Symdeko (tezacaftor and ivacaftor)

Coverage Criteria:

1. Reserved for members 12 years and older who have homozygous F508del mutation or at least one mutation in the CFTR gene that is responsive to tezacaftor/ivacaftor based on the table in the package insert (For other mutation(s) in the CFTR gene (not listed in the table below), *in vitro* data and/or clinical evidence of responsiveness to tezacaftor/ivacaftor is required):

Table 4: List of *CFTR* Gene Mutations that Produce CFTR Protein and are Responsive to SYMDEKO					
E56K	*R117C*	*A455E*	*S945L*	*R1070W*	*3272-26A→G*
P67L	*E193K*	*F508del**	*S977F*	*F1074L*	*3849+10kbC→T*
R74W	*L206W*	*D579G*	*F1052V*	*D1152H*	
D110E	*R347H*	*711+3A→G*	*K1060T*	*D1270N*	
D110H	*R352Q*	*E831X*	*A1067T*	*2789+5G→A*	
*A patient must have two copies of the *F508del* mutation or at least one copy of a responsive mutation presented in Table 4 to be indicated.					

Prescriber Restriction:

Prescribed and managed by specialists from a cystic fibrosis treatment center

Coverage Duration:

Initial approvals will be provided for twelve months.

Other Criteria:

Limited to the FDA-approved dosing regimen

Renewal Criteria:

Renewals will be provided annually with documentation that the patient has been seen within the last 12 months at the cystic fibrosis treatment center and the medication is effective.