CareSource

PHARMACY POLICY STATEMENT
Arkansas PASSE

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 (Preferred Product) QUANTITY LIMIT— 56 tablets per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Symdeko (tezacaftor/ivacaftor) 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 6 years of age or older; AND
2. Member has a diagnosis of cystic fibrosis; 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; OR
4. Member has at least one of the following mutations in the CFTR gene: 546insCTA, E92K, G576A, L346P, R117G, S589N 711+3A→G, E116K, G576A;R668C, L967S, R117H, S737F 2789+5G→A, E193K, G622D, L997F, R117L, S912L, 3272-26A→G, E403D, G970D, L1324P, R117P, S945L, 3849+10kbC→T, E588V, G1069R, L1335P, R170H, S977F, A120T, E822K, G1244E, L1480P, R258G, S1159F, A234D, E831X, G1249R, M152V, R334L, S1159P, A349V, F191V, G1349D, M265R, R334Q, S1251N, A455E, F311del, H939R, M952I, R347H, S1255P, A554E, F311L, H1054D, M952T, R347L, T338I, A1006E, F508C, H1375P, P5L, R347P, T1036N, A1067T, F508C;S1251N, I148T, P67L, R352Q, T1053I, D110E, F508del, I175V, P205S, R352W, V201M, D110H, F575Y, I336K, Q98R, R553Q, V232D, D192G, F1016S, I601F, Q237E, R668C, V562I, D443Y, F1052V, I618T, Q237H, R751L, V754M, D443Y;G576A;R668C, F1074L, I807M, Q359R, R792G, V1153E, D579G, F1099L, I980K, Q1291R, R933G, V1240G, D614G, G126D, I1027T, R31L, R1066H, V1293G, D836Y, G178E, I1139V, R74Q, R1070Q, W1282R, D924N, G178R, I1269N, R74W, R1070W, Y109N, D979V, G194R, I1366N, R74W;D1270N, R1162L ,Y161S, D1152H, G194V, K1060T, R74W;V201M, R1283M, Y1014C, D1270N, G314E, L15P, R74W;V201M;D1270N, R1283S, Y1032C, E56K, G551D, L206W, R75Q, S549N, E60K, G551S, L320V, R117C, S549R.
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.

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; AND
3. Chart notes submitted with any of the following:
   a) Improved FEV1 and/or other lung function tests;
   b) Improvement in sweat chloride;
   c) Decrease in pulmonary exacerbations;
   d) Decrease in pulmonary infections;
   e) Increase in weight-gain;
   f) Decrease in hospitalizations.

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.
12/31/2020	Age changed to 6 years old and older (previously only approved for patients 12 years and older). Added approved mutations based on new FDA approvals. Diagnosis of cystic fibrosis added to initial criteria. Changed status to Preferred. Removed requiring trials of Orkambi and Kalydeco. Reauthorization criteria updated to ask for evidence of disease improvement.
12/22/2021	Removed prescriber specialty requirement.

References:

1. Symdeko [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; December, 2020.
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: 01/01/2022
Revised date: 12/22/2021