UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Symdeko

Program	Prior Authorization
Medication	Symdeko (tezacaftor/ivacaftor)
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New Mexico, New York, New York EPP, Ohio, Rhode Island
Issue Date	2/2018
Pharmacy and Therapeutics Approval Date	2/2018
Effective Date	4/2018

1. Background:

Symdeko is a combination of tezacaftor and ivacaftor, indicated for the treatment of patients with cystic fibrosis (CF) aged 12 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.

If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use.

2. Coverage Criteria:

A. <u>Initial Authorization</u>

1. **Symdeko** will be approved based upon **<u>all</u>** of the following criteria:

   a. Diagnosis of cystic fibrosis (CF)

   -AND-

   b. Submission of laboratory resulting documenting **<u>one</u>** of the following:

      (1) The patient is homozygous for the F508del mutation in the CFTR gene

      -OR-

      (2) The patient has at least **<u>one</u>** of the following mutations in the CFTR gene that is responsive to Symdeko:

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

-AND-

c. The patient is ≥ 12 years of age

-AND-

d. Prescribed by or in consultation with a specialist affiliated with a CF care center

Authorization will be issued for 6 months.

B. Reauthorization

1. **Symdeko** will be approved based on **both** of the following criteria:

a. Provider attests that the patient has achieved a clinically meaningful response while on Symdeko therapy to **one** of the following:

(1) Lung function as demonstrated by percent predicted expiratory volume in 1 second ($ppFEV_1$)
(2) Body mass index (BMI)
(3) Pulmonary exacerbations
(4) Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score

-AND-

b. Prescribed by or in consultation with a specialist affiliated with a CF care center

Authorization will be issued for 12 months.

3. References:

1. Symdeko. Cambridge, MA: Vertex Pharmaceuticals, Inc.; February 2018.

Program	Prior Authorization
Change Control	
Date	Change
2/2018	New Program