Health PEI
One Island Health System

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PEI Pharmacare Bulletin

Issue (2023 - 3) **March 13, 2023**

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

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Amlodipine	**pdp-Amlodipine**	**1 mg/ml**	**Oral Solution**	**02484706**	**PEN**
Criteria	For patients who require administration through a feeding tube. For patients 19 years of age and younger, who cannot use a tablet or capsule.				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program**,** Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Budesonide/ glycopyrronium/ formoterol	**Breztri**	**182 mcg-8.2 mcg-5.8 mcg per actuation**	**Metered Dose Inhaler**	**02518058**	**AZE**
Criteria	For the treatment of chronic obstructive pulmonary disease (COPD), as defined by spirometry, in patients who experience inadequate control while being treated with a long-acting beta-2 agonist/long-acting muscarinic antagonist (LABA/LAMA). Clinical Notes 1. COPD is defined by spirometry as a post-bronchodilator FEV1/FVC ratio of less than 0.70. Spirometry reports from any point in time will be accepted. 2. Inadequate control while being treated with a LABA/LAMA for at least two months is defined as persistent symptoms or experiencing two or more exacerbations of COPD in the previous year requiring treatment with antibiotics and/or systemic corticosteroids or at least one exacerbation of COPD requiring hospitalization. Patients should not be started on a LABA, LAMA and an inhaled corticosteroid (triple inhaled therapy) as initial therapy				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program**,** Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Everolimus	**Various Generics**	**2.5 mg 5 mg 10 mg**	**Tablet Tablet Tablet**	**Various DIN's**	**Various Manufacturers**
Criteria	For the treatment of patients with advanced or metastatic renal cell carcinoma following disease progression on tyrosine kinase inhibitor therapy. Clinical Notes:				

	• Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Requests for everolimus will not be considered for patients who experience disease progression on axitinib, cabozantinib or nivolumab monotherapy. Claim Notes: • Initial approval period: 6 months. • Renewal approval period: 1 year. In combination with exemestane for postmenopausal patients (ECOG PS ≤2) with documented hormone receptor positive, HER2 negative-advanced breast cancer after recurrence or progression following a non-steroidal aromatase inhibitor (NSAI). Clinical Notes: • Patients must have a good performance status. • Treatment should be discontinued upon disease progression or unacceptable toxicity. Claim Notes**:** • Requests for everolimus will not be considered for patients who experience disease progression on CDK4/6 inhibitor therapy. • Approval period: 1 year. For the treatment of patients with progressive, unresectable, well or moderately differentiated, locally advanced or metastatic pancreatic neuroendocrine tumors (pNET) with good performance status (ECOG 0-2), until disease progression. Claim Notes: • Patients whose disease progresses on sunitinib are not eligible for funded treatment with everolimus for pNET. • Approval period: 1 year. As a single agent treatment for patients with unresectable, locally advanced or metastatic; well-differentiated nonfunctional neuroendocrine tumours (NETs) of gastrointestinal or lung origin (GIL) in adults with documented radiological disease progression within six months and with a good performance status. • Treatment should continue until confirmed disease progression or unacceptable toxicity. Claim Notes: • Approval period: 1 year.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Levetiracetam	**pdp-Levetiracetam**	**100 mg/ml**	**Oral Solution**	**02490447**	**PEN**
Criteria	For patients who require administration through a feeding tube. For patients 19 years of age and younger, who cannot use a tablet or capsule.				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program**,** Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Levodopa/carbidopa	**Duodopa**	**20 mg/ml; 5 mg/ml**	**Intestinal Gel Cassette**	**02292165**	**ABV**

Criteria	For the treatment of patients with advanced levodopa-responsive Parkinson's Disease (PD) who meet all of the following criteria: • Experiences severe disability with at least 25% of the waking day in the off state and/or ongoing levodopa-induced dyskinesias, despite having tried frequent dosing of levodopa (at least five doses per day). • Received an adequate trial of maximally tolerated doses of levodopa, with demonstrated clinical response. • Failed an adequate trial of the following adjunctive medications, if not contraindicated and/or contrary to the clinical judgement of prescriber: entacapone, a dopamine agonist, a monoamine oxidase-B (MAO-B) inhibitor and amantadine. • Must be able to administer the medication and care for the administration port and infusion pump. Alternatively, trained personnel or care partner must be available to perform these tasks reliably. Exclusion Criteria: • Patients with a contraindication to the insertion of a PEG-J tube. • Patients with severe psychosis or dementia. Renewal criteria: • Patients continue to demonstrate a significant reduction in the time spent in the off state and/or ongoing levodopa-induced dyskinesias, along with and an improvement in the related disability. Clinical Note: • Time in the off state, frequency of motor fluctuations, and severity of associated disability should be assessed by a movement disorder subspecialist and be based on an adequate and reliable account from longitudinal speciality care, clinical interview of a patient and/or care partner, or motor symptom diary. Claim Notes: • Must be prescribed by a movement disorder subspecialist who has appropriate training in the use of Duodopa and is practicing in a movement disorder clinic that provides ongoing management and support for patients receiving treatment with Duodopa. • Approval period: 1 year.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Natalizumab	**Tysabri**	**300 mg/15 ml**	**Vial**	**02286386**	**BGN**
Criteria	Initial Request: For the treatment of Relapsing-Remitting Multiple Sclerosis (RRMS) who meet all the following criteria: • The patient's physician is a neurologist experienced in the management of relapsing-remitting multiple sclerosis (RRMS); AND the patient; o has a current EDSS less than or equal to 5.0; AND o has failed to respond to a full and adequate course[1] (at least six months) of at least ONE disease modifying therapy OR has contraindications/intolerance to at least TWO disease modifying therapies; AND o has had ONE of the following types of relapses in the past year: ▪ the occurrence of one relapse with partial recovery during the past year AND has at least ONE gadolinium-enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI; OR ▪ the occurrence of two or more relapses with partial recovery during the past year; OR ▪ the occurrence of two or more relapses with complete recovery during the past year AND has at least ONE gadolinium-				

	enhancing lesion on brain MRI, OR significant increase in T2 lesion load compared to a previous MRI. • Approval period: 1 year. Requirements for Initial Requests: • the patient's physician provides documentation setting out the details of the patient's most recent neurological examination within ninety (90) days of the submitted request. This must include a description of any recent attacks, the dates, and the neurological findings. • MRI reports do NOT need to be submitted with the initial request. Renewal: Date and details of the most recent neurological examination and EDSS scores must be provided (exam must have occurred within the last 90 days); AND • Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year; AND • Recent Expanded Disability Status Scale (EDSS) score less than or equal to 5.0. 1.Failure to respond to a full and adequate course is defined as a trial of at least one approved first line therapy for a minimum of 6 months AND experienced at least one disabling relapse (attack) while on this
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Ofatumumab	**Kesimpta**	**20 mg/0.4 ml**	**Prefilled Pen**	**02511355**	**NVR**
Criteria	For the treatment of adult patients with relapsing remitting multiple sclerosis (RRMS) who meet all of the following criteria: • An Expanded Disability Status Scale (EDSS) score of less than 6.0 • Evidence of active disease defined as at least one of the following: ▪ One relapse during the previous year ▪ Two relapses during the previous 2 years ▪ A positive gadolinium (Gd)-enhancing MRI scan during the year before starting treatment with ofatumumab. Renewal Criteria: • EDSS score less than 6.0. Date and details of the most recent neurological examination and EDSS score must be provided (exam must have occurred within the last 90 days); AND • Patients must be stable or have experienced no more than 1 disabling attack/relapse in the past year. Claim Notes: • Approval: 1 year. • Combined use with other disease modifying therapies to treat multiple sclerosis will not be reimbursed. • Must be prescribed by a neurologist with experience in the diagnosis and management of multiple sclerosis.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Progesterone micronized	**Various generics**	**100 mg**	**Capsule**	**Various DIN's**	**Various Manufacturers**
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				

Propranolol	**Hemangiol**	**3.75 mg/ml**	**Oral Solution**	**02457857**	**PFB**
Criteria	For the treatment of patients with proliferating infantile hemangioma that is:				

	• Life-or function-threatening OR • Ulcerated with pain or not responding to simple wound care measures OR • At risk of permanent scarring or disfigurement
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program**,** Catastrophic Drug Program

Risdiplam	**Evrysdi**	**0.75 mg/ml**	**Pws for Sol**	**02514931**	**HLR**

Criteria	For patients diagnosed with 5q Spinal Muscular Atrophy (SMA) under the care of a specialist with experience in the diagnosis and management of SMA, if the following clinical criteria are met:
	• Genetic documentation of 5q SMA homozygous gene deletion or compound heterozygote, AND
	• Patients who:
	  ○ are symptomatic and have genetic documentation of two or three copies of the SMN2 gene, AND
	  ○ aged between 2 months and 7 months (inclusive), OR
	  ○ aged 8 months up to 25 years and are non-ambulatory
	• Patient is not currently requiring permanent invasive ventilation*, AND
	• A baseline assessment using an age-appropriate scale (the Hammersmith Infant Neurological Examination [HINE] Section 2, Children's Hospital of Philadelphia Infant Test of Neuromuscular Disorders [CHOP INTEND], or Hammersmith Functional Motor Scale-Expanded [HFMSE]) must be completed prior to initiation of risdiplam treatment.
	• For continued coverage, the patient must meet the following criteria:
	There is demonstrated achievement or maintenance of motor milestone function (as assessed using age-appropriate scales: the [HINE] Section 2, CHOP INTEND, or HFMSE) after treatment initiation in patients aged between 2 months and 2 years at the time of treatment initiation; OR
	  ○ There is demonstrated maintenance of motor milestone function (as assessed using age-appropriate scales: the HINE Section 2, CHOP INTEND, or HFMSE) after treatment initiation in patients aged between 2 years and 25 years at the time of treatment initiation; AND
	  ○ Patient does not require permanent invasive ventilation*.
	The decision to discontinue reimbursement should be based on 2 assessments separated by no longer than a 12-week interval.
	Claim Notes:
	• Approval: 12 months
	
	* Permanent invasive ventilation is defined as the use of tracheostomy and a ventilator due to progression of SMA that is not due to an identifiable and reversible cause.				

Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Siponimod	**Mayzent**	**0.25 mg** **2 mg**	**Tablet** **Tablet**	**02496429** **02496437**	**NVR**
Criteria	Initiation Criteria: For the treatment of patients with active secondary progressive multiple sclerosis, who meet all the following criteria: • a history of relapsing-remitting multiple sclerosis (RRMS) • an Expanded Disability Status Scale (EDSS) score of 3.0 to 6.5 • documented EDSS progression during the two years prior to initiating treatment with siponimod (≥ 1 point if EDSS < 6.0; ≥ 0.5 points if EDSS ≥ 6.0 at screening). Renewal Criteria:				

	• Patients who do NOT exhibit evidence of disease progression since the previous assessment. Disease progression is defined as: o an increase in the EDSS score of greater than or equal to 1 point if the EDSS score was 3.0 to 5.0 at siponimod initiation *OR* o an increase of greater than or equal to 0.5 points if the EDSS score was 5.5 to 6.5 at siponimod initiation Patients who do NOT exhibit one of the following: o progression to an EDSS score of equal to or greater than 7.0 at any time during siponimod treatment o confirmed worsening of at least 20% on the timed 25-foot walk (T25W) since initiating siponimod treatment Clinical Notes: • Patients should be assessed for a response to siponimod every six months. Claims Notes: • The patient is under the care of a neurologist with experience in the diagnosis and management of multiple sclerosis. • Siponimod should not be used in combination with other disease-modifying treatments (DMTs) used to treat multiple sclerosis. • Approval period: 1 year
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

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

Effective immediately, currently listed Donepezil medications will no longer require a Special Authorization Request and will be available as open benefits in listed Pharmacare programs.

Effective immediately, any requests for consideration of coverage of currently listed Multiple Sclerosis medications may be submitted using a Standard Special Authorization Request form.
The PEI Multiple Sclerosis Medications Program Medical Screening Form is no longer in use.