Health PEI
One Island Health System

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PEI Pharmacare Bulletin

Issue (2023 - 11) **November 14, 2023**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: November 27, 2023)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Abrocitinib	**Cibinqo**	**50 mg** **100 mg** **200 mg**	**Tablet** **Tablet** **Tablet**	**02528363** **02528371** **02528398**	**PFI**
Criteria	For the treatment of moderate to severe atopic dermatitis (AD) in patients 12 years of age and older who meet all the following criteria: • Patients must have had an adequate trial (with a documented refractory disease, including the relief of pruritis), or were intolerant (with documented intolerance), or are ineligible for each of the following therapies: ○ Maximally tolerated medical topical therapies for AD combined with phototherapy (where available), and ○ Maximally tolerated medical topical therapies for AD combined with at least 1 of the 4 systemic immunomodulators (methotrexate, cyclosporine, mycophenolate mofetil, or azathioprine) • Baseline Physician Global Assessment score of 3 or greater and Eczema Area and Severity Index (EASI) of 7.1 or greater. Renewal Criteria: • Requests for renewal must provide proof of beneficial clinical effect defined as a 75% or greater improvement from baseline in the EASI score (EASI-75) six months after treatment initiation. • Proof of maintenance of EASI-75 response from baseline must be provided for subsequent authorizations. Clinical Note: • Not to be used in combination with phototherapy or any immunomodulatory agents (including biologics or other janus kinase inhibitor treatment) for moderate to severe AD. Treatment should continue until disease progression or unacceptable toxicity. Claim Notes:				

	• The patient must be under the care of a dermatologist, allergist, clinical immunologist, or pediatrician who has expertise in the management of moderate to severe AD. • Approvals will be for a maximum of 200 mg once daily. • Initial approval period: 6 months. • Renewal approval period: 1 year.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Acalabrutinib	**Calquence**	**100 mg**	**Tablet**	**02535696**	**AZE**
Criteria	As per the currently listed Calquence capsule criteria. Please see the online Formulary for details.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Acetylcysteine	**Acetylcysteine**	**200 mg/ml**	**Vial (30 ml)**	**02243098**	**SDZ**
Criteria	Open benefit				
Program Eligibility	Cystic Fibrosis Drug Program, Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Amifampridine	**Ruzurgi**	**10 mg**	**Tablet**	**02503034**	**MDU**
Criteria	For the treatment of Lambert-Eaton myasthenic syndrome (LEMS) in patients 6 years of age or older. Initial Renewal Criteria: • An improvement of at least 30% on the Triple Timed Up and Go (3TUG) test compared to baseline measurement. Subsequent Renewal Criteria: • The patient continues to maintain an improvement of at least 30% on the 3TUG test compared to baseline measurement. Clinical Note: 1. The 3TUG test score must be provided with initial and renewal requests. Claim Notes: 1. Must be prescribed by a neurologist. 2. Approvals will be up to a maximum daily dose of 40 mg for patients weighing less than 45 kg and 100 mg for patients weighing 45 kg or more. 3. Initial approval period: 3 months. Renewal approval period: 1 year.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Asciminib	**Scemblix**	**20 mg** **40 mg**	**Tablet**	**02528320** **02528339**	**NVR**
Criteria	For the treatment of adult patients with Philadelphia chromosome-positive chronic myeloid leukemia (Ph+ CML) in the chronic phase who meet the following criteria: • Treatment failure on or intolerance to a minimum of two prior tyrosine kinase inhibitor (TKI) therapies. • No evidence of a T315I or V299L mutation. Clinical Notes: 1. Patients should have a good performance status.				

	2. Not for use in the acute phase or blast phase.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Dapsone	**Dapsone** **Mar-Dapsone** **Riva-Dapsone**	**100 mg** **100 mg** **100 mg**	**Tablet** **Tablet** **Tablet**	**02528320** **02528339** **02489058**	**JAC** **MAR** **RIV**
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, HIV Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Guselkumab	**Tremfya** **Tremfya**	**100 mg/ml** **100 mg/ml**	**Autoinjector** **Prefilled Syringe**	**02487314** **02469758**	**JAN**
Criteria	Plaque Psoriasis: See online Formulary for eligibility criteria. Psoriatic Arthritis: See online Formulary for eligibility criteria.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Levofloxacin	**Apo-Levofloxacin**	**750 mg**	**Tablet**	**02325942**	**APX**
Criteria	Note: For Cystic Fibrosis and Nursing Home Programs, no Special Authorization is required. a) For the treatment of infections in persons allergic to alternative agents. Up to 10 days of therapy will be considered. b) For the treatment of infections in patients with asthma or COPD not responding to first-line antibiotics. Up to 10 days of therapy will be considered. c) For the treatment of infections caused by organisms known to be resistant to alternative antibiotics. Up to 10 days of therapy will be considered. d) For the completion of treatment started in the hospital inpatient setting. Up to 7 days of therapy will be considered.				
Program Eligibility	Cystic Fibrosis Drug Program, Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Lorlatinib ***Use PDIN when drug cost in excess of CPHA maximum**	**Lorbrena**	**25 mg** **100 mg** **100 mg**	**Tablet** **Tablet**	**02485966** **02485974** **00900025***	**PFI**
Criteria	As monotherapy for the first-line treatment of adult patients with anaplastic lymphoma kinase (ALK)- positive locally advanced (not amenable to curative therapy) or metastatic non-small cell lung cancer. Clinical Note: 1. Treatment should be discontinued upon clinically meaningful disease progression or unacceptable toxicity. Claim Notes: 1. Approval period: 1 year. 2. No further ALK inhibitor will be reimbursed following disease progression on lorlatinib.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Luspatercept	**Reblozyl**	**25 mg**	**Vial**	**02505541**	**CEL**

***Use PDIN when drug cost in excess of CPHA maximum**		**75 mg**	**Vial**	**00904728* 02505568 00904729***	

Criteria	Beta-Thalassemia Anemia
	• For the treatment of adult patients with RBC transfusion-dependent anemia associated with beta-thalassemia. Patients must be receiving regular transfusions, defined as:
	  ○ 6 to 20 RBC units in the 24 weeks prior to initiating treatment with luspatercept, AND
	  ○ No transfusion-free period greater than 35 days in the 24 weeks prior to initiating treatment with luspatercept.
	Renewal Criteria:
	• Patients must demonstrate an initial response, defined as a ≥33% reduction in transfusion burden (RBC units/time) compared to the pre-treatment baseline RBC transfusion burden, measured over 24 weeks prior to initiating treatment with luspatercept.
	• For continued coverage, patients should maintain a reduction in transfusion burden of ≥33% compared to the pre-luspatercept transfusion burden.
	• Luspatercept should be discontinued if a patient does not respond after nine weeks of treatment (three doses) at the maximum dose.
	Claim Notes:
	• The patient should be under the care of a specialist with experience in managing patients with beta-thalassemia.
	• The maximum dose of luspatercept should not exceed 1.25mg/kg (or 120mg total dose) once every three weeks.
	• Initial Approval: 6 months
	• Renewal Approval: 1 year
	Myelodysplastic Syndromes
	• For the treatment of adult patients with red blood cell (RBC) transfusion–dependent anemia associated with very low- to intermediate-risk MDS who have ring sideroblasts and who have failed or are not suitable for erythropoietin-based therapy.
	Renewal Criteria:
	• Patients should be RBC transfusion independent over a minimum of 16 consecutive weeks within the first 24 weeks of treatment initiation.
	• For continued coverage, patients should be RBC transfusion independent over a minimum of 16 consecutive weeks within the previous approval period.
	Claim Notes:
	• Treatment should be initiated by a specialist with expertise in managing and treating patients with MDS.
	• The maximum dose of luspatercept should not exceed 1.75mg/kg (or 168mg total dose) once every three weeks.
	• Approval: 6 months				

Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Sodium phenylbutyrate & Ursodoxicol taurine *Use PDIN when drug cost in excess of CPHA maximum	Albrioza	3 g/1 g	Oral powder	02527707 00904825*	ALY
Criteria	For the treatment of amyotrophic lateral sclerosis (ALS), if the following criteria are met: Initiation: • Patient with a diagnosis of definite ALS; AND • Patient who meets all of the following: 1. have had ALS symptoms for 18 months or less 2. have a forced vital capacity of at least 60% of predicted value 3. not require permanent non-invasive ventilation or invasive ventilation Renewal: • Reimbursement of treatment should be discontinued in patients who meet any one of the following criteria: 1. the patient becomes non-ambulatory and is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place; OR 2. patient requires permanent non-invasive ventilation Claim Notes: • Patient must be under the care of a specialist with experience in the diagnosis and management of ALS.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Triheptanoin *Use PDIN when drug cost in excess of CPHA maximum	Dojolvi	8.3 kcal/ml	Oral Liquid	02512556 00900021*	UGX
Criteria	For the treatment of adult and pediatric patients with an acute life-threatening long-chain fatty acid oxidation disorder (LC-FAOD) who meet the following criteria: • patients with a confirmed diagnosis of LC-FAOD and acute life-threatening events who require alternative therapy to conventional even-chain medium-chain triglyceride (MCT) supplementation, OR • patients without a confirmed diagnosis of LC-FAOD presenting with acute life-threatening events consistent with LC-FAOD who require alternative therapy to conventional even-chain MCT supplementation. Claim Notes: 1. Triheptanoin should only be prescribed by clinicians experienced in the management of LC-FAOD. 2. Approval: 1 year. Confirmation of continued response required.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Tucatinib	Tukysa	50 mg	Tablet	02499827	SGC

***Use PDIN when drug cost in excess of CPHA maximum**		**150 mg**	**Tablet**	**02499835 00904820***	
Criteria	In combination with trastuzumab and capecitabine for the treatment of patients with locally advanced unresectable or metastatic HER2-positive breast cancer who have received prior treatment with trastuzumab, pertuzumab and a HER2-targeted antibody-drug conjugate (e.g., trastuzumab emtansine or trastuzumab deruxtecan), where at least one was given in the advanced or metastatic setting. Clinical Notes: 1. Patients should have a good performance status. 2. Treatment should be discontinued upon disease progression, unacceptable toxicity, or if both trastuzumab and capecitabine are discontinued.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Zanubrutinib	**Brukinsa**	**80 mg**	**Capsule**	**02512963**	**BGN**
Criteria	For the treatment of adult patients with relapsed or refractory Waldenstrom macroglobulinemia who have received at least one prior therapy and have not experienced disease progression on a Bruton's tyrosine kinase inhibitor. Clinical Notes: 1. Patients must meet at least one criterion for treatment as per IWWM consensus panel. 2. Patients must have a good performance status and no evidence of disease transformation. 3. Treatment should be discontinued upon disease progression or unacceptable toxicity.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

CRITERIA UPDATE

Effective immediately, the criteria for currently listed **Lenvima (lenvatinib)** medications have been updated to include the following indications:

1. Advanced Endometrial Carcinoma

   Lenvatinib combined with pembrolizumab for the treatment of adult patients with advanced endometrial carcinoma that is not microsatellite instability high (MSI-H) or mismatch repair deficient (dMMR), who have disease progression following prior platinum-based systemic therapy, and are not candidates for curative surgery or radiation.

2. Advanced and Metastatic Renal Cell Carcinoma

   Lenvatinib combined with pembrolizumab for the treatment of adult patients with advanced (not amenable to curative surgery or radiation) or metastatic renal cell carcinoma (RCC) who have had no prior systemic therapy for metastatic disease.

Program eligibility remains the same (Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program).

Effective immediately, the criteria for currently listed **Rituximab** medications have been updated to the following:

For the treatment of patients with:

1. Rheumatoid arthritis who have a severe intolerance or other contraindication to an anti-TNF agent or failed an adequate trial of an anti-TNF agent.
2. Vasculitis who have a severe intolerance or other contraindication to cyclophosphamide or failed an adequate trial of cyclophosphamide.
3. Other autoimmune diseases whom have failed previous treatments.

Clinical Note: A detailed description of previously failed treatments must be provided.

Claim Notes:

1. Must be prescribed by a specialist.
2. Initial approval period: 6 months. Confirmation of response is required.

Effective immediately, the criteria for currently listed **Tagrisso (osimertinib)** medications have been updated to include the following indication:

- For adjuvant therapy after tumour resection in patients with Stage IB-IIIA (AJCC 7th edition or equivalent) non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) exon 19 deletions [exon 19 del] or exon 21 [L858R] substitution mutations.

Clinical Notes:

- Patients should have a good performance status.
- Treatment with osimertinib should continue for a total duration of 3 years, or until disease recurrence or unacceptable toxicity.
- Osimertinib treatment should be initiated within 10 weeks of complete surgical resection if adjuvant chemotherapy was not administered, or within 26 weeks if adjuvant chemotherapy was administered.
- Retreatment with osimertinib in the metastatic setting will be considered if disease recurrence is at least 6 months following completion of adjuvant therapy.
- Program eligibility remains the same (Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program).

MEDICATIONS MOVING FROM SPECIAL AUTHORIZATION TO OPEN BENEFIT

Effective immediately, the following currently listed medications no longer require Special Authorization, and will be open benefit in their applicable Pharmacare program(s). Please refer to the online Formulary for eligible medications.

MEDICATION	STRENGTH	DOSAGE FORM
Duloxetine	30 mg 60 mg	Capsule
Dapagliflozin	5 mg 10 mg	Tablet Tablet
Itraconazole	100 mg	Capsule
Lacosamide	50 mg 100 mg 150 mg 200 mg	Tablet Tablet Tablet Tablet
Lurasidone	20 mg 40 mg 60 mg 80 mg 120 mg	Tablet Tablet Tablet Tablet Tablet
Raloxifene	60 mg	Tablet
Terbinafine	250 mg	Tablet
Zoledronic Acid	5 mg/100 ml	IV Solution

MEDICATIONS WITH EXPANDED PROGRAM COVERAGE

Effective November 27, 2023, the following list of medications currently listed in the Catastrophic Drug Program only, will be eligible for coverage in the following Pharmacare Program(s) as well.

There has been no change in Special Authorization criteria; please see the online Formulary for details on Special Authorization criteria for each medication.

MEDICATION	STRENGTH/DOSAGE FORM	NEW PROGRAM COVERAGE (IN ADDITION TO CDP) EFFECTIVE NOVEMBER 27, 2023
Asenapine	5 mg sublingual tablet 10 mg sublingual tablet	Family Health Benefits Drug Program Financial Assistance Drug Program Nursing Home Drug Program Seniors Drug Program
Deferasirox	90 mg tablet 180 mg tablet 360 mg tablet 125 mg dispersible tablet 250 mg dispersible tablet 500 mg dispersible tablet	High Cost Drug Program Financial Assistance Drug Program Nursing Home Drug Program
Febuxostat	80 mg tablet	Family Health Benefits Drug Program Financial Assistance Drug Program Generic Drug Program Nursing Home Drug Program Seniors Drug Program
Onabotulinum Toxin A	200 unit vial	Family Health Benefits Drug Program Financial Assistance Drug Program Nursing Home Drug Program Seniors Drug Program
Rufinamide	100 mg tablet 200 mg tablet 400 mg tablet	Family Health Benefits Drug Program Financial Assistance Drug Program Nursing Home Drug Program Seniors Drug Program