Health PEI
One Island Health System

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PEI Pharmacare Bulletin

Issue (2021 - 3) **March 15, 2021**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: MARCH 29, 2021)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Benralizumab	Fasenra	30 mg/ml 30 mg/ml	Syringe Autoinjector	02473232 02496135	AZN
Criteria	As add-on maintenance treatment for adult patients with severe eosinophilic asthma, if the following criteria are met: Initiation Criteria: • Patient must have a documented diagnosis of asthma. • Patient is inadequately controlled with high-dose inhaled corticosteroids, defined as greater or equal to 500 mcg of fluticasone propionate or equivalent daily, and one or more additional asthma controller(s) (e.g., long-acting beta agonists). • Patient has one of the following: ○ blood eosinophil count of ≥ 300 cells/µL within the past 12 months AND has experienced two or more clinically significant asthma exacerbations in the past 12 months, or ○ blood eosinophil count of ≥ 150 cells/µL AND is receiving maintenance treatment with oral corticosteroids (OCS). Renewal Criteria: • The effects of treatment should be assessed every 12 months to determine whether reimbursement should continue. • Reimbursement of treatment should be discontinued if: ○ the 12 month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment, or ○ the asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or ○ the number of clinically significant exacerbations has increased within the previous 12 months, or ○ in patients on maintenance treatment with OCS, there has been no decrease in the OCS dose in the first 12 months of treatment, or ○ in patients on maintenance treatment with OCS, the reduction in the dose of OCS achieved after the first 12 months of treatment is not maintained subsequently.				

	Clinical Notes: • Benralizumab should not be used in combination with other biologics used to treat asthma. • A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of benralizumab treatment. • Patients should be managed by a physician with expertise in treating asthma.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Mepolizumab	Nucala	100 mg 100 mg/ml 100 mg/ml	Vial Autoinjector Syringe	02449781 02492989 02492997	GSK
Criteria	As add-on maintenance treatment for adult patients with severe eosinophilic asthma, if the following criteria are met: Initiation Criteria: • Patient must have a documented diagnosis of asthma. • Patient is inadequately controlled with high-dose inhaled corticosteroids, defined as greater or equal to 500 mcg of fluticasone propionate or equivalent daily, and one or more additional asthma controller(s) (e.g., long-acting beta agonists). • Patient has one of the following: o blood eosinophil count of ≥ 300 cells/µL within the past 12 months AND has experienced two or more clinically significant asthma exacerbations in the past 12 months, or o blood eosinophil count of ≥ 150 cells/µL AND is receiving maintenance treatment with oral corticosteroids (OCS). Renewal Criteria: • The effects of treatment should be assessed every 12 months to determine whether reimbursement should continue. • Reimbursement of treatment should be discontinued if: o the 12 month asthma control questionnaire score has not improved from baseline, when baseline represents the initiation of treatment, or o the asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or o the number of clinically significant exacerbations has increased within the previous 12 months, or o in patients on maintenance treatment with OCS, there has been no decrease in the OCS dose in the first 12 months of treatment, or o in patients on maintenance treatment with OCS, the reduction in the dose of OCS achieved after the first 12 months of treatment is not maintained subsequently. Clinical Notes: • Mepolizumab should not be used in combination with other biologics used to treat asthma. • A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be completed prior to initiation of mepolizumab treatment. • Patients should be managed by a physician with expertise in treating asthma.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Omalizumab	Xolair	150 mg	Vial	02260565	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 a 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, re-initiation 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				

BENEFIT STATUS/CRITERIA CHANGES
(EFFECTIVE DATE: MARCH 15, 2021)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN/PDIN	MFR
Bisacodyl	Magic Bullet	10 mg	Suppository	02241091	D&C
Criteria	The Special Authorization criteria has expanded to include: For use as part of a bowel program for neurogenic bowel dysfunction in patients with spinal cord injuries				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Program, Nursing Home Drug Program, Seniors Drug Program				