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PEI Pharmacare Bulletin

Issue (2022 - 2) **February 14, 2022**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: (FEBRUARY 28, 2022)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN/PDIN	MFR
Baricitinib	Olumiant	2 mg	Tablet	02480018	LIL
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) , alone or in combination with another DMARD, at a dose of ≥ 20mg weekly (≥ 15mg in patient is ≥ 65 years of age), for a minimum of 12 weeks AND • Methotrexate in combination with at least two other DMARDs, such as hydoxychloroquine and sulfasalazine, for a minimum of 12 weeks. Combined use of more than one biologic DMARD will not be reimbursed. Clinical Notes: 1. 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. 2. Optimal treatment response to DMARDs may take up to 24 weeks, however coverage can be considered if no improvement is seen after 12 weeks of triple DMARD use. 3. For patients who have intolerances preventing the use of triple DMARD therapy, these must be described and dual therapy with DMARDs must be tried. 4. Refractory is defined as lack of effect at the recommended doses and for duration of treatments specified above. 5. Intolerant is defined as demonstrating serious adverse effects. The nature of intolerance(s) must be clearly documented. Claim Notes:				

	• Must be prescribed by a rheumatologist. • Combined use of more than one biologic drug will not be reimbursed. • Approvals will be for a maximum of 2 mg daily. • Initial Approval: 6 months. • Renewal Approval: 1 year. Confirmation of response is required.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Eplerenone	Mint-Eplerenone Mint-Eplerenone	25 mg 50 mg	Tablet Tablet	02471442 02471450	MNT
Criteria	For the treatment of patients with New York Heart Association (NYHA) class II chronic heart failure with left ventricular systolic dysfunction (with ejection fraction ≤ 35%), as a complement to standard therapy. Clinical Note: Patients must be on optimal therapy with an angiotensin-converting–enzyme (ACE) inhibitor or angiotensinreceptor blocker (ARB), and a beta-blocker (unless contraindicated) at the recommended dose or maximal tolerated dose				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Generic Drug Program, Nursing Home Drug Program, Seniors Drug Program, Catastrophic Drug Program				

Evolocumab	Repatha Repatha	120 mg/ml 140 mg/ml	Prefilled mini-doser Prefilled autoinjector	02459779 02446057	AMG
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 ofcontinuous 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 140mg every 2 weeks or 420mg monthly. • 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

CRITERIA UPDATE

Osimertinib	Tagrisso	40 mg 80 mg	Tablet Tablet	02456214 02456222	AZE
Criteria	Criteria for currently listed Tagrisso products has been expanded to now include: For the first-line treatment of patients with locally advanced (not amenable to curative intent therapy) or metastatic non-small cell lung cancer (NSCLC) whose tumors have epidermal growth factor receptor (EGFR) mutations (exon 19 deletions [exon 19 del] or exon 21 [L858R]]. Eligible patients should be previously untreated in the locally advanced or metastatic setting and have a good performance status. Treatment should continue until clinically meaningful disease progression or until unacceptable toxicity				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Palbociclib	Ibrance	75 mg 75 mg 100 mg 100 mg 125 mg 125 mg	Capsule Tablet Capsule Tablet Capsule Tablet	02453150 02493535 02453169 02493543 02453177 02493551	PFI
Criteria	Effective February 28, 2022, criteria for currently listed Ibrance products has been expanded to include: In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER 2 negative advanced or metastatic breast cancer, as initial endocrine-based therapy or following disease progression on endocrine therapy. Patients may have also received up to one prior line of chemotherapy for advanced disease. Patients should have a good performance status, without active or uncontrolled metastases to the central nervous system and in the case of women can be of any menopausal status (Perimenopausal and premenopausal women must be treated with an LHRH agonist). Clinical Notes: • Treatment should continue until unacceptable toxicity or disease progression. • Patients who progress ≤ 12 months from (neo) adjuvant therapy are eligible for treatment with palbociclib plus fulvestrant.				

	• Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with palbociclib with fulvestrant. • Patients currently receiving fulvestrant monotherapy, and who have not progressed may have palbociclib added, provided they are CDK 4/6 inhibitor naïve and otherwise meet funding criteria. • Patients who previously received everolimus plus exemestane will be eligible for funding of palbociclib plus fulvestrant on progression, provided that treatment was started prior to funding of CDK 4/6 + fulvestrant, patient must be CDK 4/6 naïve and otherwise meet funding criteria.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Tocilizumab	Actemra	80 mg/4 mL 200 mg/10 mL 400 mg/20 mL 162 mg/0.9 mL 162 mg/0.9 mL	Vial Vial Vial Prefilled syringe *Prefilled autoinjector (*RECENTLY ADDED FORMAT)	02350092 02350106 02350114 02424770 02483327	HLR
Criteria	Effective Feb 28, 2022, criteria for currently listed Actemra products has been expanded to include: For the treatment of adult patients with new onset or relapsed giant cell arteritis (GCA) in combination with glucocorticoids (at initiation of therapy, or with relapse) Initial coverage will be for 16 weeks. • Reassessment should occur after between 12 weeks and 16 weeks of therapy to determine response. Renewal requests: • Confirmation of response to treatment (i.e absence of flares AND normalization of C-reactive protein (CRP) to <1mg/dL) Clinical Note: • Flare is defined as the recurrence of signs or symptoms of GCA and/or erythrocyte sedimentation rate (ESR) greater or equal to 30 mm/hr attributable to GCA. Claim Note: • Must be prescribed by, or in consultation with, a rheumatologist or other physician experienced in the treatment of GCA. • Combined use of more than one biologic DMARD will not be reimbursed. • Subcutaneous injection: Approvals will be for 162 mg every week • Duration of therapy will be limited to 52 weeks per treatment course Authorization may be granted following any new episode of the disease, according to the treatment terms and conditions previously mentioned for the initial episode.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				