Health PEI
One Island Health System

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PEI Pharmacare Bulletin

Issue (2022 - 8) **July 11, 2022**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: JULY 25, 2022)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
ADALIMUMAB	SIMLANDI	40 mg/0.4 ml 40 mg/0.4 ml 80 mg/0.8 ml	PREFILLED SYRINGE AUTO-INJECTOR PREFILLED SYRINGE	02523949 02523957 02523965	JPC
Criteria	For the treatment of ankylosing spondylitis, Crohn's disease, plaque psoriasis, psoriatic arthritis, ulcerative colitis and rheumatoid arthritis with the same criteria as for existing adalimumab products listed in the PEI Pharmacare Formulary. For adalimumab naïve patients, requests for adalimumab will be approved for a biosimilar product.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

ALIROCUMAB	PRALUENT	75 mg/ml 150 mg/ml	PREFILLED PEN PREFILLED PEN	02453819 02453835	SAV
Criteria	For the treatment of heterozygous familial hypercholesterolemia (HeFH) in adult patients who require additional lowering of low-density lipoprotein cholesterol (LDL-C) if the following criteria are met: • Definite or probable diagnosis of HeFH using the Simon Broome or Dutch Lipid Network criteria or genetic testing; and • Patient is unable to reach LDL-C target (less than 2.0 mmol/L or at least a 50% reduction in LDL-C from untreated baseline) despite confirmed adherence to at least 3 months of continuous treatment with: high-dose statin (e.g.atorvastatin 80 mg, rosuvastatin 40 mg) in combination with ezetimibe; or–ezetimibe alone, if high dose statin is not possible due to rhabdomyolysis, contraindication or intolerance. **Initial renewal criteria:** • A reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L. **Subsequent renewal criteria:** • The patient continues to maintain a reduction in LDL-C of at least 40% from baseline or has reached a target LDL-C less than 2.0 mmol/L.				

	Clinical Notes: 1. LDL-C levels must be provided. 2. Intolerance to high dose statin will be considered if patient has developed documented myopathy or abnormal biomarkers (i.e. creatinine kinase greater than 5 times the upper limit of normal) after trial of at least two statins and−for each statin, dose reduction was attempted rather than statin discontinuation, and intolerance was reversible upon statin discontinuation, but reoccurred with statin re-challenge where clinically appropriate; and −at least one statin was initiated at the lowest daily starting dose; and−other known causes of intolerance have been ruled out. 3. For patients who cannot take ezetimibe due to an intolerance or contraindication, details must be provided. **Claim Notes:** • Approvals will be for a maximum of 300mg every 4 weeks. • Initial approval period: 6 months. Renewal approval period: 1 year.
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program

BUROSUMAB	CRYSVITA	10 mg/ml 20 mg/ml 30 mg/ml	VIAL VIAL VIAL	02483629 02483637 02483645	ULT
Criteria	For the treatment of patients with X-linked hypophosphatemia (XLH) who meet the following criteria: • Initiated in a pediatric patient who is at least one year of age and in whom epiphyseal closure has not yet occurred • Fasting hypophosphatemia • Normal renal function (defined as a serum creatinine below the age-adjusted upper limit of normal) • Radiographic evidence of rickets with a rickets severity score (RSS) of two or greater • Confirmed phosphate-regulating endopeptidase homolog, X-linked (PHEX) gene variant in either the patient or in a directly related family member with appropriate X-linked inheritance Discontinuation Criteria: In pediatric patients under 18 years of age in whom epiphyseal closure has not yet occurred and who met the above criteria, treatment should be discontinued if : • there is no demonstrated improvement in the 12-month RSS total score from baseline RSS total score; or • the patient's RSS total score achieved after the first 12 months of therapy has not been maintained subsequently. In adolescent patients who are 13 to 17 years of age in whom epiphyseal closure has occurred and who met the above criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur: • Hyperparathyroidism; or • Nephrocalcinosis; or • Evidence of fracture or pseudo-fracture based on radiographic assessment. In adult patients who met the above criteria and initiated treatment as a pediatric patient, treatment should be discontinued if any of the following occur: • Hyperparathyroidism; or • Nephrocalcinosis; or • Evidence of fracture or pseudo-fracture based on radiographic assessment. Claim Notes: • Requests will not be considered for treatment-naïve adults					

	. • Must be prescribed by a physician working in a multidisciplinary team of health care providers who are experienced in the diagnosis and management of XLH . • Approvals for children (1-17 years of age) will be up to a maximum of 90mg every 2 weeks . • Approvals for adults (18 years of age and older) will be up to a maximum of 90mg every 4 weeks. • Approval period: 1 year.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

CRITERIA UPDATE

Currently listed Lenalidomide products (Revlimid and generics) criteria for Multiple Myeloma have been updated to the following:

For the treatment of newly diagnosed Multiple Myeloma, in combination with daratumumab and dexamethasone, for patients who are not suitable for autologous stem cell transplant and have a good performance status.

For the treatment of Multiple Myeloma when used in combination with dexamethasone, in patients who:

- Are not candidates for autologous stem cell transplant;
  AND
- Where the patient is either:
  - Refractory to or has relapsed after the conclusion of initial or subsequent treatments and who is suitable for further chemotherapy;
  OR
  - Has completed at least one full treatment regimen therapy and is experiencing intolerance to their current chemotherapy.

For the Maintenance Treatment of patients with newly diagnosed Multiple Myeloma, following autologous stem-cell transplantation (ASCT), in patients who are with stable disease or better, with no evidence of disease progression.

NOTICE

Effective immediately, currently listed naltrexone 50 mg tablets and acamprosate 333 mg tablets will no longer require special authorization for clients registered in the Substance Use Harm Reduction Program.

Special authorization criteria will continue to be in place for clients accessing either of these medications through the Financial Assistance Drug Program, Family Health Benefit Drug Program, Nursing Home Drug Program, Seniors Drug Program, and Catastrophic Drug Program with the following criteria:

- Naltrexone 50 mg tablets – For the treatment of alcohol use disorder
- Acamprosate 333 mg tablets – For the treatment of alcohol use disorder

For currently listed Eylea and Lucentis products, initial approval is for a 12 month period, and renewals are considered on an annual basis.