



STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES



Office of Pharmacy Services
Prior Authorization Criteria
TRIKAFTA®
(elexacaftor, tezacaftor, and ivacaftor tablets)
Prior Authorization Request Form
Effective 5/26/2023

Trikafta is a combination of ivacaftor, a CFTR potentiator, tezacaftor, and elexacaftor indicated for the treatment of cystic fibrosis (CF) in patients aged 6 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. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one F508del mutation or a mutation that is responsive based on *in vitro* data.

CRITERIA FOR APPROVAL:

1. The patient is within the age range as recommended by the FDA label; **AND**
2. Patient must have a confirmed diagnosis of Cystic Fibrosis; **AND**
3. Patient must be determined to 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 as confirmed by an FDA-approved CF mutation test; **AND**
4. Patient must have a documented baseline AST, ALT and **for patients 6 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 6 months for the first year, followed thereafter by an annual prior authorization.

Criteria for reauthorization:

1. Patients under the age of 18 years must have follow up ophthalmic examinations at least annually (documentation required); **AND**
2. Patient must have LFTs/bilirubin monitored every 6 months for the first year of treatment and annually thereafter (documentation required); **AND**
3. Serum ALT or AST < 5 times the upper limit of normal (ULN); **OR**
4. Serum ALT or AST < 3 times the ULN with bilirubin < 2 times the ULN.

References

- 1) Trikafta package insert revised 10/2019, 7/2021, 5/23
- 2) Lexi-Comp Clinical Application 11/15/2019, 7/2021, 5/23