Health PEI
One Island Health System

PEI Pharmacare
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Programmes provinciaux de medicaments
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PEI Pharmacare Bulletin

Issue (2024 - 3) **March 12, 2024**

NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: MARCH 25, 2024)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Estradiol-Progesterone	**Bijuva**	**1 mg-100 mg**	**Capsule**	**02505223**	**KNI**
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Financial Assistance Drug Program, Catastrophic Drug Program				

Filgrastim	**Nypozi**	**300 mcg/0.5ml** **480 mcg/0.8ml**	**Prefilled syringe** **Prefilled syringe**	**02520990** **02521008**	**TAV**
Criteria	See online Formulary for filgrastim criteria				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

Sapropterin ***Use PDIN when drug cost in excess of CPHA maximum**	**Reddy-Sapropterin**	**100 mg** **500 mg**	**Powder for Oral Solution** **Powder for Oral Solution**	**02534533** **96599937*** **02535610** **96599936***	**RCH**
Criteria	For the ongoing treatment of hyperphenylalaninemia (HPA) due to tetrahydrobiopterin (BH4)-responsive phenylketonuria (PKU) in conjunction with a phenylalanine (Phe)-restricted diet in patients who meet all of the following criteria: • Confirmed diagnosis based on genetic testing. • Response to sapropterin provided by the manufacturers initial 6 month trial through the Patient Support Program (PSP) 'Reddy-Sapropterin Support Program for Patients with HPA due to PKU'. • Baseline blood Phe levels greater than 360 umol/L despite compliance with a low protein diet and formulas (nonpregnant patients require at least 2 baseline levels and pregnant patients require at least 1 baseline level during a 3 to 6 month time frame).				

	• Achievement of the following during a 6-month trial of treatment: - For pregnant or non-pregnant patients, normal sustained blood Phe levels of 120 umol/L to 360 umol/L; or - For non-pregnant patients, sustained blood Phe reduction of at least 30% compared to baseline if the baseline blood Phe level is less than 1200 umol/L; or - For non-pregnant patients, sustained blood Phe reduction of at least 50% compared to baseline if the baseline blood Phe level is greater than 1200 umol/L. • For non-pregnant patients, documented increase in dietary protein tolerance based on targets set between the clinician and patient. Renewal Criteria: • Confirmation of continued response to sapropterin based on Phe levels achieved during the 6-month trial. Two Phe levels taken at least 1 month apart must be provided. Clinical Notes: 1. Patients must be initiated on treatment and followed in a specialized clinic with expertise in the diagnosis and management of PKU. 2. Phe blood levels and Phe tolerance levels must be provided. 3. Pregnant patients who have maintained a decrease in Phe levels below 360 umol/L during the 6-month trial period will be eligible for coverage of sapropterin for the duration of the pregnancy. 4. Confirmation of compliance with a low protein diet is required before initiation and in conjunction with ongoing use. Claim Notes: • Approvals will be for a maximum of 20 mg/kg per day. • Renewals for sapropterin in pregnant patients will not be considered. • Approval period: 1 year
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program

Somatrogon	**Ngenla**	**24 mg/1.2 ml** **60 mg/1.2 ml**	**Prefilled Pen** **Prefilled Pen**	**02521679** **02521687**	**PFI**
Criteria	For the long-term treatment of pediatric patients who have growth failure due to an inadequate secretion of endogenous growth hormone (growth hormone deficiency [GHD]) only is the following conditions are met: Initiation Criteria: Pre-pubertal children who are at least 3 years of age, and who are diagnosed with either isolated GHD, or growth hormone insufficiency as part of multiple pituitary hormone deficiency. Discontinuation Criteria: Treatment with somatrogon must be discontinued upon the occurrence of any of the following: 1. Height velocity is less than 2 cm per year and bone age is more than 16 years in boys and 14 years in girls 2. Closure of the epiphyseal growth plates				

	Clinical Notes: 1. Patient height and weight must be provided with all requests. 2. Confirmation there is no evidence of epiphyseal growth plate closure and a copy of the bone age report must be provided with all requests. 3. Bone age assessments may be based on the Greulich Pyle Atlas, Tanner-Whitehouse, or other appropriate methods of assessment. Claim Notes: • Must be prescribed by, or in consultation with, an endocrinologist. • Approvals will be for a maximum of 0.66 mg/kg weekly. • Approval period: 1 year
Program Eligibility	Growth Hormone Drug Program

Zopiclone	**pms-Zopiclone**	**3.75 mg**	**Tablet**	**02458543**	**PMS**
Criteria	Open benefit				
Program Eligibility	Family Health Benefit Drug Program, Nursing Home Drug Program, Financial Assistance Drug Program, Catastrophic Drug Program				

CLAIM SUBMISSIONS

Some out of province physicians have been assigned a PEI billing number. When provided, this billing number **must** be used when submitting a prescription for reimbursement.

If a prescription has been written by an out of province clinician and does not contain a PEI billing number, continue to use 999 as a billing number.

The use of 999 for PEI based clinicians is not permitted; please ensure you are submitting the correct billing number to enable claims to adjudicate properly.

BIOSIMILAR INITIATIVE UPDATE

The ongoing PEI Biosimilar Initiative requires patients who have coverage for any of the following originator drugs through PEI Pharmacare to switch to a biosimilar version before the end of the switching period for that drug to maintain coverage.

For patients prescribed Humalog®, Lantus® and NovoRapid® - the switching period ends *June 30, 2024.*

- During the switching period, pharmacies will be reimbursed for a biosimilar insulin therapeutic substitution by a pharmacist. Details about the fee can be found under the "Biosimilars" section on the HPEI Staff Resource Centre - Resources for Pharmacists page
- Some patients may require continued access to an originator insulin because their insulin pump has not yet been approved for use with the biosimilar version of their insulin. Coverage of the originator insulin will be extended beyond the end of the switching period (June 30, 2024) if compatibility has not yet been confirmed.
- Insulin pump and biosimilar insulin compatibility information was previously shared in a PEI Pharmacare Memo which can be found under the "Biosimilars" section on the HPEI Staff Resource Centre - Resources for Pharmacists page

For patients prescribed Copaxone®, Enbrel®, Humira®, Remicade® and Rituxan® - the switching period ends *September 30, 2024*.

- No special authorization renewal requests for originator biologics will be considered during the switching phase unless the patient has an approved exemption.
- For patients who do not have a scheduled appointment with their prescriber before their special authorization needs to be renewed, the patient or a health care provider may complete the online or paper switching exemption form. If the patient's appointment is scheduled before September 30, 2024, the special authorization coverage for the originator biologic may be extended for 1 month following your appointment date.

For further information about the PEI Biosimilar Initiative, please refer to:

- PEI Biosimilar Initiative webpage
- HPEI Staff Resource Centre Biosimilar Initiative Information for Health Care Providers
- Email: pei-biosimilar-initiative@gov.pe.ca
- Call: 902-218-4653