PEI Pharmacare
P.O. Box 2000
Charlottetown, PE
C1A 7N8
www.princeedwardisland.ca

Programmes provinciaux de médicaments
C.P. 2000
Charlottetown, PE
C1A 7N8
www.princeedwardisland.ca

PEI Pharmacare Bulletin

Issue (2026-05) **April 14, 2026**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: APRIL 28, 2026)

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

Aflibercept	**Enzeevu**	**2mg/0.05mL**	**Pre-Filled Syringe**	**02562510**	**SDZ**
Criteria	See online Formulary for Aflibercept criteria.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program, Seniors Drug Program, Family Health Benefit Drug Program				

Crovalimab	**Piasky**	**340mg/2mL**	**Vial**	**02558262** **00900094***	**HLR**
Criteria	*use when drug cost in excess of CPhA maximum For the treatment of paroxysmal nocturnal hemoglobinuria (PNH) in adults and adolescents 13 years of age and older with a body weight of at least 40 kg who meet the following criteria: The diagnosis of PNH has been made based on the following confirmatory results: • Flow cytometry/FLAER exam with granulocytes or monocyte clone ≥ 10%; AND • LDH > 1.5 ULN; AND • At least one of the following: ○ A thrombotic or embolic event which required the institution of therapeutic anticoagulant therapy; ○ Minimum transfusion requirement of 4 units of red blood cells in the previous 12 months; ○ Chronic or recurrent anemia where causes other than hemolysis have been excluded and demonstrated by more than one measure of less than or equal to 70g/L or by more than one measure of less than or equal to 100g/L with concurrent symptoms of anemia; ○ Pulmonary insufficiency: Debilitating shortness of breath and/or chest pain resulting in limitation of normal activity (New York Heart Association Class III) and/or established diagnosis of pulmonary arterial hypertension, where causes other than PNH have been excluded; ○ Renal insufficiency: History of renal insufficiency, demonstrated by an eGFR less than or equal to 60 mL/min/1.73m^2, where causes other than				

PNH have been excluded;
    - Smooth muscle spasm: Recurrent episodes of severe pain requiring hospitalization and/or narcotic analgesia, where causes other than PNH have been excluded.

Renewal Criteria:

- Renewals will be considered for patients who:
    - Demonstrate clinical improvement while on therapy OR
    - Where therapy has been shown to stabilize the patient's condition.
- Requests for renewal should be accompanied by confirmation of granulocyte clone size (by flow cytometry).

Exclusion Criteria:
Exclusion criteria for both initiation and renewal requests:

- Small granulocyte or monocyte clone size - the treatment of patients with a granulocyte and monocyte clone size below 10% will not be eligible for treatment; OR
- Aplastic anemia with two or more of the following: neutrophil count below 0.5 x 10^9/L, platelet count below 20 x 10^9/L, reticulocytes below 25 x 10^9/L, or severe bone marrow hypocellularity; OR
- Patients afflicted with PNH and another life-threatening or severe disease where the long-term prognosis is unlikely to be influenced by therapy (for example acute myeloid leukemia or high-risk myelodysplastic syndrome); OR
- The presence of another medical condition that might reasonably be expected to compromise a response to therapy.

Exclusion criteria for renewal requests:

- The patient or treating physician fails to comply adequately with treatment or measures, including monitoring requirements, taken to evaluate the effectiveness of the therapy; OR
- If therapy fails to relieve the symptoms of disease that originally resulted in the patient being approved for subsidized treatment.

Clinical Notes:

- Patients with insufficient initial response or who have failed treatment with eculizumab or ravulizumab at the Health Canada– recommended dosage are not eligible for reimbursement of crovalimab.
- All patients must receive meningococcal vaccination with a tetravalent vaccine at least two weeks prior to receiving the first dose of crovalimab.

Claim Notes:

- Approvals will be for a maximum of:

	≥ 40 kg to < 100 kg	**≥ 100kg**
Loading Doses		
Day 1	1000 mg (IV)	1500 mg (IV)
Day 2, 8, 15, 22	340 mg (SC)	340 mg (SC)
Maintenance Dose		
Day 29 and every 4 weeks thereafter	680 mg (SC)	1020 mg (SC)

- Initial Approval: 6 months
- Renewal Approval: 1 year
- The patient must be under the care of a pediatric nephrologist, a nephrologist, a pediatric hematologist or a hematologist.

Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

<table>
<tr><th>Guselkumab</th><th>Tremfya</th><th>10 mg/mL
100 mg/ml</th><th>Vial
Pre-filled Pen</th><th>02559153
02559145</th><th>JAN</th></tr>
<tr><td>Criteria</td><td colspan="5">

See online Formulary for Guselkumab criteria.

Additionally, special authorization criteria for these and currently listed products have been amended to include the following indications:

<u>Crohn's Disease</u>
For the treatment of patients with moderate to severe Crohn’s disease who have active disease and are refractory, intolerant or have contraindications to:

- Prednisone 40mg (or equivalent) daily for ≥ 2 weeks (not required for treatment of Fistulizing Crohn’s Disease),

AND

- Azathioprine ≥ 2 mg/kg/day for ≥ 3 months, OR
- Mercaptopurine ≥ 1 mg/kg/day for ≥ 3 months, OR
- Methotrexate (SC or IM) ≥ 15 mg/week for ≥ 3 months

Clinical Notes:

- Refractory is defined as lack or loss 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.
- Consideration will be given for the approval of a biologic DMARD (disease modifying antirheumatic drug) without a trial of a traditional DMARD for patients who have an aggressive/severe disease course (e.g. extensive disease, a modified Harvey Bradshaw Index score > 16) and are refractory, intolerant or have contraindications to systemic corticosteroids.

Claim Notes:

- Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
- Combined use with other biologic drugs or janus kinase (JAK) inhibitors will not be reimbursed.
- Approvals will be for a maximum of 200mg intravenously or 400mg subcutaneously at Weeks 0, 4 and 8, followed by a maximum maintenance dose of 100mg subcutaneously at Week 16 and every 8 weeks thereafter or 200mg subcutaneously at Week 12 and every 4 weeks thereafter.
- Initial Approval: 6 months
- Renewal Approval: 1 year

<u>Ulcerative Colitis</u>
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).

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

</td></tr>
</table>

	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
	
	Claim Notes:
	• Must be prescribed by a gastroenterologist or physician with a specialty in gastroenterology.
	• Combined therapy with other biologic therapies, JAK inhibitors or sphingosine 1-phosphate receptor modulators for UC will not be reimbursed.
	• Approvals will be for a maximum of 200mg intravenously or 400mg subcutaneously at Weeks 0, 4 and 8, followed by a maximum maintenance dose of 100mg subcutaneously at Week 16 and every 8 weeks thereafter or 200mg subcutaneously at Week 12 and every 4 weeks thereafter.
	• Initial approval: 6 months
	• Renewal Approval: 1 year.
	• Renewal requests must include information demonstrating the beneficial effects of the treatment, specifically:
	  ○ a decrease in the partial Mayo score ≥ 2 from baseline, and
	  ○ a decrease in the rectal bleeding subscore ≥ 1.

Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Inebilizumab	**Uplizna**	**10 mg/mL**	**Vial**	**02543931**	**AMG**
Criteria	For the treatment of adult patients with neuromyelitis optica spectrum disorder (NMOSD) who meet all of the following criteria: • Aquaporin-4 antibody positive • Expanded Disability Status Scale (EDSS) score of 8 points or less • Experienced at least one relapse in the previous 12 months or at least two relapses in the previous 24 months • Relapse occurred despite an adequate trial of other accessible preventive treatments[1] for NMOSD, or because the patient cannot tolerate other preventive treatments for NMOSD Renewal Criteria: • Requests for renewal will be considered for patients who maintain an EDSS score of 8 points or less. Clinical Note: • Inebilizumab should not be initiated during a NMOSD relapse. Claim Notes: • Must be prescribed by a neurologist with experience in the treatment of NMOSD. • Combined use of more than one biologic drug for the treatment of NMOSD will not be reimbursed. • Approvals will be for 300 mg at week 0 and 2 followed by 300 mg every 6 months (starting six months from the first infusion). • Approval period: 1 year [1]Other accessible preventative treatments include, but are not limited to, monoclonal antibodies and other immunosuppressants.				
Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Piroxicam	-	10 mg	Capsule	00642886	APO
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				

Ustekinumab	Wezlana	45mg/0.5mL 90mg/mL	Prefilled auto injector	02553317 02553309	AMG
Criteria	See online Formulary for Ustekinumab criteria.				
Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Ustekinumab	Yesintek Yesintek I.V.	45mg/0.5mL 45mg/0.5mL 90mg/mL 130mg/26mL	Prefilled syringe Vial Prefilled syringe Vial	02562081 02562081 02562103 02562111	BHD
Criteria	See online Formulary for Ustekinumab criteria.				
Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

CRITERIA UPDATE

Effective immediately, special authorization criteria for the below currently listed multiple sclerosis products have been amended to an approval period of 2 years.

- Dimethyl Fumarate delayed release capsules
- Glatiramer Acetate pre-filled syringes
- Interferon Beta-1A pre-filled syringes and cartridges
- Interferon Beta-1B (Betaseron) injection powder
- Peginterferon Beta-1A (Plegridy) injection
- Teriflunomide tablet
- Fingolimod capsule
- Natalizumab (Tysabri) vial
- Ocrelizumab (Ocrevus) vial

GENERIC AND BRAND NAME COVERAGE REMINDER

When a brand name product is requested, patients are responsible for paying for the standard pharmacy co-pay, plus any difference between the brand name cost and the price reimbursed by government for the lowest-cost generic. PEI Pharmacare **will not** consider Special Authorization requests for brand name coverage when generic products are available.

PEI BIOSIMILAR INITIATIVE REMINDER

Patients with existing PEI Pharmacare coverage for either Eylea® or Lucentis® must switch to a biosimilar version by May 31, 2026, to maintain coverage under PEI Pharmacare. After May 31, 2026, Eylea® and Lucentis® will be delisted as benefits under the Pharmacare Programs.

CHANGE IN BENEFIT STATUS

Effective immediately, the following product will be delisted as a benefit under the Pharmacare Programs.

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Ranibizumab	Byooviz	2.3mg/0.23mL	Vial	02525852	BGH