AETNA BETTER HEALTH® Coverage Policy/Guideline					
Name:	Symdeko			Page:	1 of 2
Effective Date:	7/15/2024			Last Review Date:	5/2024
Applies to:	☒Illinois ☐New Jersey ☒Pennsylvania Kids	☐Florida ☒Maryland ☒Virginia		☒Florida Kids ☐Michigan ☐Texas	

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Symdeko under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Symdeko

Policy/Guideline:

I. Submission of the following information is necessary to initiate the prior authorization review:

A. Genetic testing report confirming the presence of the appropriate *CFTR* gene mutation.

Criteria for Initial Approval:

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

A. This medication must be prescribed by or in consultation with a pulmonologist
B. Genetic testing was conducted to detect a mutation in the CFTR gene.
C. The member is homozygous for the F508del mutation, or the member has one of the following mutations in the CFTR gene:
   i. 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.

A. The member is at least 6 years of age.
B. Symdeko will not be used in combination with other medications containing ivacaftor

Criteria for Continuation of Therapy

III. Reauthorization may be granted for cystic fibrosis when the following criteria is met:

A. Member is experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in FEV1 from baseline).

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:
100 mg/150 mg: 56 tablets per 28 days
50 mg/75 mg: 56 tablets per 28 days

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