Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

ALYFTREK™ (*vanzacaftor, tezacaftor, and deutivacaftor*) PA:

ALYFTREK™ (*vanzacaftor, tezacaftor, and deutivacaftor)* is indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene.

Prior authorization is required for ALYFTREK™. 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

1. Age of the 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 ALYFTREK™ 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 at least one indicated mutation.
    - Please submit laboratory results documenting the patient's CFTR mutation upon request; **AND**

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

6. Patient has one of the following:
    a. An inadequate response to a 90-day trial of Trikafta®; **OR**
    b. An intolerance or contraindication to Trikafta®; **OR**
    c. A CFTR gene mutation not responsive to Trikafta® as outlined in the FDA label; **OR**
    d. Prescriber provides detailed rationale explaining why Trikafta® is not appropriate for the patient; **AND**

7. 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**

8. Dose does not exceed vanzacaftor 20 mg, tezacaftor 100 mg, and deutivacaftor 250 mg (two tablets of vanzacaftor 10 mg, tezacaftor 50 mg, and deutivacaftor 125 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. ALYFTREK™ is not prescribed concurrently with other CFTR modulators (e.g., Trikafta®, Orkambi®, Kalydeco®, Symdeko®); **AND**

3. Provider attests that the patient has achieve a clinically meaningful response and displayed tolerance while on ALYFTREK™ 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. Dose does not exceed vanzacaftor 20 mg, tezacaftor 100 mg, and deutivacaftor 250 mg (two tablets of vanzacaftor 10 mg, tezacaftor 50 mg, and deutivacaftor 125 mg) per day.

ALYFTREK™ Dosing:

The recommended dosage of ALYFTREK™ in patients aged 6 years and older is listed in the table below. Please see the full prescribing information for dose modifications when ALYFTREK™ is used concomitantly with strong or moderate CYP3A inhibitors.

Age	Weight	Once Daily Oral Dosage
6 to Less than 12 Years Old	Less than 40 kg	Three tablets of vanzacaftor 4 mg/tezacaftor 20 mg/ deutivacaftor 50 mg
	Greater than or equal to 40 kg	Two tablets of vanzacaftor 10 mg/tezacaftor 50 mg/ deutivacaftor 125 mg
12 Years and Older	Any Weight	Two tablets of vanzacaftor 10 mg/tezacaftor 50 mg/ deutivacaftor 125 mg

Formulations:

- Available as a fixed-dose combination containing vanzacaftor 4 mg, tezacaftor 20 mg, and deutivacaftor 50 mg and a fixed-dose combination containing vanzacaftor 10 mg, tezacaftor 50 mg, and deutivacaftor 125 mg.