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P.E.I. Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY
(Effective Date: July 22, 2019)

Product (Generic Name)	Product (Brand Name)	Strength	Dosage Form	DIN	MFR
Sarilumab	**Kevzara**	150mg/1.14 ml 150mg/1.14ml 200mg/1.14ml 200mg/1.14ml	Syringe Pen Syringe Pen	02460521 02472961 02460548 02472988	AVN
Criteria	For the treatment of severely active rheumatoid arthritis, in combination with methotrexate or other disease-modifying antirheumatic drugs (DMARDs), in adult patients who are refractory or intolerant to: Methotrexate (oral or parenteral) at a dose of ≥20 mg weekly (15mg if patient is 65 years of age), (or use in combination with another DMARD) for a minimum of 12 weeks AND Methotrexate in combination with at least two other DMARDs, such as hydroxychloroquine and sulfasalazine, for a minimum of 12 weeks; Clinical Notes: For patients who do not demonstrate a clinical response to oral methotrexate, or who experience gastrointestinal intolerance, a trial of parenteral methotrexate must be considered. Optimal treatment response to DMARDs may take up to 24 weeks, however coverage of a biologic therapy can be considered if no improvement is seen after 12 weeks of triple DMARD use. If patient factors (e.g. intolerance) prevent the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried. 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. Claim Notes: Must be prescribed by a rheumatologist. Combined use of more than one biologic DMARD will not be reimbursed. Initial Approval: 6 months Renewal Approval: 1 year. Confirmation of continued response is required.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				
Sevelamer carbonate	**Accel Sevelamer**	800 mg	Tablet	02461501	ACC
Criteria	For the treatment of hyperphosphetemia (>1.8 mmol/L) in patients with end stage renal disease (eGFR<15ml/min) who have: - Inadequate control of phosphate levels on a calcium based phosphate binder, or - Hypercalcemia (corrected for albumin), or - Calciphylaxis (calcific arteriolopathy) Initial approval for 6 months, renewed at 1 year intervals with demonstration of clinically meaningful improvement of phosphate levels (lab values must be provided). Note: This product is not considered interchangeable with currently listed sevelamer hcl (Renagel).				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Program, Generic Drug Program, Seniors Drug Program, Nursing Home Program, Catastrophic Drug Program				

Edoxaban	**Lixiana**	15 mg 30 mg 60 mg	Tablet Tablet Tablet	02458640 02458659 02458667	SER

Criteria	For the treatment of deep vein thrombosis (DVT) or pulmonary embolism (PE) for up to six (6) months. NOTE: The recommended dose of edoxaban for patients initiating DVT or PE treatment is 60mg once daily following initial use of a parenteral anticoagulant for 5 to 10 days. Edoxaban 30mg once daily is recommended in patients with one or more of the following clinical factors: • Moderate renal impairment (creatinine clearance (CrCl) 30-50 mL/min) • Low body weight less than or equal to 60kg, or • Concomitant use of P-glycoprotein (P-gp) inhibitors except amiodarone and verapamil Since renal impairment can increase bleeding risk, it is important to monitor renal function regularly. Other factors that increase bleeding risks should also be assessed and monitored (see product monograph). **For the prevention of stroke and systemic embolism in at-risk patients with non-valvular atrial fibrillation for whom:** a) Anticoagulation is inadequate following at least a two month trial of warfarin; OR b) Warfarin is contraindicated or not possible due to inability to regularly monitor through International Normalized Ratio (INR) testing (i.e. no access to INR testing services at a laboratory, clinic, pharmacy, and at home). The following patient groups are **excluded** from coverage for edoxaban for atrial fibrillation: a) Patients with impaired renal function (creatinine clearance or estimated glomerular filtration rate <30 mL/min) b) Patients ≥75 years of age or older without documented stable renal function c) Patients who have hemodynamically significant rheumatoid valvular heart disease (especially mitral stenosis), or who have prosthetic heart valves. • Safety and efficacy have not been studied in patients with prosthetic (mechanical or biological) heart valves or those with hemodynamically significant rheumatic heart disease, especially mitral stenosis. The recommended dose of edoxaban for patients initiating treatment is 60 mg once daily. Edoxaban 30 mg once daily is recommended in patients with one or more of the following clinical factors: moderate renal impairment (creatinine clearance 30 mL/min to 50 mL/min); low body weight ≤ 60 kg; or concomitant use of P-glycoprotein inhibitors, except amiodarone and verapamil.
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Seniors Drug Program, Nursing Home Drug Program, Catastrophic Drug Program