UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Symdeko

Program	Prior Authorization
Medication	Symdeko (tezacaftor/ivacaftor)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	2/2018
Pharmacy and Therapeutics Approval Date	8/2020
Effective Date	10/2020

1. Background:

Symdeko is a combination of tezacaftor and ivacaftor, indicated for the treatment of patients with cystic fibrosis (CF) age 6 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. Initial Authorization

1. **Symdeko** will be approved based upon **all** of the following criteria:

   a. Diagnosis of cystic fibrosis (CF)

   -AND-

   b. Submission of laboratory resulting documenting **one** of the following:

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

   -OR-

   (2) The patient has at least **one** 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 ≥ 6 years of age

-AND-

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

Authorization will be issued for 12 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. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes

(ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Symdeko [package insert]. Cambridge, MA: Vertex Pharmaceuticals, Inc.; December 2019.

Program	Prior Authorization
Change Control	
Date	Change
2/2018	New Program
2/2019	Annual review. No changes to program.
8/2019	Revised age requirement due to expanded indication. Changed initial authorization duration to 12 months to align with other CF programs. Updated reference.
8/2020	Annual review. No updates to clinical criteria Added Additional Clinical Rules section. Updated reference.