



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



**Office of Pharmacy Service
Prior Authorization Criteria**

**SYMDEKO®
(tezacaftor/ivacaftor + ivacaftor)
Prior Authorization Request Form
Effective 6/01/2018**

SYMDEKO is a combination of tezacaftor and ivacaftor, indicated for the treatment of patients with cystic fibrosis (CF) age 6 years and older who are **homozygous** for the F508del mutation **OR** who have at least one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.

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 **OR** have at least one other mutation in the CFTR gene which is responsive to tezacaftor/ivacaftor as confirmed by an FDA-approved CF mutation test; **AND**
- 4) Patient must have a documented baseline AST, ALT and FEV₁ (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) Symdeko package insert revised 6/2019
- 2) Lexi-Comp Clinical Application 11/15/2019