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PEI Pharmacare Bulletin

Issue (2022 - 10) **November 16, 2022**

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

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Omalizumab	Xolair	150 mg	Prefilled syringe	02459795	NVR
Criteria	For the treatment of patients ≥ 12 years of age with moderate to severe chronic idiopathic urticaria (CIU) who remain symptomatic (presence of hives and/or associated itching) despite optimum management with H1 antihistamines. Initiation Criteria: • Documentation of the most recent Urticaria Activity Score over 7 days (UAS7) to be provided on the submitted request. • Approvals will be for a maximum dose of 300mg every four weeks. • Initial approval period: 24 weeks. Renewal Criteria: • Requests for renewal will be considered if the patient has achieved: • Complete symptom control for less than 12 consecutive weeks; or • Partial response to treatment, defined as at least a ≥ 9.5 point reduction in baseline UAS7 Clinical Notes: 1. Moderate to severe CIU is defined as UAS7 ≥16. 2. Treatment cessation could be considered for patients who experience complete symptom control for at least 12 consecutive weeks at the end of a 24 week treatment period. 3. In patients who discontinue treatment due to temporary symptom control, reinitiation can be considered if CIU symptoms reappear. 4. Optimal management is defined as H1 antihistamines at up to 4 times the standard daily dose.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Ribociclib	Kisqali	200 mg	Tablet	02473569	NVR
Criteria	In combination with an aromatase inhibitor for the treatment of patients with hormone receptor positive, HER2 negative or advanced or metastatic breast cancer who: • have not received prior endocrine therapy for advanced or metastatic disease, and • are not resistant to prior (neo) adjuvant non-steroidal aromatase inhibitor (NSAI) therapy and • do not have active or uncontrolled metastases to the central nervous system				

	Renewal criteria: • Confirmation that the patient has responded to treatment and there is no evidence of disease progression Clinical Notes: • Patients must have a good performance status • Resistance is defined as disease progression occurring during or within 12 months following NSAI therapy • Treatment should be discontinued upon disease progression or unacceptable toxicity Claim Notes: • Initial approval period: 1 year • Renewal approval period: 1 year In combination with fulvestrant for the treatment of patients with hormone receptor (HR) positive, HER2 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 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 ribociclib plus fulvestrant. • Patients who experience disease progression on prior CDK 4/6 inhibitor therapy, fulvestrant or everolimus are not eligible for treatment with ribociclib with fulvestrant. • Patients currently receiving fulvestrant monotherapy, and who have not progressed may have ribociclib 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 ribociclib 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. Claim Notes: • Initial approval period: 1 year • Renewal approval period: 1 year
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

REMOVAL OF SPECIAL AUTHORIZATION CRITERIA

Effective immediately, the following medications will no longer require special authorization, and will be open benefits in currently listed programs. Please disregard any special authorization expiry alerts, communicated through the Integrated Claims System, for these medications.

Generic Name	Brand Name	Strength	Programs
Brexipiprazole	Rexulti	0.25 mg tablet 0.5 mg tablet 1 mg tablet 2 mg tablet 3 mg tablet 4 mg tablet	Family Health Benefit Drug Program Financial Assistance Drug Program Nursing Home Drug Program Seniors Drug Program Catastrophic Drug Program