OPTIMA FAMILY CARE MEDALLION 4.0
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)

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 or authorization process will be delayed.

Initial Approval for One (1) Year – all of the following MUST be met:

1. Is the member 12 ≥ years of age? ❑ Yes ❑ No

   AND

2. Does the member have a diagnosis of Cystic Fibrosis. ❑ Yes ❑ No

   AND

3. Is member homozygous for the **F508del** mutation in the CFTR gene as confirmed by an FDA-cleared CF mutation Test? ***(Document required; include a copy of the test with this request)*** ❑ Yes ❑ No

   OR

4. Does member have one (1) of the following mutations (see chart below) in the CFTR gene as confirmed by an FDA-cleared CF mutation Test? ***(Lab documentation required; include a copy of the test with this request)***
   ❑ Yes ❑ No

***CFTR Mutations Responsive to Symdeko:**

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

5. Has baseline ALT and AST testing been done? ***(Documentation required; include a copy of the test with this request)*** ❑ Yes ❑ No

(continued on next page)

For <u>Re-Authorization approval</u>, liver function testing (LFT) documentation is required.

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

<u>For Optima Commercial Members:</u>

- ❑ **PropriumRx**

<u>For Optima Family Care Members</u>:

- ❑ **Sentara Norfolk General CM Pharmacy**

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

****<u>Previous therapies will be verified through pharmacy paid claims or submitted chart notes.</u>****

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: 7/1/2018