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_1 > 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_1 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_1 by at least 5% from baseline and compliant with Symdeko® therapy

Baseline Date: _____ ***(prior to Symdeko® 1st dose)***

FEV_1:_____

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;