source • recipient of a haploidentical transplant • recipient of T-cell depleted transplant • treated with antithymocyte globulin (ATG) for conditioning • requiring high-dose steroids or other immunosuppression for acute graft versus host disease (GVHD) • treated with ATG for steroid-refractory acute GVHD • documented history of CMV disease prior to transplantation Clinical Note: • High-dose steroids is defined as the use of greater than or equal to 1 mg/kg/day of prednisone or equivalent dose of another corticosteroid. Claim Notes: • Must be prescribed by a medical oncologist, hematologist, or infectious disease specialist or other physician with experience in the management of HSCT. • Approvals will be for a maximum dose of 480 mg per day. • Approval period: 100 days per HSCT				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Obeticholic	Ocaliva	5 mg 10 mg	Tablet Tablet	02463121 02463148	INT
Criteria	For the treatment of adult patients with primary biliary cholangitis (PBC) as either:				

	• combination therapy with ursodeoxycholic acid (UDCA) in patients who have experienced an inadequate response to a minimum of 12 months of UDCA treatment; or • monotherapy in patients who have experienced unmanageable intolerance to UDCA. Requirement for Initial Requests: • Alkaline phosphatase (ALP) and bilirubin levels prior to initiation of treatment with obeticholic acid must be provided. Renewal Criteria: • Requests for renewal will be considered if the patient achieved: o a reduction in the ALP to less than 1.67 times the upper limit of normal (ULN); or o at least a 15% reduction in the ALP level from baseline (i.e. prior to initiation of treatment with obeticholic acid). <u>Clinical Notes:</u> • Diagnosis confirmed by positive antimitochondrial antibodies or liver biopsy results consistent with PBC. • An inadequate response is defined as: o ALP ≥ 1.67 times ULN, or o bilirubin > ULN and < 2 times the ULN, or o evidence of compensated cirrhosis. • For patients who experience unmanageable intolerance to UDCA, details must be provided. <u>Claim Notes:</u> • Must be prescribed by, or in consultation with, a gastroenterologist, hepatologist or other physician experienced in the treatment of PBC. • Approval period: 12 months.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Pegfilgrastim	**Lapelga**	**6 mg/0.6 ml**	**Prefilled syringe**	**02474565**	**APO**
Criteria	For the prevention of febrile neutropenia in patients receiving myelosuppressive chemotherapy with curative intent who: • are at high risk of febrile neutropenia due to chemotherapy regimen, co-morbidities or pre-existing severe neutropenia; or • have had an episode of febrile neutropenia, neutropenic sepsis or profound neutropenia in a previous cycle of chemotherapy; or • have had a dose reduction, or treatment delay greater than one week due to neutropenia. Clinical Note: Patients with non-curative cancer receiving chemotherapy with palliative intent are not eligible for coverage of pegfilgrastim for prevention of febrile neutropenia.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Vortioxetine	**Trintellix** **Trintellix** **Trintellix**	**5 mg** **10 mg** **20 mg**	**Tablet** **Tablet** **Tablet**	**02432919** **02432927** **02432943**	**LUD**
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

PROGRAM CHANGE

- Effective immediately (December 6), coverage for the following medications will be moved from the High Cost Drug Program and Catastrophic Drug Program, and will be eligible for coverage through the Cystic Fibrosis Drug Program.

- Patients who have previously been approved for medication listed below will be able to access their medication through Provincial Pharmacy, in a similar manner in which they access other cystic fibrosis medication through this program.

- The Special Authorization criteria for medications listed below remains the same as currently outlined in the online PEI Pharmacare Formulary.

- The medications moved to the Cystic Fibrosis Drug Program are:
    1. Kalydeco (ivacaftor) 150mg tablet DIN 02397412
    2. Pulmozyme (dornase) 1mg/ml inhalation solution DIN 02046733
    3. Trikafta (elexacaftor/tezacaftor/ivacaftor/ivacaftor) tablet DIN 02517140

- Coverage for Orkambi (ivacaftor/lumacaftor) 100mg/125mg & 150mg/188 granule packets and 100mg/125mg & 200mg/125mg tablets may be available through the Cystic Fibrosis Drug Plan for the treatment of cystic fibrosis patients who meet certain medical criteria. Please contact the PEI Pharmacare Program office at 1-877-577-3737 for more information regarding coverage availability and the Special Authorization application process for this product.

UPDATE CLAIM SUBMISSION REMINDER

Please remember that Smart Cards/Copay Assist Cards are required to be submitted to copay-based Pharmacare programs at the end of a claim submission, as these cards assist a client with their copay.The copay based programs include Family Health Benefits, Generic Drug Program, Diabetes Drug Program, High Cost Drug Program, and Seniors Drug Program.

The Catastrophic Drug Program is a deductible-based program, and operates under a deductible based on the applicant's household income, which must be satisfied before the client will receive benefits. As a Smart Card/Copay Assist Card is for assisting with a copay, it is to be applied to the end of a Pharmacare claim for clients enrolled in a copay based program.
For clients enrolled in Catastrophic Drug Program only, a Smart Card/Copay Assist Card cannot be used to accumulate toward the CDP deductible; therefore, if a client is enrolled in CDP, a Smart Card/Copay Assist card will need to be applied before the claim goes to CDP to ensure the client's out of pocket expense is captured by the Catastrophic Drug Program.