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 mutation or who have at least one mutation 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 mutation test should be used to detect the presence of CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation 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 mutation.

Reference number(s)
2516-A

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist.

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 mutation in the CFTR gene.
- The member is homozygous for the F508del mutation (positive for the F508del mutation on both alleles), or the member has one of the following mutations 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 section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in 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).

Reference number(s)
2516-A

References

1. Symdeko [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; August 2023.
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