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

Office of Pharmacy Service
Prior Authorization Criteria

ORKAMBI®
(lumacaftor/ivacaftor)

Prior Authorization Request Form
Effective 9/13/2018

ORKAMBI is a combination of lumacaftor and ivacaftor, a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator, indicated for the treatment of cystic fibrosis (CF) in patients age 2 years and older who are **homozygous** for the F508del mutation in the CFTR gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene.

Criteria for Approval

1) Individual is 2 years or older; **AND**
2) Patient must have a confirmed diagnosis of Cystic Fibrosis; **AND**
3) Patient must be determined to be **homozygous** for the ***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 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 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) Orkambi package insert revised 7/2019
2) Lexi-Comp Clinical Application 11/15/2019