

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

*FHK- Florida Healthy Kids

Symdeko (tezacaftor/ivacaftor)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Symdeko (tezacaftor/ivacaftor)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Symdeko (tezacaftor/ivacaftor) may be approved if the following are met:

- I. Individual has a diagnosis of cystic fibrosis (CF); **AND**
- II. Individual is 12 years of age or older; **AND**
- III. A copy of the CF mutation analysis test result must be provided; **AND**
- IV. Individual has a mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene with one of the following mutation types:

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	

*Individual must have two copies of the F508del mutation.

NOTE: All requests for California Medicaid individuals less than 21 years of age will be reviewed by the health plan.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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State Specific Mandates		
<u>State name</u> California Medicaid	<u>Date effective</u> 3/5/2018	Request from California Children's Services to have all requests for Symdeko in individuals less than 21 years of age to be reviewed by the health plan.

Key References:

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: February 13, 2018.

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