Division: Pharmacy Policy	Subject: State of Florida's Agency for Health Care Administration's Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	March 30, 2018 June 18, 2018, June 28, 2019, November 19, 2019, September 17, 2021

SYMDEKO® (tezacaftor/ivacaftor)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 6 years old.
- Patient must have a diagnosis of Cystic Fibrosis confirmed via "health conditions" or medical records.
- Patient is homozygous for the *F508del* mutation or patient has 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.
- Patient must have baseline liver function tests required prior to initiating therapy.
- Patients ages 6 to < 18 must have undergone a baseline ophthalmic examination to monitor lens opacities/cataracts.
- Patient must have baseline documented percent predicted FEV_1 within the previous 30 days.

CONTINUATION OF THERAPY:

- Disease response as indicated by two or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline.
  - Improvement or stabilization of lung function (as measured by percent predicted FEV1) compared to baseline or decrease in the rate of decline of lung function.
  - Weight gain
  - Clinical notes documenting improvement of patient symptoms.
- Patient must not have received a lung transplant.
- Patient must not have experienced unacceptable toxicity from the drug.
- Submission of liver function tests (every three months), then one liver function test annually thereafter.
- Patients ages 6 to < 18 should have a follow up ophthalmic examination at least annually.

DOSING and ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as:
  - Tezacaftor 50 mg/ivacaftor 75 mg fixed-dose combination tablets co-packaged with ivacaftor 75 mg tablets.
  - Tezacaftor 100 mg/ivacaftor 150 mg fixed-dose combination tablets co-packaged with ivacaftor 150 mg tablets.