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PEI Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: JUNE 17, 2025)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Berotralstat Hydrochloride	**Orladeyo**	**150 mg**	**Capsule**	**02527693**	**BCP**
Criteria	For the routine prevention of attacks of type I or II hereditary angioedema (HAE) in adults and pediatric 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 berotralstat compared to the number of attacks observed before initiating treatment with berotralstat; 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 berotralstat. 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 berotralstat, pre-treatment attack rate prior to long-term prophylactic treatment must be provided. Claim Notes: • The patient must be under the care of a physician experienced in the diagnosis and treatment of HAE. • Not be used in combination with other medications used for long-term prophylaxis (LTP) treatment of angioedema (e.g., C1-esterase inhibitors or lanadelumab). • Approvals will be for a maximum of 150mg daily. • Initial approval period: 3 months.				

	• Renewal approval period: 6 months.
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Mesalamine	**Mezera**	**1000 mg**	**Tablet**	**02545012**	**AVI**
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Nursing Home Drug Program, Catastrophic Drug Program, Seniors Drug Program, Financial Assistance Drug Program				

Selumetinib	**Koselugo**	**10 mg** **25 mg**	**Capsule**	**02530139** **02530147**	**ALX**
Criteria	For pediatric patients aged 2 to 18 years with neurofibromatosis type 1 (NF1) with symptomatic, inoperable plexiform neurofibromas (PNs). Initial renewal: • The physician must document the beneficial clinical effect when requesting continuation of reimbursement. • Patients on therapy should be monitored for response (e.g., a reduction in pain, improved function, reduction in tumour volume and/or size, disease stabilization) using clinical judgment and/or standard imaging. Second and subsequent renewal criteria (at 18 months after initiation and thereafter): • The patient does not have disease worsening or progression (e.g., worsening of motor function or pain). Claim Notes: • The patient must be under the care of either a neurooncologist or a pediatrician with expertise in neurooncology. • Initial approval: 18 months • Renewal Approval: 12 months				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

CRITERIA UPDATE

Effective immediately, methylphenidate hydrochloride (Foquest) extended-release capsules will no longer require Special Authorization and will be open benefit in the Family Health Benefit Drug Program, Financial Assistance Drug Program, and Catastrophic Drug Program.