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 FEV_1 (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