

## PHARMACY POLICY STATEMENT

### Georgia 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 <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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 90 days or contraindication to Orkambi for at least 90 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 90 days or contraindication to Kalydeco for at least 90 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