

STATE OF WEST VIRGINIA DEPARTMENT OF HUMAN SERVICES BUREAU FOR MEDICAL SERVICES

Alex J. Mayer Cabinet Secretary Cynthia Beane, MSW, LCSW
Commissioner

Office of Pharmacy Services Prior Authorization Criteria Alyftrek™

(vanzacaftor, tezacaftor, and deutivacaftor)

Effective 2/26/2025

Prior Authorization Request Form

ALYFTREK is a combination of deutivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, tezacaftor, and vanzacaftor indicated for the treatment of cystic fibrosis (CF) in patients aged six years and older who have at least one F508del mutation or another responsive mutation in the CFTR gene.

CRITERIA FOR APPROVAL:

- 1. The patient is within the age range as recommended by the Food and Drug Administration (FDA) label; **AND**
- 2. The patient must have a confirmed diagnosis of Cystic Fibrosis; AND
- 3. The patient must be determined to have at least one F508del mutation in the CFTR gene or another responsive mutation in the CFTR gene as confirmed by an FDA-approved CF mutation test: **AND**
- 4. The patient must have documented baseline liver function tests (ALT, AST, alkaline phosphatase, and bilirubin) and for patients six years of age and older- FEV1 (forced expiratory volume in one second) presented with the prior authorization request; **AND**
- 5. Patients under the age of 18 years must have undergone a baseline ophthalmic examination to monitor for lens opacities/cataracts.

Approval Duration: Initial approval will be for six months for the first year, followed thereafter by an annual prior authorization.

Criteria for reauthorization:

- 1. Demonstrate continued documented compliance; AND
- Patients under the age of 18 years must have follow up ophthalmic examinations at least annually (documentation required); AND
- 3. Patient must have liver function tests* (ALT, AST, alkaline phosphatase, and bilirubin) every month during the first 6 months of treatment, then every three months for the next 12 months, then at least annually thereafter (documentation required).

<u>NOTE</u>: Documentation should show ALT or AST < 5 times the upper limit of normal (ULN) or ALT or AST < 3 times the ULN with bilirubin < 2 times the ULN.

