UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Trikafta

Program	Prior Authorization
Medication	Trikafta® (elexacaftor/tezacaftor/ivacaftor)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, New Jersey, Nevada, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	12/2019
Pharmacy and Therapeutics Approval Date	11/2020
Effective Date	12/2020

1. Background:

Trikafta is a combination of elexacaftor, tezacaftor, and ivacaftor, indicated for the treatment of patients with cystic fibrosis (CF) age 12 years and older who have at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.

If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of at least one F508del mutation.

2. Coverage Criteria:

A. Initial Authorization

1. Trikafta will be approved based upon **all** of the following criteria:

a. Diagnosis of cystic fibrosis (CF)

-AND-

b. Submission of laboratory results documenting that the patient has at least one F508del mutation in the CFTR gene.

-AND-

c. The patient is ≥ 12 years of age

-AND-

d. Prescribed by or in consultation with a specialist affiliated with a CF care center

Authorization will be issued for 6 months.

B. Reauthorization

1. Trikafta will be approved based on **both** of the following criteria:

a. Provider attests that the patient has achieved a clinically meaningful response while on Trikafta therapy to **one** of the following:

(1) Lung function as demonstrated by percent predicted expiratory volume in 1 second ($ppFEV_1$)
(2) Body mass index (BMI)
(3) Pulmonary exacerbations
(4) Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

-AND-

b. Prescribed by or in consultation with a specialist affiliated with a CF care center

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Trikafta [Package Insert]. Cambridge, MA: Vertex Pharmaceuticals, Inc.; January 2020.

Program	Prior Authorization – Trikafta (elexacaftor/tezacaftor/ivacaftor)
Change Control	
Date	Change
12/2019	New program

11/2020	Annual review. Updated reference.