

# OPTIMA HEALTH PLAN

## PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST

**Directions:** *The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; fax to 1-800-750-9692. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. Incomplete form will delay authorization process.*

**Drug Requested:** Symdeko® (tezacaftor/ivacaftor) (*Initial Authorization*)

**DRUG INFORMATION:** Complete all information below or authorization process will be delayed.

Drug Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

**Recommended dose:** 1 tablet (tezacaftor 100mg/ivacaftor 150mg) in the morning and 1 tablet (ivacaftor 150mg) in the evening (*approximately 12 hours apart*).

- **Positive cultures for Burkholderia cencopacia, Burkholderia dolosa, or Mycobacterium abscessus will NOT be covered**
- **Symdeko® will NOT be covered for patients with FEV<sub>1</sub> > 90 %**

**Initial Authorization is Limited to 6 months.**

**CLINICAL CRITERIA:** ALL boxes below MUST be checked to qualify. Lab results and chart notes MUST be attached. If not included, authorization process will be delayed.

- Patient is **12 years of age or older** with a diagnosis of Cystic Fibrosis.
- Patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene (*Lab documentation required*)

**OR**

- The patient has at least one of the following mutations in the CFTR gene that is responsive to Symdeko based on in vitro data and/or clinical evidence. (*Lab documentation required*)

### \*CFTR Mutations Responsive to Symdeko:

E56K	R352Q	K1060T
P67L	A455E	A1067T
R74W	F508del*	R1070W
D110E	D579G	F1074L
D110H	711+3A→G	D1152H
R117C	E831X	D1270N
E193K	S945L	2789+5G→A
L206W	S977F	3272-26A→G
R347H	F1052V	3849+10kbC→T

- Baseline FEV<sub>1</sub> within the last 30 days (*Lab documentation required*)
- Baseline eGFR or SCr within the last 3 months (*Lab documentation required*)
- Baseline LFTs prior to initiating therapy, then every 3 months the first year, then annually (*Lab documentation required*)
- Pulmonary exacerbations - number in preceding 6 months: \_\_\_\_\_
- Baseline body mass index: \_\_\_\_\_
- Baseline ophthalmic examination to monitor lens opacities/cataracts (*Lab documentation required*)
- Patient does not have positive cultures for Burkholderia cencopacia, Burkholderia dolosa, or Mycobacterium abscessus (*Lab documentation required within last six (6) months of THIS request.*)

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- Member is currently **COMPLIANT** on at least **two (2)** of the following:
  - Dornase alfa
  - Hypertonic saline
  - Inhaled or oral antibiotics within the last three months
  - CFTR modulator therapy (Orkambi lumacaftor/ivacaftor) (*Must be compliant on Orkambi if switching to Symdeko®*)

***For Re-authorization, member must show improvement of FEV<sub>1</sub> by at least 5% from baseline and compliant with Symdeko® therapy***

Baseline Date: \_\_\_\_\_ (*prior to Symdeko® I<sup>st</sup> dose*)

FEV<sub>1</sub>: \_\_\_\_\_

***Medication being provided by a Specialty Pharmacy (check applicable box below):***

**For Optima Commercial Members:**

- PropriumRx

**For Optima Family Care Members:**

- Sentara Norfolk General CM Pharmacy

***\*\*Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.\*\****

***\*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.\****

Patient Name: \_\_\_\_\_

Member Optima #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

**DEA OR NPI #:** \_\_\_\_\_

**\*Approved by Pharmacy and Therapeutics Committee: 4/19/2018**

**REVISED/UPDATED: 6/20/2018**