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Programmes provinciaux de médicaments
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PEI Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: SEPTEMBER 2, 2025)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Finerenone	**Kerendia**	**10 mg 20 mg**	**Tablet**	**02531917 02531925**	**BAY**
Criteria	For the treatment of patients with chronic kidney disease (CKD) and type 2 diabetes (T2D) who have an estimated glomerular filtration rate (eGFR) level of at least 25mL/min/1.73 m^2 and albuminuria level of at least 30mg/g (or 3mg/mmol). Exclusion Criteria: • Patients with chronic heart failure (CHF) New York Heart Association (NYHA) class II to IV; OR • Patients receiving a mineralocorticoid receptor antagonist (MRA). Discontinuation Criteria: • eGFR less than 15 mL/min/1.73 m^2 ; OR • Urinary albumin-to-creatinine ratio (UACR) increased from baseline level. Claim Notes: • Must be prescribed by, or in consultation with, a nephrologist or prescriber with experience in the diagnosis and management of patients with CKD and T2D. • Approval Period: 1 year				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program, Seniors Drug Program				

Icosapent ethyl	**Vascepa**	**1 gram**	**Capsule**	**02495244**	**HLS**
Criteria	To reduce the risk of cardiovascular events (cardiovascular death, non-fatal myocardial infarction, non-fatal stroke, coronary revascularization, or hospitalization for unstable angina) in statin treated patients with elevated triglycerides who meet all of the following criteria: • 45 years of age and older • Established cardiovascular disease				

	• Baseline fasting triglyceride between 1.7 mmol/L and 5.6 mmol/L measured within the three months prior to initiating treatment with icosapent ethyl. • Baseline low-density lipoprotein cholesterol (LDL-C) between 1.0 mmol/L and 2.6 mmol/L • Receiving a maximally tolerated statin dose for a minimum of 4 weeks, targeted to achieve an LDL-C lower than 2.0 mmol/L Renewal Criteria: • Patient continues to be treated with a maximally tolerated statin dose Clinical Note: • LDL-C and triglyceride levels must be provided. Claim Notes: • Approvals will be for a maximum of 4 g daily. • Approval period: 1 year
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program, Seniors Drug Program

Mavacamten	**Camzyos**	**2.5 mg** **5 mg** **10 mg** **15 mg**	**Capsule**	**02532549** **02532557** **02532565** **02532573**	**BMS**
Criteria	For the treatment of patients with symptomatic obstructive hypertrophic cardiomyopathy (oHCM) of New York Heart Association (NYHA) class II to III who meet all of the following criteria: • Documented left ventricular ejection fraction (LVEF) ≥ 55% at rest determined by echocardiography. • Left ventricular (LV) wall thickness ≥15 mm (or ≥13 mm with a family history of hypertrophic cardiomyopathy). • Left ventricular outflow tract (LVOT) peak gradient ≥ 50 mm Hg at rest, after Valsalva maneuver, or post exercise, as confirmed by echocardiography. • Must be receiving beta-blocker or calcium channel blocker therapy and experience clinical deterioration in symptoms or echocardiography while receiving either of these treatments or for patients who have an intolerance or contraindication to treatments, details must be provided. Renewal Criteria: • Patients must not have any of the following: o LVEF ≤ 30% o Received septal reduction therapy. Claim Notes: • Must be prescribed by, or in consultation with a specialist in cardiology. • Approvals will be for a maximum of up to 5mg daily for 12 weeks, then up to 15mg daily thereafter. • Initial Approval: 12 weeks • Renewal Approval: 1 year				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Secukinumab	Cosentyx	150 mg/mL 75 mg/0.5 mL	Pre-filled syringe Pre-filled syringe	02547724 02525569	NVR
Criteria	Effective September 2, 2025, special authorization criteria for currently listed secukinumab (Cosentyx) have been amended to include the following: <u>Plaque Psoriasis</u> For the treatment of patients 6 years of age or older with chronic moderate to severe plaque psoriasis who meet all of the following: • Psoriasis Area Severity Index (PASI) greater than 10 and Dermatology Life Quality Index (DLQI) greater than 10, OR major involvement of visible areas, scalp, genitals, or nails; • Failure to, contraindication to or intolerant of methotrexate (oral or parenteral) at a dose of ≥ 20mg weekly (≥15mg if patient is ≥65 years of age) for a minimum of 12 weeks; • Failure to, intolerant of or unable to access phototherapy. Continued coverage is dependent on evidence of improvement, specifically: • A >75% reduction (provide baseline and current score) in the Psoriasis Area and Severity Index (PASI) score; or • A >50% reduction (provide baseline and current score) in PASI with a > 5-point improvement in DLQI (Dermatology Life Quality Index); or • Significant reduction in BSA involved, with consideration of important regions such as the face, hands, feet or genitals. 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. • Failure 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. • For patients aged 6 to 16, a Children's Dermatology Life Quality Index (CDLQI) greater than 7 will be considered. • For pediatric patients an adequate trial of a weight-based appropriate dose of methotrexate will be considered. • Treatment should be discontinued if a response has not been demonstrated after 16 weeks. Claim Notes: • Approvals will be for a maximum adult dose of 300 mg at 0, 1, 2, 3, and 4 weeks followed by monthly maintenance dosing, up to 12 weeks. If response criteria are met at 12 weeks, approval will be continued to a maximum dose of 300 mg. • For pediatric patients weighing less than 50kg, approvals will be for a maximum of 75mg given at weeks 0, 1, 2, 3 and 4, then monthly. • Concurrent use of biologics not approved • Initial Approval: 12 weeks • Renewal Approval: 1 year <u>Hidradenitis Suppurativa</u> For the treatment of patients with active moderate to severe hidradenitis suppurativa (HS) who have not responded to conventional therapy and who meet all of the following criteria:				

	• A total abscess and nodule count of 3 or greater • Lesions in at least two distinct anatomic areas, one of which must be Hurley Stage II or III • An inadequate response to a 90-day trial of oral antibiotics Initial renewal criteria: • Requests for renewal should provide objective evidence of a treatment response, defined as at least a 50% reduction in abscess and inflammatory nodule count with no increase in abscess or draining fistula count relative to baseline at week 12. Subsequent renewal criteria: • Requests for renewal should provide objective evidence of the preservation of treatment effect (i.e. the current abscess and inflammatory nodule count and draining fistula count should be compared to the count prior to initiating treatment with secukinumab). Claim Notes: • Must be prescribed by a dermatologist or physician with experience in the treatment of HS. • Combined use of more than one biologic DMARD will not be reimbursed. • Approvals will be for 300mg given at weeks 0, 1, 2, 3, and 4, followed by monthly maintenance dosing. Based on clinical response, a maintenance dose of 300 mg every 2 weeks can be considered. • Initial Approval: 6 months • Renewal Approval: 1 year
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

CRITERIA UPDATE

Effective September 2, 2025, special authorization criteria for currently listed **mepolizumab (Nucala)** have been amended to include the following:

Severe Chronic Rhinosinusitis with Nasal Polyps

For the treatment of patients with severe chronic rhinosinusitis with nasal polyps (CRSwNP) who meet all of the following criteria:

- have endoscopically or CT-documented bilateral nasal polyps, and
- have undergone at least 1 prior surgical intervention for nasal polyps or have a contraindication to surgery, and
- are tolerant and able to continue use of inhaled nasal corticosteroids but have refractory symptoms despite use of inhaled corticosteroids for 3 months at maximally tolerated doses.

Renewal Criteria:

- Requests for renewal must exhibit a clinically meaningful response defined as:
    - a decrease of 8.9 points or greater on the Sino-nasal Outcome Test (SNOT-22) relative to their baseline score, or
    - a decrease of 1 point or greater on the endoscopic Nasal Polyp Score (NPS) relative to their baseline score.

Clinical Notes:

- A baseline and annual SNOT-22 or endoscopic NPS must be provided.
- Patients should be assessed for a response to mepolizumab every 12 months.

- Maximum dose approved: 100mg every 4 weeks
- Renewal Approval: 12 months

Claim Note:

- Must be prescribed by an otolaryngologist, allergist or respirologist with expertise in managing severe CRSwNP

Effective September 2, 2025, special authorization criteria for currently listed **trifluridine-tipiracil (Lonsurf)** have been amended to include the following:

Unresectable or Metastatic Colorectal Cancer

In combination with bevacizumab for the treatment of adult patients with unresectable or metastatic colorectal cancer who:

- Have previously been treated with, or are not candidates for, available therapies including fluoropyrimidine, oxaliplatin, and irinotecan-based chemotherapies, anti-VEGF biological agents, and, if RAS wild-type, anti-EGFR agents; and
- Have disease progression or demonstrated intolerance to a maximum of 2 prior chemotherapy regimens for the treatment of unresectable or metastatic colorectal cancer.

Clinical Notes:

- Patients should have a good performance status.
- Treatment should continue until disease progression or unacceptable toxicity.
- No active CNS metastases (eligible if treated/stable).
- Patients with small bowel or appendiceal adenocarcinoma are eligible.
- Patients who were unable to receive bevacizumab in a prior line of therapy due to a contraindication will be eligible.
- Patients who have received adjuvant/neoadjuvant chemotherapy and had recurrence during or within 6 months of completion can count the adjuvant/neoadjuvant therapy as 1 of the maximum of 2 required prior chemotherapy regimens. Regimens which contain only targeted therapy or immunotherapy will not be considered as chemotherapy regimens.
- If bevacizumab is discontinued due to intolerance or contraindication, trifluridine-tipiracil can be continued at the discretion of the physician.