CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Trikafta (elexacaftor, tezacaftor and ivacaftor tablets; ivacaftor tablets), co-packaged for oral use
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 84-count tablet carton for 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Trikafta (elexacaftor, tezacaftor and ivacaftor tablets; ivacaftor tablets) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CYSTIC FIBROSIS

For **initial** authorization:

1. Member is 12 years old or older; AND
2. Medication must be prescribed by pulmonologist or an infectious disease specialist; AND
3. Member has had genetic testing documented in chart notes with at least one F508del mutation in the CFTR gene.
4. **Dosage allowed:** Morning dose: two elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg tablets. Evening dose: one ivacaftor 150 mg tablet. Morning and evening dose should be taken approximately 12 hours apart with fat-containing food.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member's adherence to medication is confirmed by claims history; AND
3. Chart notes submitted with any of the following:
   a) Improved FEV1 and/or other lung function tests;
   b) Improvement in sweat chloride;
   c) Decrease in pulmonary exacerbations;
   d) Decrease in pulmonary infections;
   e) Increase in weight-gain;
   f) Decrease in hospitalizations.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Trikafta (elexacaftor, tezacaftor and ivacaftor tablets; ivacaftor tablets) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
11/12/2019	New policy for Trikafta created.

References:

1. Trikafta [prescribing information]. Boston, MA: Vertex Pharmaceuticals Inc; October, 2019.
2. National Guideline Clearinghouse (NGC). Guideline summary: Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 Apr 01. Available: https://www.atsjournals.org/doi/full/10.1164/rccm.201207-1160OE.
3. Trikafta prescribing Information: https://www.accessdata.fda.gov/drugsatfda_docs/label/2019/212273s000lbl.pdf

Effective date: 04/01/2020
Revised date: 11/12/2019