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PEI Pharmacare Bulletin

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NEW PRODUCT(S) ADDED TO THE PEI PHARMACARE FORMULARY (EFFECTIVE DATE: MARCH 11, 2025)

Product (Generic name)	Product (Brand name)	Strength	Dosage Form	DIN	MFR
Ivacaftor/Lumacaftor	**Orkambi**	**94 mg/75 mg**	**Sachet**	**02537087**	**VTX**
Criteria	See online Formulary for Ivacaftor/Lumacaftor criteria.				
Program Eligibility	Cystic Fibrosis Drug Program				

Ustekinumab	**Steqeyma**	**45 mg/0.5 mL 90 mg/mL 130 mg/26 mL**	**Prefilled Syringe Prefilled Syringe Single-use Vial**	**02550245 02550253 02550261**	**CLT**
Criteria	See online Formulary for Ustekinumab criteria for Plaque Psoriasis, Psoriatic Arthritis, and Crohn's Disease.				
Program Eligibility	Financial Assistance Drug Program, High Cost Drug Program, Nursing Home Drug Program, Catastrophic Drug Program				

CRITERIA UPDATE

Effective immediately, coverage for biosimilar molecules including Adalimumab, Infliximab, Etanercept, Ustekinumab, and Glatiramer Acetate will no longer require annual reassessment of the patient and submission of a new Special Authorization Request Form. The submission of an initial request and subsequent renewal will still be required; however, coverage will be set up long term thereafter assuming confirmation of continued response to therapy.

Effective immediately, special authorization criteria for currently listed **ivacaftor/elexacaftor/tezacaftor & ivacaftor (Trikafta)** tablets have been amended to include the following:

- For the treatment of cystic fibrosis (CF) in patients aged two (2) years and older who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to lexacaftor/tezacaftor/ivacaftor and ivacaftor based on clinical and/or in vitro data. Patients should be optimized with best supportive care for their CF at the time of initiation.

For patients aged 2 to 5 years of age:

Initial Renewal Criteria:
The patient must meet one of the following criteria:

- Decrease in the total number of days for which the patient received treatment with oral and/or intravenous (IV) antibiotics for pulmonary exacerbations compared with the 6-month period prior to initiating treatment. OR
- Decrease in the total number of pulmonary exacerbations requiring oral and/or IV antibiotics compared with the 6-month period prior to initiating treatment. AND
- No decrease in Body Mass Index (BMI) z-score compared with baseline.

Subsequent Renewal Criteria:
Evidence of continued benefit must be provided for at least one of the parameters noted above at the end of each 12-month period.

Clinical Notes:

1. The following baseline measurements must be provided prior to initiation of treatment:
    a. Total number of days treated with oral and/or IV antibiotics for pulmonary exacerbations in the 6 months prior to initiation of treatment
    b. Total number of pulmonary exacerbations requiring oral and/or IV antibiotics in the 6 months prior to initiation of treatment
    c. BMI z-score
2. Requests will not be considered for patients who have undergone lung transplantation.

Claim Notes:

- The patient must be under the care of a physician with experience in the diagnosis and management of CF.
- Combined use of more than one CFTR modulator will not be reimbursed.
- Approval period: 1 year.

For patients aged 6 years and older who:

Initial renewal criteria:
For the initial renewal, the patient must meet at least ONE of the following criteria:

- Improvement of lung function by 5% of predicted or more (ppFEV1 compared to baseline (baseline lung function should be measured within a 3-month period prior to beginning treatment with Trikafta); OR
- 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
- Decreased number of CF-related hospitalizations at 6 months compared with the 6-month period prior to initiating Trikafta treatment; OR
- No decline in BMI (BMI z score in children) at 6 months compared with the baseline BMI assessment; OR
- Improvement by 4 points or more in the CF Questionnaire-Revised (CFQ-R) Respiratory Domain scale compared to baseline.

Subsequent Renewal Criteria:

- Evidence of continued benefit from treatment with Trikafta for subsequent renewals (e.g. ppFEV1, CFQ-R, pulmonary exacerbations).

Clinical Notes:

1. The following measurements must be completed prior to initiating treatment with Trikafta:
    a. Baseline spirometry measurements of FEV1 and ppFEV1 within the last 90 days prior to initiating treatment ;

b. Number of days treated with oral and IV antibiotics for pulmonary exacerbations in the previous 6 months;
c. Number of pulmonary exacerbations requiring oral and/or IV antibiotics in the previous 6 months;
d. Number of CF-related hospitalizations in the previous 6 months;
e. Weight, height, and BMI; and
f. CFQ-R Respiratory Domain score.

2. Requests will not be considered for patients who have undergone lung transplantation

Claim Notes:

- The patient must be under the case of a physician with experience in the diagnosis and management of CF.
- Combined use of more than one CFTR modulator will not be reimbursed.
- Initial approval: 6 months.
- Renewal approval period: 1 year
- Approved dose:
    - 6 to < 12 years of age weighing < 30kg: Two tablets (each containing elexacaftor 50 mg/tezacaftor 25 mg/ivacaftor 37.5 mg) in the morning & one tablet (ivacaftor 75 mg) taken in the evening with fat-containing food, approximately 12 hours apart.
    - 6 to < 12 years of age weighing ≥ 30kg: 2 tablets (each containing elexacaftor/ tezacaftor/ ivacaftor 100mg/ 50mg/ 75mg) taken in the morning & one tablet (ivacaftor 150mg) taken with fat-containing food, in the evening approximately 12 hours apart.
    - 12 years and older: 2 tablets (each containing elexacaftor/ tezacaftor/ ivacaftor 100mg/ 50mg/ 75mg) taken in the morning & one tablet (ivacaftor 150mg) taken in the evening with fat-containing food, approximately 12 hours apart.