

PHARMACY POLICY STATEMENT

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:

- Member is at least 6 years of age; AND
- Medication must be prescribed by or in consultation with a pulmonologist or an infectious disease specialist; AND
- Member has a diagnosis of cystic fibrosis; AND
- Member has had genetic testing documented in chart notes with two copies (homozygous) of the F508del mutation (F508del/F508del) in their CFTR gene; OR
- Member has at least one of the following mutations in the CFTR gene: 546insCTA, E92K, G576A, / 3 5 * 6 1 \$: * (. * \$ 5 & / 6 5 + 6) *: \$ E193K, G622D, L997F, R117L, S912L, 3272- \$: * (' * ' / 3 5 3 6 / NE & : 7 (9 * 5 / 3 5 + 6) \$ 7 (. * (/ 3 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,

(56 tablets per 28 days).

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