**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 6/01/2018***

KALYDECO is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients age 6 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 6 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 $FEV_1$ (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



v2019.4a – updated 11-15-2019 (BMT)
Original Approval by DUR Board - 5/23/2018