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
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
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02/27/2018 | New policy for Symdeko created.

References:

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