Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 13, 2025

Alyftrek™ (vanzacaftor/tezacaftor/deutivacaftor)

LENGTH OF AUTHORIZATION: Up to one year

REVIEW CRITERIA:

- Patient must be ≥ 6 years of age; **AND**
- Patient must have a diagnosis of cystic fibrosis (CF); **AND**
- Patient has ≥ 1 *F508del* mutation or other responsive mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene, as confirmed by genetic testing (medical records required); **AND**
- Alyftrek will NOT be used in combination with another *CFTR* modulator; **AND**
- Liver function tests (e.g., alanine aminotransferase [ALT], aspartate aminotransferase [AST], alkaline phosphatase, bilirubin) have been assessed prior to initiation of Alyftrek and will be monitored regularly during treatment; **AND**
- Patient does NOT have severe hepatic impairment (Child-Pugh Class C); **AND**
- The prescriber is a specialist in the area of the patient's diagnosis (e.g., CF, pulmonologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Patient must have disease improvement or stabilization with treatment (e.g., improvement or stabilization of any of the following: forced expiratory volume in one second [FEV1], sweat chloride concentration, weight/body mass index [BMI], Cystic Fibrosis Questionnaire-Revised [CFQ-R] respiratory domain score, respiratory symptoms related to cystic fibrosis [e.g., cough, sputum production, difficulty breathing], number of pulmonary exacerbations); **AND**
- Patient has NOT experienced any treatment-restricting adverse effects (e.g., severe liver injury or liver failure, severe hypersensitivity reactions); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as fixed-dose combination of vanzacaftor 4 mg/tezacaftor 20 mg/ deutivacaftor 50 mg and vanzacaftor 10 mg/tezacaftor 50 mg/ deutivacaftor 125 mg tablets.