Reference number(s)
2516-A

Specialty Guideline Management Symdeko

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Symdeko	tezacaftor/ivacaftor

Indications

FDA-approved Indication[1]

Symdeko is indicated for the treatment of cystic fibrosis (CF) in patients age 6 years and older who are homozygous for the F508del variant or who have at least one variant in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to tezacaftor/ivacaftor based on in vitro data and/or clinical evidence.

If the patient's genotype is unknown, an FDA-cleared CF variant test should be used to detect the presence of CFTR variant followed by verification with bi-directional sequencing when recommended by the variant test instructions for use.

All other indications are considered experimental/investigational and are not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: For initial requests, genetic testing report confirming the presence of the appropriate CFTR gene variant.

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Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or a prescriber specialized in the treatment of cystic fibrosis.

Coverage Criteria

Cystic Fibrosis[1-3]

Authorization of 12 months may be granted for treatment of cystic fibrosis when all of the following criteria are met:

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

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in forced expiratory volume 1 [FEV1] from baseline).

Other

Symdeko will not be used in combination with another CFTR modulator for the treatment of cystic fibrosis (e.g., Kalydeco, Trikafta).

References

1. Symdeko [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; March 2026.
2. Rowe SM, Daines C, Ringshausen FC, et al. Tezacaftor-ivacaftor in residual function heterozygotes with cystic fibrosis. N Engl J Med. 2017;377:2024-2035. doi: 10.1056/NEJMoa1709847
3. Taylor-Cousar JL, Munck A, McKone EF, et al. Tezacaftor–ivacaftor in patients with cystic fibrosis homozygous for Phe508del. N Engl J Med 2017;377:2013-2023. doi: 10.1056/NEJMoa1709846