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 7/21/2021

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 as confirmed by an FDA-approved CF mutation test; **AND**
4) Patient must have a documented baseline AST, ALT and FEV_1 (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.

Prior authorizations will be for every 6 months in the first year, followed thereafter by an annual prior authorization.

Criteria for Continuation of Therapy

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
2) Lexi-Comp Clinical Application 11/15/2019, 7/2021

Approved by DUR Board on 11/21/2019
Updated: 7/21/21