Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

TRIKAFTA® (elexacaftor/ivacaftor/tezacaftor; ivacaftor) PA

TRIKAFTA® is indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on *in vitro* data.

Prior authorization is required for TRIKAFTA®. Prior authorization approval will be considered when the following criteria are met. Along with the Universal PA Form, please submit any supporting clinical documentation.

Initial Authorization: 6 months

Prior authorization will be considered for patients when **ALL** the following criteria are met:

1. Age of patient is within the age range as recommended by the FDA label; **AND**

2. Diagnosis of CF; **AND**

3. Prescribed by or in consultation with a CF specialist/pulmonologist specializing in treating CF patients. Please submit the name of the CF-treating or consulting specialist/pulmonologist on the request. Please also provide chart documentation from the consulting provider, including the name, strength, and dosing instructions of CF drug; **AND**

4. Patient has a diagnosis of CF with a CFTR gene mutation responsive to TRIKAFTA® as outlined in the FDA labeling.
   - If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of a CFTR mutation.
   - Please submit laboratory results documenting the patient's CFTR mutation upon request; **AND**

5. TRIKAFTA® is not prescribed concurrently with other CFTR modulators (e.g., Orkambi®, Kalydeco®, Symdeko®); AND

6. Baseline measures submitted by provider of **ALL** of the following:
    a. For age-appropriate patients, percent predicted expiratory volume in 1 second (ppFEV1)
    b. Body mass index (BMI)
    c. Pulmonary exacerbations- number in preceding 6 months
    d. Liver function tests (e.g., ALT, AST, alkaline phosphatase, bilirubin); **AND**

7. Dose does not exceed elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg (2 tablets elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg and 1 tablet ivacaftor 150 mg) per day

<u>Reauthorization</u>: 12 months with evidence of appropriate clinical response to therapy

1. Prescribed by or in consultation with a CF specialist/pulmonologist specializing in treating CF patients. Please submit the name of the CF-treating or consulting specialist/pulmonologist on the request. Please also provide chart documentation from the consulting provider, including the name, strength, and dosing instructions of CF drug; **AND**

2. TRIKAFTA® is not prescribed concurrently with other CFTR modulators (e.g., Orkambi®, Kalydeco®, Symdeko®); **AND**

3. Provider attests that the patient has achieve a clinically meaningful response and displayed tolerance while on TRIKAFTA® based on ALL the following:
    a. For age-appropriate patients, improved or stable lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)
    b. Body mass index (BMI)
    c. Pulmonary exacerbations – number of exacerbations compared to the number of exacerbations prior to medication initiation
    d. Liver function tests; **AND**

4. If request is for a dose increase, new dose does not exceed elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg (2 tablets elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg and 1 tablet ivacaftor 150 mg) per day.

<u>How Supplied:</u>

84-count tablet carton

(4 wallets, each wallet containing 14 tablets of elexacaftor, tezacaftor and ivacaftor and 7 tablets of ivacaftor)