Humana.

CareSource™

PHARMACY POLICY STATEMENT **Kentucky Medicaid**	
DRUG NAME	Symdeko (tezacaftor/ivacaftor)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred products include Orkambi and Kalydeco QUANTITY LIMIT— 56 tabs for 4 weeks
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Symdeko (tezacaftor/ivacaftor) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CYSTIC FIBROSIS

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Medication must be prescribed by a pulmonologist or an infectious disease specialist; AND
3. Member has had genetic testing documented in chart notes with two copies (homozygous) of the F508del mutation (F508del/F508del) in their CFTR gene and has documented trial and failure of Orkambi for at least 30 days or contraindication to Orkambi for at least 30 days; OR
4. Member has at least one of the following mutations in the CFTR gene: E56K, R117C, A455E, S945L, R1070W, 3272-26A→G, P67L, E193K, F508del, S977F, F1074L, 3849+10kbC→T, R74W, L206W, D579G, F1052V, D1152H, D110E, R347H, 711+3A→G, K1060T, D1270N, D110H, R352Q, E831X, A1067T, 2789+5G→A and has documented trial and failure of Kalydeco for at least 30 days or contraindication to Kalydeco for at least 30 days.
5. **Dosage allowed:** One tablet (containing tezacaftor 100 mg/ivacaftor 150 mg) in the morning and one tablet (containing ivacaftor 150 mg) in the evening, approximately 12 hours apart. Symdeko should be taken with fat-containing food.

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member's adherence to medication is confirmed by claims history.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Symdeko (tezacaftor/ivacaftor) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
02/27/2018	New policy for Symdeko created.

References:

1. Symdeko [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; February, 2018.
2. National Guideline Clearinghouse (NGC). Guideline summary: Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 Apr 01. Available: https://www.guideline.gov.

Effective date: 06/20/2018
Revised date: 02/27/2018