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PEI Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: APRIL 23, 2024)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Anifrolumab	**Saphnelo**	**150 mg/mL**	**Vial**	**02522845**	**AZE**
Criteria	For the treatment of adult patients with moderate to severe autoantibody positive, systemic lupus erythematosus (SLE) who meet all of the following criteria: • Systemic lupus erythematosus disease activity index 2000 (SLEDAI-2K) score of 6 or greater. • Refractory to oral corticosteroids (OCS) at a dose of at least 10 mg per day of prednisone or its equivalent, in addition to standard of care. Renewal criteria: • OCS dose has decreased to less than or equal to 7.5 mg per day of prednisone or its equivalent OR OCS dose decreased by at least 50% from baseline; and • Reduction in disease activity as measured by: ▪ Reduction in the SLEDAI-2K index score to 5 or less; or ▪ British Isles lupus assessment group (BILAG)-2004 index score improvement in involved organ systems and no new worsening in other organ systems. Subsequent renewal criteria: • Initial response achieved after the first twelve months of treatment with anifrolumab has been maintained. Clinical notes: • Standard of care is defined as using an immunosuppressive drug (e.g., rituximab, hydroxychloroquine, mycophenolic acid, or azathioprine) with or without NSAIDS. • A baseline SLEDAI-2K must be provided. If BILAG-2004 is used for assessment on renewal, then a baseline BILAG-2004 assessment of organ systems must also be provided. The same scale should be used on all subsequent renewals. • Improvement in organ systems is defined as a reduction of all severe BILAG-2004				

	A) or moderately severe BILAG-2004 B) to lower rating levels. • Worsening in organ systems is defined as at least one new BILAG-2004 A item or at least two new BILAG-2004 B items. Exclusion criteria: • Severe or unstable neuropsychiatric SLE. • Active severe SLE nephritis. Claim notes: • Patient should be under the care of a physician with expertise in the diagnosis and management of SLE. • Combined use with other biologic drugs will not be reimbursed. • Approvals will be for a maximum of 300 mg every four weeks. • Approval period: 1 year.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Budesonide	**Uceris**	**2mg/Actuation**	**Rectal Foam**	**02498057**	**BLO**
Criteria	Open Benefit				
Program Eligibility	Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program, Seniors Drug Program, Family Health Benefit Drug Program				

Mesalamine	**Mezera**	**500 mg**	**Tablet**	**02524481**	**AVI**
Criteria	Open Benefit				
Program Eligibility	Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program, Seniors Drug Program, Family Health Benefit Drug Program				

Ripretinib ***Use PDIN when drug cost in excess of CPHA maximum**	**Qinlock**	**50 mg**	**Tablet**	**02500833** **00900026*** **00900027***	**MDP**
Criteria	For the treatment of adult patients with advanced gastrointestinal stromal tumours (GIST) who have progression on or intolerance to imatinib, sunitinib, and regorafenib. Clinical Notes: • Patients must have a good performance status and no active central nervous system metastases. • Treatment should be discontinued upon disease progression or unacceptable toxicity.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Selinexor ***Use PDIN when drug cost in excess of CPHA maximum**	**Xpovio**	**20 mg**	**Tablet**	**02527677** **00900031***	**FTI**
Criteria	In combination with bortezomib and dexamethasone for the treatment of adult patients with multiple myeloma and who have received at least one prior therapy. Clinical Notes: 1. Prior treatment with bortezomib/proteasome inhibitor is permitted if all the following criteria are met: • Best response achieved with bortezomib/proteasome inhibitor was at least a partial response				

	• Bortezomib/proteasome inhibitor not discontinued for grade 3 or higher toxicity • Bortezomib/proteasome inhibitor treatment-free interval has been at least six months. 2. Treatment should continue until disease progression or unacceptable toxicity.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Tezepelumab	**Tezspire**	**210 mg/1.91 mL** **210 mg/1.91 mL**	**Pre-filled pen** **Pre-filled pen**	**02529548** **02529556**	**AZE**
Criteria	For the treatment of severe asthma in patients 12 years and older who are inadequately controlled with high-dose inhaled corticosteroids (ICS), and one or more additional asthma controller(s) (e.g., long-acting beta-agonist), and have experienced 2 or more clinically significant asthma exacerbations in the past 12 months. Initial Discontinuation Criteria: • Baseline asthma control questionnaire score has not improved at 12 months since initiation of treatment, or • No decrease in the daily maintenance OCS dose in the first 12 months of treatment, or • The number of clinically significant asthma exacerbations has increased within the previous 12 months. Subsequent Discontinuation Criteria: • Asthma control questionnaire score achieved after the first 12 months of therapy has not been maintained subsequently, or • The reduction in the daily maintenance dose of OCS achieved after the first 12 months of treatment is not maintained or improved subsequently, or • The number of clinically significant asthma exacerbations has increased within the previous 12 months. Clinical Notes: • A baseline assessment of asthma symptom control using a validated asthma control questionnaire must be provided. • A baseline and annual number of clinically significant asthma exacerbations must be provided. • High dose ICS is defined as ≥ 500 mcg of fluticasone propionate or equivalent daily dose. • A significant clinical exacerbation is defined as worsening of asthma such that the treating physician elected to administer systemic glucocorticoids for at least 3 days or the patient visited an emergency department or was hospitalized. Claim Notes: • Must be prescribed by a respirologist, clinical immunologist, allergist or internist experienced in the treatment of severe asthma. • Combined use of tezepelumab with other biologics used to treat asthma will not be reimbursed. • Approvals will be for a maximum of 210mg subcutaneous injection every 4 weeks. • Approval period: 1 year.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				