

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

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 6 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.

Symdeko (tezacaftor/ivacaftor) may not be approved for the following:

- I. Concurrent use with Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor) or Trikafta (elixacaftor/tezacaftor/ivacaftor).

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

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	NA

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:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 27, 2020.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
4. Simon RH. Cystic fibrosis: Overview of the treatment of lung disease. Last updated: March 10, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: March 24, 2020.
5. Simon RH. Cystic fibrosis: Treatment with CFTR modulators. Last updated: February 13, 2020. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: March 24, 2020.

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.