Prior Authorization Criteria

Symdeko® (*tezacaftor/ivacaftor*) PA CRITERIA:

MISSISSIPPI DIVISION OF MEDICAID

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

Select the diagnosis:

☐ Cystic fibrosis (CF); ICD-10 code(s): _____

Initial authorization: 6 months

Prior authorization will be considered for patients when **ALL** the following criteria are met:

☐ Yes ☐ No Age of patient is within the age range as recommended by the FDA label; ***AND***

☐ Yes ☐ No Prescribed by or in consultation with a CF specialist/pulmonologist who specializes in treating CF patients. **AND**

a. Name of CF treating or consulting specialist/pulmonologist:

_____

b. Provide chart documentation from consulting provider including name, strength and dosing instructions of CF drug:

_____

AND

☐ Yes ☐ No Has a diagnosis of CF with a CFTR mutation* responsive to Symdeko.
If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. Submission upon request of laboratory results documenting ONE of the following:

a. Patient is homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene.
OR

b. The patient has at least one of the following mutations in the CFTR gene that is responsive to Symdeko based on in vitro data and/or clinical evidence.

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*CFTR Mutations Responsive to Symdeko:

List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to SYMDEKO					
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*	

* Clinical data for these mutations in Clinical Studies

^ A patient must have two copies of the *F508del* mutation or at least one copy of a responsive mutation presented to be indicated.

† Complex/compound mutations where a single allele of the *CFTR* gene has multiple mutations; these exist independent of the presence of mutations on the other allele.

- A patient must have two copies of the F508del mutation or at least one copy of a responsive mutation presented in the above table to be indicated. **AND**

☐ Yes ☐ No Baseline measures submitted by provider of **ALL** of the following:

a. For age appropriate patients, percent predicted expiratory volume in 1 second (ppFEV1):_____

b. Body mass index (BMI):_____

c. Pulmonary exacerbations- number in preceding 6 months: _____

<u>Reauthorization</u>: 12 months with evidence of appropriate clinical response to therapy

□ Yes □ No Prescribed by or in consultation with a CF specialist/ pulmonologist who specializesin treating CF patients.

a. Name of CF treating/consulting specialist/pulmonologist:

_____

b. Provide chart documentation from consulting provider including name, strength, and dosing instruction of CF drug:

_____

AND

□ Yes □ No Provider attests that the patient has achieved a clinically meaningful response while on Symdeko based on **ALL** of the following:

a. For age appropriate patients , improved or stable lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1): _____

b. Body mass index (BMI):_____

c. Pulmonary exacerbations- number of exacerbations compared to number of exacerbations prior to medication initiation:_____

How Supplied:

Symdeko is co-packaged as a tezacaftor/ivacaftor fixed-dose combination tablet and an ivacaftor tablet

Symdeko (tezacaftor 50mg/ivacaftor 75 mg fixed dose combination + ivacaftor 75 mg)

56 count tablet carton containing a 4- week supply (containing 4 weekly wallets, each with 14 tablets)

Symdeko (tezacaftor 100mg/ ivacaftor 150 mg fixed dose combination + ivacaftor 150mg)

56 count tablet carton containing a 4 week supply (containing 4 weekly wallets, each with 14 tablets)