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 - 9) **November 9, 2021**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: (NOVEMBER 22, 2021)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Dupilumab	Dupixent Dupixent Dupixent	200 mg/1.14 ml 300 mg/2 ml 300 mg/2 ml	Syringe Prefilled pen Prefilled syringe	02492504 02510049 02470365	AVN
Criteria	For the treatment of moderate to severe atopic dermatitis in patients 12 years and older who meet all of the following criteria: • Refractory or have contraindications to an adequate trial of topical prescription therapies • Refractory, intolerant or have contraindications to an adequate trial of phototherapy (where available), methotrexate, and cyclosporine. • Baseline Eczema Area and Severity Index (EASI) score of ≥ 7.1 and Physician Global Assessment score of ≥3 at the time of initial request for reimbursement. • The maximum duration of initial authorization is 6 months. Renewal Criteria: • Renewal requests 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: • The patient must be under the care of a dermatologist. • Dupilumab is not to be used in combination with phototherapy or immunosuppressant drugs, such as methotrexate or cyclosporine. • Approvals will be for a maximum of 600 mg at week 0, then 300 mg every two weeks thereafter				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Edaravone	Radicava	0.3 mg/ml	Solution for injection	02475472	BMT
Criteria	For the treatment of patients with probable or definite amyotrophic lateral sclerosis (ALS) who meet all of the following criteria: Initiation Criteria: • Scores of at least two points on each item of the ALS Functional Rating Scale – Revised (ALSFRS-R)				

	• Forced vital capacity is greater than or equal to 80% of predicted • ALS symptoms for two years or less • Not currently requiring permanent non-invasive or invasive ventilation. Discontinuation Criteria: • Patient becomes non-ambulatory (ALSFRS-R score ≤ 1 for item 8) AND is unable to cut food and feed themselves without assistance, irrespective of whether a gastrostomy is in place (ALSFRS-R score < 1 for item 5a or 5b); or • Patient requires permanent non-invasive or invasive ventilation. Clinical Note : • Patient must be under the care of a specialist with experience in the diagnosis and management of ALS. • Approval period: 6 months
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Etonogestrel	Nexplanon	68 mg	SC Implant	02499509	ORG
Criteria	Open benefit				
Program Eligibility	Family Health Benefits Drug Program, Financial Assistance Drug Program, Catastrophic Drug Program				

Fluticasone propionate	Aermony Respiclick Aermony Respiclick Aermony Respiclick	55 mcg 113 mcg 232 mcg	Aerosol Powder Aerosol Powder Aerosol Powder	02467895 02467909 02467917	TEV
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				

Rivaroxaban	Xarelto	2.5 mg	Tablet	02480808	BAY
Criteria	For use in combination with acetylsalicylic acid (75 mg to 100 mg) for the prevention of atherothrombotic events1in patients with concomitant coronary artery disease (CAD) and peripheral artery disease (PAD) who meet the following criteria: •Patients with CAD are defined as having one or more of the following: • Myocardial infarction within the last 20 years. • Multi-vessel CAD (i.e., stenosis of ≥ 50% in two or more coronary arteries, or in one coronary territory if at least one other territory has been revascularized) with symptoms or history of stable or unstable angina. • Multi-vessel percutaneous coronary intervention. • Multi-vessel coronary artery bypass graft surgery. AND •Patients with CAD as defined above, must also meet one of the following criteria: • Aged 65 years or older; OR • Aged younger than 65 years with documented atherosclerosis or revascularization involving at least two vascular beds (coronary and other vascular) or at least two additional risk factors (current smoker, diabetes mellitus, estimated glomerular filtration rate < 60 mL/min, heart failure, non-lacunar ischemic stroke 1 month or more ago). •Patients with PAD are defined as having one or more of the following: • Previous aorto-femoral bypass surgery, limb bypass surgery, or percutaneous transluminal angioplasty revascularization of the iliac or infrainguinal arteries. • Previous limb or foot amputation for arterial vascular disease. • History of intermittent claudication and one or more of the following: an ankle-				

	brachial index of less than 0.90, OR significant peripheral artery stenosis greater than or equal to 50% documented by angiography or duplex ultrasound. • Previous carotid revascularization or asymptomatic carotid artery stenosis greater than or equal to 50% diagnosed by angiography or duplex ultrasound. Exclusion Criteria: •Patients who have CAD or PAD alone; OR •In patients with any one of the following characteristics: • At high risk of bleeding. • A history of stroke within one month of treatment initiation or any history of hemorrhagic or lacunar stroke. • Severe heart failure with a known ejection fraction less than 30% or New York Heart Association class III or IV symptoms. • An Estimated glomerular filtration rate less than 15 mL/min. • Require dual antiplatelet therapy, other non-ASA antiplatelet therapy, or oral anticoagulant therapy. Clinical Notes: 1. Atherothrombotic events include stroke, myocardial infarction, cardiovascular death, acute limb ischemia and mortality.
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program

Tafamidis meglumine	Vyndaqel	20 mg	Capsule	02495732	PFI
Criteria	For the treatment of cardiomyopathy in adult patients with documented hereditary or wild-type transthyretin-mediated amyloidosis (ATTR) who meet all of the following criteria: • New York Heart Association (NYHA) class I to III heart failure • At least one prior hospitalization for heart failure or clinical evidence of heart failure that required treatment with a diuretic • Has not previously undergone a heart or liver transplant • Does not have an implanted cardiac mechanical assist device (CMAD) Discontinuation Criteria: The patient has: • NYHA class IV heart failure, or • received an implanted CMAD, or • received a heart or liver transplant. Clinical Notes: 1. Wild-type ATTR-cardiomyopathy (CM) consists of all of the following: • absence of a variant transthyretin (TTR) genotype • TTR precursor protein identification by immunohistochemistry, scintigraphy, or mass spectrometer • evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm • presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connection tissue sheath, or cardiac tissue) 2. Hereditary ATTR-CM consists of all of the following: • presence of a variant TTR genotype associated with CM and presenting with a CM phenotype • evidence of cardiac involvement by echocardiography with end-diastolic interventricular septal wall thickness greater than 12 mm • presence of amyloid deposits in biopsy tissue (fat aspirate, salivary gland, median nerve connective tissue sheath, or cardiac tissue)				

	Claim Notes: • The patient must be under the care of a physician with experience in the diagnosis and treatment of ATTR-CM. • Combination therapy with other interfering ribonucleic acid drugs or transthyretin stabilizers used to treat ATTR-CM will not be reimbursed. • Initial approval period: 9 months. • Renewal approval period: 1 year.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Vedolizumab	Entyvio SC Entyvio SC	108 mg/0.68 ml 108 mg/0.68 ml	Prefilled Syringe Prefilled Pen	02497875 02497867	TAK
Criteria	Crohn's Disease: For the treatment of patients with moderate to severe Crohn's disease who have active disease and are refractory, intolerant or have contraindications to: • Prednisone 40mg (or equivalent) daily for ≥ 2 weeks, AND • Azathioprine ≥ 2 mg/kg/day for ≥ 3 months, OR • Mercaptopurine ≥ 1 mg/kg/day for ≥ 3 months, OR • Methotrexate (SC or IM) ≥ 15 mg/week for ≥ 3 months Clinical Notes: • Refractory is defined as lack or loss of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects to treatments. The nature of intolerance(s) must be clearly documented. • Consideration will be given for the approval of a biologic DMARD (disease modifying antirheumatic drug) without a trial of a traditional DMARD for patients who have an aggressive/severe disease course (e.g. extensive disease, a modified Harvey Bradshaw Index score > 16) and are refractory, intolerant or have contraindications to systemic corticosteroids. • Intravenous infusion: Approvals will be for maximum of 300 mg at week 0, 2, and 6, then 300 mg every eight weeks. • Subcutaneous injection: Approvals will be for a maximum of 108 mg every two weeks following at least two intravenous infusions of vedolizumab. Claim notes: • Initial approval: 12 weeks. Renewal Approval: 1 year. Confirmation of continued response is required. • Combined use of more than one biologic DMARD will not be reimbursed. Ulcerative Colitis: 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. Clinical Notes: • Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. • Intolerant is defined as demonstrating serious adverse effects or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be				

	clearly documented. • Patients with severe disease (partial Mayo > 6)do not require a trial of 5-ASA • Intravenous infusion: Approvals will be for maximum of 300 mg at week 0, 2, and 6, then 300 mg every eight weeks. • Subcutaneous injection: Approvals will be for a maximum of 108 mg every two weeks following at least two intravenous infusions of vedolizumab. Claim Notes: • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Combined use of more than one biologic DMARD will not be reimbursed. • Initial Approval: As per induction approval. • Renewal Approval: 1 year.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

CRITERIA UPDATE

Perampanel	Fycompa	2 mg 4 mg 6 mg 8 mg 10 mg 12 mg	Tablet Tablet Tablet Tablet Tablet Tablet	02404516 02404524 02404532 02404540 02404559 02404567	EIS
Criteria	The criteria has been update to the following: For the adjunctive treatment of refractory partial-onset seizures or primary generalized tonic-clonic seizures in patients who are currently receiving two or more antiepileptic drugs, and who have had an inadequate response to at least three other antiepileptic drugs.				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

INFORMATION

Effective immediately, Idacio (adalimumab) Prefilled Syringe DIN 02502682 has been added to the High Cost Drug Program and Catastrophic Drug Program. The coverage will be the same as currently listed adalimumab products and criteria can be found in the PEI Pharmacare online Formulary.

CLAIM SUBMISSION REMINDER

Please remember that Smart Cards/Copay Assist Cards are required to be submitted to Pharmacare at the end of a claim submission.

Effective July 2014, PEI Pharmacare became Payer of Last Resort as per legislation, requiring all Pharmacare claims to be submitted to private insurance first, and Pharmacare last. However, Smart Cards/Copay Assist Cards are not considered private insurance and do not fall under this legislation, and are required to be submitted at the end of any Pharmacare claim submission.

The following are some examples of the order of claim submission.

1. For a claim where the client has Pharmacare and a Smart Card/Copay Assist card, submit to Pharmacare first, and then to the Smart Card/Copay Assist Program
2. For a claim where the client has private insurance, Pharmacare coverage and a Smart Card/Copay Assist Card, submit to private insurance, then Pharmacare, and finally to the Smart Card/Copay Assist Program