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PEI Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: (FEBRUARY 20, 2023)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Adalimumab	**Yuflyma**	40 mg/0.4 ml 40 mg/0.4 ml	Prefilled Pen Prefilled Syringe	02523779 02523760	LIL
Criteria	For the treatment of ankylosing spondylitis, Crohn's disease, hidradenitis suppurativa, plaque psoriasis, psoriatic arthritis, rheumatoid arthritis, ulcerative colitis, and uveitis with the same criteria as for existing adalimumab products listed in the PEI Pharmacare Formulary.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Apalutamide	**Erleada**	60 mg	Tablet	02478374	JAN
Criteria	1. In combination with androgen deprivation therapy (ADT) for the treatment of patients with castration-resistant prostate cancer (CRPC) who have no detectable distant metastasis (M0) by either CT, MRI or technetium-99m bone scan and who are at high risk of developing metastases[1]. Patients should have a good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or radiographic disease progression. Clinical Notes: • Castration-resistance must be demonstrated during continuous ADT and is defined as 3 PSA rises at least one week apart,with the last PSA> 2 ng/mL. • Castrate levels of testosterone must be maintained. • Patients with N1 disease, pelvic lymph nodes < 2cm in short axis located below the common iliac vessels are eligible for apalutamide. • Apalutamide will not be funded for patients who experience disease progression on enzalutamide. • Patients receiving apalutamide for the treatment of non-metastatic CRPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on apalutamide. • Either abiraterone or enzalutamide may be used to treat metastatic CRPC in patients who discontinued apalutamide in the non-metastatic setting due to intolerance without disease progression. • [1] High risk of developing metastases is defined as a prostate-specific antigen (PSA) doubling time of ≤ 10				

	months during continuous ADT 2. In combination with androgen deprivation therapy (ADT) for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC). Patients must have had either no prior ADT, or are within six months of beginning ADT in the metastatic setting. Clinical Notes: • Patients should have a good performance status and no risk factors for seizures. Treatment should continue until unacceptable toxicity or disease progression. Claim Notes: • Patients receiving apalutamide for the treatment of metastatic CSPC will be eligible for funding of abiraterone at the time of disease progression to metastatic CRPC. • Enzalutamide is not funded for patients who experience disease progression to metastatic CRPC while on apalutamide.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Cladribine	**Mavenclad**	10 mg	Tablet	02470179	EMD
Criteria	For the treatment of adult patients with relapsing-remitting multiple sclerosis (RRMS) who meet all the following criteria: • Confirmed diagnosis based on McDonald criteria. • Has experienced one or more disabling relapses or new MRI activity in the past year. • Ambulatory with or without aid (i.e. has a recent Expanded Disability Status Scale (EDSS) score of less than or equal to 6.5). • Refractory or intolerant to at least one disease modifying therapy (e.g., interferon, glatiramer, dimethyl fumarate, teriflunomide, ocrelizumab). Clinical Notes: • Treatment should be discontinued for patients with an EDSS score of greater than or equal to 7. • A relapse is defined as the appearance of new or worsening neurological symptoms in the absence of fever or infection, lasting at least 24 hours yet preceded by stability for at least one month and accompanied by new objective neurological findings observed through evaluation by a neurologist. Claim Notes: • Must be prescribed by a neurologist with experience in the treatment of multiple sclerosis. • Approvals will be for 1.75mg/kg to a maximum of 200mg per treatment year. Approval period: 2 years				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Insulin aspart	**Kirsty**	100 units/ml	Vial Prefilled Pen	02520982 02520974	EMD
Criteria	Open benefit				
Program Eligibility	Diabetes Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Insulin glargine	**Semglee**	100 units/ml	Prefilled Pen	02526441	BGP
Criteria	Open benefit				
Program Eligibility	Diabetes Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Insulin regular	**Entuzity**	500 units/ml	Prefilled Pen	02466864	LIL
Criteria	For the treatment of diabetes mellitus in patients with unacceptable glycemic control who require more than 200 units of insulin per day, with or without other therapies. • Treatment should be initiated by a specialist with experience in treating severe insulin resistance.				
Program Eligibility	Diabetes Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Lanadelumab	**Takhzyro**	300 mg/2 ml 300 mg/2 ml	Vial Prefilled Syringe	02480948 02505614	TAK
Criteria	For the prevention of attacks of type I or II hereditary angioedema (HAE) in patients 12 years of age and older who have experienced at least three HAE attacks within any four-week period and required the use of an acute injectable treatment. Discontinuation Criteria: • No reduction in the number of HAE attacks for which acute injectable treatment was received during the first three months of treatment with lanadelumab compared to the number of attacks observed before initiating treatment with lanadelumab; or • Increase in the number of HAE attacks for which acute injectable treatment was received compared to the number of attacks before initiating treatment with lanadelumab. Clinical Note: • The pre-treatment attack rate must be provided for those patients who are already receiving long-term prophylactic treatment for HAE and intend to transition to lanadelumab. Claim Notes: • The patient must be under the care of a physician experienced in the diagnosis and treatment of HAE • Not to be used in combination with other long-term prophylactic treatment of HAE (e.g., C1 esterase inhibitor). • Approvals will be for a maximum of 300 mg every two weeks. • Initial approval period: 3 months. • Renewal approval period: 6 months.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Tildrakizumab	**Ilumya**	100 mg/ml	Prefilled Syringe	02516098	SUN
Criteria	For the treatment of patients with chronic moderate to severe plaque psoriasis who meet all of the following criteria: • Psoriasis Area Severity Index (PASI) > 10; and Dermatology Life Quality Index (DLQI) > 10; or • Major involvement of visible areas, scalp, genitals, at least two finger nails, presence of itch leading to scratching or the presence of recalcitrant plaques; AND • Refractory, intolerant or have contraindications to: - Phototherapy (unless restricted by geographic location); and - Methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks or cyclosporine for a minimum of 6 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 • 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 to treatments. The nature of intolerance(s) must be clearly documented. Claim notes: • Combined use of more than one biologic DMARD will not be reimbursed • Maximum dosages as per existing criteria on the PEI Pharmacare Formulary • Initial approval: 16 weeks. Renewal approval: 1 year. Confirmation of continued response is required
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

CRITERIA UPDATE/ PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE IMMEDIATELY)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR

Sunitinib	**Sutent and generic**	Currently listed strengths	Tablet	Currently listed DINs	PFI TAR
Criteria	Criteria for this medication has been expanded to include the following: For the treatment of patients with progressive, unresectable, locally advanced or metastatic, well or moderately differentiated pancreatic neuroendocrine tumours. Clinical Notes: 1.Patients must have a good performance status. 2.Treatment should be discontinued upon disease progression or unacceptable toxicity.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Adalimumab	**Idacio**	Currently listed strengths	Currently listed products	Currently listed DINs	FKB
Criteria	Criteria for this medication has been expanded to include the following: For the treatment of patients with active moderate to severe hidradenitis suppurativa (HS); please see the PEI Pharmacare Formulary for HS criteria For the treatment of patients with non-infectious uveitis who are refractory, intolerant or have contraindications to conventional therapy; please see the PEI Pharmacare Formulary for uveitis criteria				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				

Lenvatinib	**Lenvima**	Currently listed strengths	Capsule	Currently listed DINs	EIS
Criteria	Criteria for this medication has been updated to include the following: For the first-line treatment of adult patients with unresectable hepatocellular carcinoma who meet all the following criteria: • Child-Pugh class status of A. • ECOG performance status of 0 or 1. • Less than 50% liver involvement and no invasion of the bile duct or main portal vein. • No brain metastases or prior liver transplantation. Clinical Notes:				

	1. Treatment should be continued until disease progression or unacceptable toxicity. Patients who are unable to tolerate lenvatinib may be switched to sorafenib if there is no disease progression and provided all other funding criteria are met. 2. Patients with disease progression on lenvatinib are not eligible for reimbursement of sorafenib For the treatment of patients with locally recurrent or metastatic, progressive, differentiated thyroid cancer (DTC) who meet the following criteria: • Pathologically confirmed papillary or follicular thyroid cancer, and • Disease that is refractory or resistant to radioactive iodine therapy, and • Radiological evidence of disease progression within the previous 13 months, and • Previous treatment with no more than one tyrosine kinase inhibitor (TKI). Clinical Notes: 1. Patients must have a good performance status. 2. Treatment should be discontinued upon disease progression or unacceptable toxicity.
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program

Ruxolitinib	**Jakavi**	Currently listed strengths	Currently listed products	Currently listed DINs	NVR
Criteria	Criteria for this medication has been expanded to include the following: For the treatment of patients with polycythemia vera who have demonstrated resistance or intolerance to hydroxyurea (HU). Renewal Criteria: • Written 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. • Treatment should be discontinued upon disease progression or unacceptable toxicity. • Resistance is considered if, after at least 3 months of HU therapy at the maximum tolerated dose, patients experience at least one of the following: o Need for phlebotomy to maintain hematocrit (HCT) < 45% o Uncontrolled myeloproliferation (i.e., platelet count > 400 x 10^9/L and white blood cell count > 10 x 10^9/L) o Failure to reduce massive splenomegaly by greater than 50%, as measured by palpation • Intolerance to HU is considered if patients experience at least one of the following: o Absolute neutrophil count < 1.0 x 10^9/L, platelet count < 100 x 10^9/L or hemoglobin < 100g/L at the lowest dose of HU required to achieve a response (a response to HU is defined as HCT <45% without phlebotomy, and/or all of the following: platelet count < 400 x 10^9/L, white blood cell count < 10 x 10^9/L, and nonpalpable spleen). o Presence of leg ulcers or other unacceptable HU-related non-hematological toxicities (defined as grade 3 or 4 or, more than one week of grade 2) such as mucocutaneous manifestations, gastrointestinal symptoms, pneumonitis, or fever. o Toxicity requiring permanent discontinuation of HU, interruption of HU until toxicity resolved, or hospitalization due to HU toxicity.				
Program Eligibility	High Cost Drug Program, Catastrophic Drug Program				