

Santé Î.-P.-É. Un système de santé unique

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PEI Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: (AUGUST 8, 2022)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Elexacaftor / Tezacaftor / Ivacaftor and Ivacaftor	Trikafta	50mg/ 25mg/ 37.5 mg tablet & 75 mg tablet	Tablet	02526670	VER
Program Eligibility	Cystic Fibrosis Drug Program				

<u>CRITERIA UPDATE</u>

➤Effective immediately, the criteria for listed Trikafta products is the following:

For the treatment of cystic fibrosis (CF) in patients 6 years of age and older who meet all of the following criteria:

- Confirmed diagnoses of CF with at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR gene); AND
- Patient has been optimized on best supportive care for their CF prior to starting Trikafta; AND
- Prescribed by a clinical specialist affiliated with a Canadian cystic fibrosis centre.

The following measurements must be completed prior to initiating treatment with Trikafta:

- Baseline spirometry measurements of FEV1 in liters and percent predicted (within the last 30 days); AND
- Number of days treated with oral and/or intravenous (IV) antibiotics for pulmonary exacerbations in the previous 6
 months OR number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months; AND
- Number of CF-related hospitalizations in the previous 6 months; AND
- Weight, height, and body mass index (BMI); AND
- A score from an age-appropriate cystic fibrosis questionnaire as follows:
 - Cystic Fibrosis Questionnaire Child (CFQ-C) and Cystic Fibrosis Questionnaire-Parent (CFQ-P), if the Patient is 6 to 13 years of age, inclusive: or
 - Cystic Fibrosis Questionnaire Revised (CFQ-R teen/adult) Respiratory Domain score, if the Patient is 14 years of age or older.

Exclusion criteria:

- Patient has undergone lung transplantation; OR
- Patient is using Trikafta as combination therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) modulator.

Initial approval duration: 6 months

Initial renewal criteria:

Renewal of funding will be considered in patients demonstrating <u>at least ONE</u> of the following improvements after 6 months of treatment with Trikafta;

- 1. Improvement of percent predicted FEV1 by 5% or more above the baseline measurement; OR
- 2. A decrease in the total number of days for which the patient received treatment with oral and/or IV antibiotics for pulmonary exacerbations compared with the 6-month period prior to initiating treatment OR a decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6-month period prior to initiating treatment; OR
- 3. Decreased number of CF-related hospitalizations in the 6 months after initiation of Trikafta treatment compared with the 6-month period prior to initiating Trikafta; OR
- 4. No decline in BMI at 6 months compared with the baseline BMI assessment; OR
- 5. Improvement by 4 points or more in the CFQ-R Respiratory Domain scale compared to baseline scores.

Subsequent renewal criteria:

For patients who have met the initiation criteria and initial renewal criteria.

- Ongoing renewal of funding will be provided for those who are continuing to benefit from therapy with Trikafta and who do not meet any of the exclusion criteria.
- At the time of renewal application, please include the patient's most recent ppFEV1 and a clinical update to confirm the treatment benefits or response experienced by the patient.

Approval duration of renewals: 1 year

Approved doses:

- 6 to < 12 years of age (weight < 30kg): 2 tablets (each containing elexacaftor/ tezacaftor/ ivacaftor 50mg/ 25mg/ 37.5mg) taken in the morning & one tablet (ivacaftor 75mg) taken in the evening approximately 12 hours apart.
- 6 to < 12 years of age (weight ≥ 30kg): 2 tablets (each containing elexacaftor/ tezacaftor/ ivacaftor 100mg/ 50mg/ 75mg) taken in the morning & one tablet (ivacaftor 150mg) taken in the evening approximately 12 hours apart.
- 12 years of age and older: 2 tablets (each containing elexacaftor/ tezacaftor/ ivacaftor 100mg/ 50mg/ 75mg) taken in the morning & one tablet (ivacaftor 150mg) taken in the evening approximately 12 hours apart.
- > Effective immediately, the criteria for currently listed Vesanoid is the following:
 - Open benefit if written by an oncologist upon notification to Pharmacare. Patient must be registered in the high cost drug program.

DRUG PROGRAM INFORMATION

- ➤ Effective immediately, registered health care professionals are required to use the new *Diabetes Drug Program Registration Form* for all Diabetes Drug Program patient registrations. The form can be found:
 - https://www.princeedwardisland.ca/en/information/health-pei/diabetes-drug-program
- ➤ Effective immediately, the following medications are covered under the Community Mental Health Drug Program:
 - Aripiprazole, injection, 300mg, 400mg (Abilify Maintena®)

- Paliperidone, injection, 50mg, 75mg, 100mg, 150mg (Invega Sustenna®)
- Paliperidone, prefilled pen, 175mg/0.875ml, 263mg/1.315ml, 350mg/1.75ml, 525mg/2.625ml (Invega Trinza®)
- Risperidone, prolonged release injection, 12.5mg/2mL, 25mg/2mL, 37.5mg/2mL, 50mg/2mL (Risperdal Consta®)

A special authorization is not required for coverage of the above medications under the Community Mental Health Drug Program.

REMOVAL OF SPECIAL AUTHORIZATION CRITERIA

➤ Effective immediately, the following medications will no longer require special authorization, and will be open benefits in currently listed programs. Please disregard any special authorization expiry alerts, communicated through the Integrated Claims System, for these medications.

Product (Generic Name)	Product (Brand Name)	Currently Listed Drug Programs
Acitretin, Capsule	Soriatane and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Aripiprazole, Tablet	Abilify and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Cefprozil, Tablets And Oral Suspension	Generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Dihydroergotamine Mesylate, Nasal Spray	Migranal	Family Health Benefit Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Entacapone, Tablet	Comtan and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Estradiol, Transdermal Patch	Estradot and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Estradiol & Norethinrone Acetate, Transdermal Patch	Estalis	Family Health Benefit Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Etidronate, Tablet	Generic	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Levodopa & Carbidopa, Controlled Release Tablets	Generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Megestrol Acetate, Tablet	Generic	HIV Drug Program, Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Midodrine HCl, Tablet	Generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Nabumetone, Tablets	Generic	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Nilutamide, Tab	Anandron	Family Health Benefit Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Octreotide, Injection	Sandostatin and generic	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Olanzapine, Orally Disintegrating Tablet	Zyprexa Zydis and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Olanzapine, Tablet	Zyprexa and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Pioglitazone, Tablet	Generics	Diabetes Program, Nursing Home Program, Catastrophic Program, Financial Assistance Program
Quetiapine, Tablet	Seroquel and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program
Ropinirole, Tablet	Generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program,

		Financial Assistance Program	
Terbinafine, Cream 1%	Lamisil cream	Family Health Benefit Program, Nursing Home Program, Catastrophic Program, Seniors Program,	
	Zamen cream	Financial Assistance Program	
Tetrabenazine, Tablet	Nitoman and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program	
Ursodiol, Tablet	URSO and URSO DS and generics	Family Health Benefit Program, Generic Program, Nursing Home Program, Catastrophic Program, Seniors Program, Financial Assistance Program	