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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: MAY 26, 2026)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Aflibercept	**Eylea HD**	**8mg/0.07mL**	**Vial Pre-Filled Syringe**	**02545004 02554798**	**BAY**
Criteria	Neovascular Age-Related Macular Degeneration **Criteria for Initial Coverage:** For the treatment of patients with neovascular (wet) age-related macular degeneration (AMD) where all of the following apply: • Treatment naive to anti-VEGF drugs for nAMD • Best Corrected Visual Acuity (BCVA) is between 6/12 and 6/96 • The lesion size is less than or equal to 12 disc areas in greatest linear dimension • There is evidence of recent (<3 months) presumed disease progression (blood vessel growth, as indicated by fluoresce in angiography, optical coherence tomography (OCT), or recent visual acuity changes. **Criteria for Continued Coverage:** • Treatment with aflibercept 8 mg should be continued only in people who maintain adequate response to therapy. • Aflibercept 8 mg should be discontinued if any of the following occur: o the patient is unable to be maintained on a 12 week or greater interval between injections o Reduction in BCVA in the treated eye to less than 15 letters (absolute) on 2 consecutive visits in the treated eye, attributed to AMD in the absence of other pathology o Reductions in BCVA of 30 letters or more compared to either baseline and/or best recorded level since baseline as this may indicate either poor treatment effect, adverse events, or both o There is evidence of deterioration of the lesion morphology despite optimum treatment over 3 consecutive visits. Coverage will not be approved for patients: • Receiving concurrent treatment with other anti-VEGF drugs for ophthalmic use.				

	• With permanent retinal damage as defined by the Royal College of Ophthalmology guidelines. Claim Notes: • Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. • Approvals will be for 1 vial/PFS per eye every 30 days for the first 3 doses, followed by 1 vial/PFS per eye every 12 to 16 weeks. • Approval period: 1 year. Confirmation of continued response is required. <u>Diabetic Macular Edema (DME)</u> **Criteria for Initial Coverage:** For the treatment of visual impairment due to diabetic macular edema (DME) in patients who meet all of the following criteria: • Clinically significant centre-involving macular edema for whom laser photocoagulation is also indicated • Hemoglobin A1C test in the past 6 months with a value of less than or equal to 11% • Best corrected visual acuity of 20/32 to 20/400 • Central retinal thickness greater than or equal to 250 micrometers **Criteria for Continued Coverage:** • The patient is able to be maintained on a 12 week or greater interval between injections. • Confirm that a hemoglobin A1C test in the past 6 months had a value of less than or equal to 11%. • Date of last visit and results of best corrected visual acuity at that visit • Date of last OCT and central retinal thickness on that examination Clinical Notes: 1. Recommended Dose: Treatment should be initiated with a monthly intravitreal injection for the first 3 consecutive doses, followed by one injection every 12 to 16 weeks. 2. Treatment should be discontinued if there is no improvement of retinal thickness or visual acuity from week 12. 3. Injection will be by a qualified ophthalmologist with experience in administering intravitreal injections. Claim Notes: • Must be prescribed and administered by a retina specialist or an ophthalmologist with experience in administering intravitreal injections. • Will not be insured in combination with other anti-VEGF drugs for ophthalmic use. • Approvals will be for 1 vial/PFS per eye every 30 days for the first 3 doses, followed by 1 vial/PFS per eye every 12 to 16 weeks. • Approval period: 1 year. Confirmation of continued response is required.
Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Clozapine	**Gen-Clozapine**	**25mg 50mg 100mg 200mg**	**Oral Disintegrating Tablet**	**02554658 02554666 02554674 02554682**	**MYL**
Criteria	See online Formulary for Clozapine criteria.				

Program Eligibility	Family Health Benefit Drug Program, Generic Drug Program, Nursing Home Drug Program, Catastrophic Drug Program, Seniors Drug Program, Financial Assistance Drug Program

Migalastat	**Galafold**	**123 mg**	**Capsule**	**02468042 00904406***	**AMT**
Criteria	*use when drug cost in excess of CPhA maximum For the treatment of Fabry Disease in adults with a lab-confirmed alpha-galactosidase (alpha-Gal A) mutation, determined to be amenable by an in vitro assay. Clinical Note: • Eligibility for the treatment of Fabry Disease is determined by the Canadian Fabry Disease Initiative. Claim Notes: • Combined use of more than one disease specific therapy (i.e. enzyme replacement therapy or chaperone therapy) will not be reimbursed. • Initial approval period: 1 year. • Renewal approval period: 1 year. Confirmation of continued response is required. • Not for use in pediatrics (i.e. patients < 18 years of age).				
Program Eligibility	High Cost Drug Program, Financial Assistance Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

CRITERIA UPDATES

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

- Ofatumumab (Kesimpta) pre-filled pen
- Siponimod (Mayzent) tablet

Effective immediately, special authorization criteria for currently listed cinacalcet tablets have been amended to the following:

- For the treatment of dialysis patients with severe hyperparathyroidism (PTH > 88 pmol/L measured twice in 3 months at least 6 weeks apart) who have maximized phosphate binder therapy and vitamin D therapy.
- Patients must have one of the following:
  - corrected serum calcium ≥ 2.2mmol/L AND serum phosphate > 1.8mmol/L; OR
  - presence of symptoms related to hyperparathyroidism (i.e. bone pain).
- Initial Approval Period: 3 months. Coverage for cinacalcet will be renewed if there is a greater than 30% decrease in PTH after at least 3 months with escalating dose, indicating the patient is responding.
- Renewal Approval Period: 12 months – provided there has been a greater than 30% decrease in PTH as stated above.

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.