HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Symdeko (tezacaftor/ivacaftor)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Symdeko (tezacaftor/ivacaftor) is a combination of ivacaftor,a CFTR potentiator, and tezacaftor, a CFTR corrector, indicated for the treatment of cystic fibrosis initially approved by the FDA in 2018. Cystic fibrosis is an autosomal recessive disease in which patients can have abnormal airways secretions, chronic endobronchial infection, and progressive airway obstruction.

Symdeko (tezacaftor/ivacaftor) will be considered for coverage when the following criteria are met:

Cystic Fibrosis

For **initial** authorization:

1. Member is at least 6 years of age; AND
2. Medication must be prescribed by or in consultation with a pulmonologist or an infectious disease specialist; AND
3. Member has a diagnosis of cystic fibrosis; AND
4. Member has had genetic testing documented in chart notes with two copies (homozygous) of the F508del mutation (F508del/F508del) in their CFTR gene; OR
5. 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.
6. **Dosage allowed/Quantity limit:**

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Age	Morning (one tablet)	Evening (one tablet)
6 to <12 years weighing <30 kg	tezacaftor 50 mg/ivacaftor 75 mg	ivacaftor 75 mg
6 to <12 years weighing ≥30 kg	tezacaftor 100 mg/ivacaftor 150 mg	ivacaftor 150 mg
≥12 years	tezacaftor 100 mg/ivacaftor 150 mg	ivacaftor 150 mg

(56 tablets per 28 days).

If all the above requirements are met, 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 must show improvement or stabilized signs and symptoms of disease demonstrated by 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 all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Symdeko (tezacaftor/ivacaftor) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

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.
05/18/2022	Policy for Symdeko transferred to new template. Added pediatric dosing.

References:

1. Symdeko [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2020.
2. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Foundation Pulmonary Guidelines. Use of Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapy in Patients with Cystic Fibrosis. *Ann Am Thorac Soc*. 2018;15(3):271-280. doi:10.1513/AnnalsATS.201707-539OT

Effective date: 01/01/2025
Revised date: 05/18/2022