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PEI Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: MAY 21, 2024)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Abemaciclib	**Verzenio**	**50 mg** **100 mg** **150 mg**	**Tablet** **Tablet** **Tablet**	**02487098** **02487101** **02487128**	**LIL**
Criteria	In combination with endocrine therapy (ET) for the adjuvant treatment of adult patients with hormone receptor (HR) positive, human epidermal growth factor receptor 2 (HER2) negative, node-positive early breast cancer at high risk of disease recurrence and a Ki-67 score of at least 20%. Clinical Notes: • Patients should have a good performance status. • Treatment should continue until disease progression, unacceptable toxicity, or completion of 2 years of adjuvant therapy. ET may be continued after abemaciclib is completed. • Patients are not eligible if they have inflammatory breast cancer, or prior treatment with a cyclin-dependent kinases 4 and 6 (CDK4/6) inhibitor. • Retreatment with a CDK4/6 inhibitor may be reasonable in the metastatic setting if disease recurrence occurs greater than or equal to 6 months after completion of adjuvant abemaciclib.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Insulin Degludec	**Tresiba Penfill**	**100 units/mL**	**Cartridge**	**02467860**	**NNO**
Criteria	Open benefit				
Program Eligibility	Diabetes Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Ozanimod	**Zeposia**	**0.23 mg & 0.46 mg Initiation Pack** **0.92 mg**	**Capsule** **Capsule**	**02506009** **02505991**	**BMS**
Criteria	For the treatment of adult patients with moderately to severely active ulcerative colitis who have a partial Mayo score > 4, and a rectal bleeding subscore ≥ 2 and are: • Refractory or intolerant to conventional therapy (i.e. aminosalicylates for a minimum of four weeks AND prednisone ≥ 40mg daily for two weeks or IV equivalent for one week) OR • Corticosteroid dependent (i.e. cannot be tapered from corticosteroids without disease recurrence; or have relapsed within three months of stopping corticosteroids; or require two or more courses of corticosteroids within one year. Claim Notes: • Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology. • Initial Approval: 12 weeks. Treatment has to be initiated in all patients with an initiation pack that lasts for 7 days. o Days 1-4 0.23 mg once daily o Days 5-7 0.46 mg once daily o Days 8 and thereafter 0.92 mg once daily. • Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically: o a decrease in the partial Mayo score ≥ 2 from baseline, and o a decrease in the rectal bleeding subscore ≥ 1. • Renewal Approval: 1 year. Maximum approved dose is 0.92mg once daily. • Combined use of more than one biologic DMARD will not be reimbursed. Clinical Notes: • 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 or contraindications to treatments as defined in product monographs. The nature of intolerance(s) must be clearly documented. • Patients with severe disease (partial Mayo > 6) do not require a trial of 5-ASA.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Selpercatinib	**Retevmo**	**40 mg** **80 mg**	**Capsule** **Capsule**	**02516918** **02516926**	**LIL**
Criteria	<u>Medullary Thyroid Cancer</u> For the treatment of patients 12 years and older with unresectable locally advanced or metastatic RET-mutant medullary thyroid cancer (MTC) who have progressed on, are intolerant to, or have a contraindication to first-line therapy. Clinical Notes: • Discontinuation for unacceptable toxicity or loss of clinical benefit. • Patients should have a good performance status.				

	• Monotherapy only. • Confirm RET mutation prior to initiating therapy. • Patients with prior progression on a RET inhibitor are ineligible. <u>Differentiated Thyroid Carcinoma (DTC)</u> For the treatment of adult patients with locally advanced or metastatic RET fusion-positive differentiated thyroid carcinoma (DTC) not amenable to surgery or radioactive iodine therapy, following prior treatment with lenvatinib. Clinical Notes: • Discontinuation for unacceptable toxicity or loss of clinical benefit. • Patients should have a good performance status. • Monotherapy only. • Confirm RET mutation prior to initiating therapy. • Patients with prior progression on a RET inhibitor are ineligible. <u>Non-Small Cell Lung Cancer</u> For the treatment of adult patients with metastatic RET fusion-positive non-small cell lung cancer (NSCLC) as first-line treatment or after prior systemic therapy. Clinical Notes: • Discontinuation for unacceptable toxicity or loss of clinical benefit. • Patients should have a good performance status. • Monotherapy only. • Confirm RET mutation prior to initiating therapy. • Patients with prior progression on a RET inhibitor are ineligible
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

TEMPORARY BENEFIT ADDITION

Health Canada allows certain drugs (designated as a Tier 3 Shortage) to be imported and sold in Canada; the drug listed below has been added as a temporary benefit.

Cholestyramine	**Juno-Cholestyramine**	**4 g/pouch**	**Oral Powder**	**PDIN 09858335**	**JNO**
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Generic Drug Program, Nursing Home Drug Program, Catastrophic Drug Program, Seniors Drug Program, Financial Assistance Drug Program				

CRITERIA UPDATE

Effective immediately, special authorization criteria for currently listed Cabozantinib (Cabometyx) has been amended to include the following indication:

Differentiated Thyroid Carcinoma (DTC)

For the treatment of adult patients with locally advanced or metastatic differentiated thyroid carcinoma (DTC) who have progressed on at least one prior line of vascular endothelial growth factor receptor (VEGFR)-targeted tyrosine kinase inhibitor (TKI) therapy.

Clinical Notes:

- Patients should have a good performance status.
- Patients should be refractory to radioactive iodine therapy (RAI-R) or not eligible for radioactive iodine therapy.
- Treatment should continue until disease progression or unacceptable toxicity.
- Patients will be eligible for funding if intolerant to the prior line of VEGFR-targeted TKI therapy.
- Cabozantinib may be used in the third line setting for RET fusion positive patients after progression on or intolerance to selpercatinib.

Effective immediately, special authorization criteria for currently listed Ruxolitinib (Jakavi) has been amended to include the following indications:

Acute Graft-Versus-Host Disease

For the treatment of steroid-refractory or steroid-dependent acute graft-versus-host disease (aGvHD) in adult and pediatric patients aged 12 years and older who meet all the following criteria:

- Clinically diagnosed grade II to IV aGvHD according to the NIH criteria (Harris et al. [2016]).
- Confirmed diagnosis of corticosteroid-refractory or corticosteroid-dependent aGvHD.

Renewal criteria:

- Achieved an overall response (i.e., CR, VGPR, PR, or stable disease with significant reduction in steroid doses), according to standard NIH criteria at day 28.
- For subsequent renewals, patients should be assessed for treatment response every 2 to 3 months, until the occurrence of any of the discontinuation criteria listed below.

Clinical Notes:

- Treatment should be discontinued upon the occurrence of any of the following:
    - progression of aGvHD, defined as worsening of aGvHD symptoms or occurrence of new aGvHD symptoms
    - unacceptable toxicity
    - addition of systemic therapies (other than calcineurin inhibitors) for aGvHD after day 28
    - recurrence or relapse of underlying hematological malignancy.

Claim Notes:

- Must be prescribed by clinicians who have experience in the diagnosis and management of patients with aGvHD.
- Must not be added to patients' concurrent treatment of systemic therapies for the treatment of aGvHD other than steroids with or without calcineurin inhibitors.
- Approval: 6 months

Chronic Graft-Versus-Host Disease

For the treatment of chronic graft-versus-host disease (cGvHD) in adults and pediatric patients aged 12 years and older who have inadequate response to corticosteroids or other systemic therapies who meet all the following criteria:

- Clinically diagnosed cGvHD staging of moderate to severe based on NIH consensus criteria
- Confirmed diagnosis cGvHD with inadequate response to corticosteroids or other systemic therapies

Renewal criteria:

- Achieved an overall response (i.e., CR or PR, or stable disease with significant reduction in steroid doses), according to NIH criteria, after 24 weeks of therapy

Clinical Notes:

- Treatment should be discontinued upon the occurrence of any of the following:
    - Progression of cGvHD, defined as worsening of cGvHD symptoms or occurrence of new cGvHD symptoms
    - recurrence or relapse of underlying hematological malignancy

Claim Notes:

- Must be prescribed by clinicians who have experience in the diagnosis and management of patients with cGvHD.
- Must not be added to patients' concurrent treatment of systemic therapies other than steroids with or without calcineurin inhibitors.
- Initial Approval: 6 months