



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](#)

Orkambi is a combination drug containing lumacaftor and ivacaftor that is indicated for the treatment of cystic fibrosis in patients age 6 years and older who are **homozygous** for the **F508del** mutation in the CFTR gene.

Criteria for Approval

- 1) Individual is 6 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 FEV₁ (forced expiratory volume in one second) presented with the prior authorization request; **AND**
- 5) If the patient is between the ages of 6-18, they must have undergone a baseline ophthalmic examination to monitor for lens opacities/cataracts.

Prior authorizations will be for every 3 months in the first year, followed thereafter by an annual prior authorization.

Criteria for Continuation of Therapy

- 1) Pediatric patients between the ages of 6 and 18 must have follow up ophthalmic examinations at least annually (documentation required); **AND**
- 2) Patient must have stable or improved FEV₁; **AND**
- 3) Clinical notes must also be supplied that document stable or improved patient symptoms; **AND**
- 4) Patient must have LFTs/bilirubin monitored every 3 months for the first year of treatment and annually thereafter; **AND**
- 5) Serum ALT or AST < 5 times the upper limit of normal (ULN); **OR**
- 6) Serum ALT or AST < 3 times the ULN with bilirubin < 2 times the ULN.

References

- 1) Orkambi package insert revised 9/2016
- 2) Lexi-Comp Clinical Application 09/30/2016