



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



Office of Pharmacy Service  
Prior Authorization Criteria

**KALYDECO®**  
(ivacaftor)  
**Prior Authorization Request Form**  
**Effective 2/01/2021**

KALYDECO is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients age 4 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

**Criteria for Approval**

- 1) Individual must be 4 months or older; **AND**
- 2) Patient must have a confirmed diagnosis of Cystic Fibrosis; **AND**
- 3) Patient must be determined have at least one mutation in the CFTR gene which is responsive to ivacaftor as confirmed by an FDA-approved CF mutation test; **AND**
- 4) Patient must have a documented baseline AST, ALT and FEV<sub>1</sub> (forced expiratory volume in one second) presented with the prior authorization request; **AND**
- 5) **Patient must NOT be homozygous for the F508del mutation in the CFTR gene; AND**
- 6) Dosage does not exceed 150 mg twice daily for ages 6 and up; **OR**
- 7) For patients ages 2 to less than 6 years, dosage should be weight-based and may not exceed 75 mg twice daily.
- 8) 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) Kalydeco package insert revised 4/2019
- 2) Lexi-Comp Clinical Application 11/15/2019, 2/9/21