

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

## Orkambi (ivacaftor/lumacaftor)

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

Medications	Quantity Limit
Orkambi (ivacaftor/lumacaftor)	May be subject to quantity limit

### APPROVAL CRITERIA

Requests for Orkambi (ivacaftor/lumacaftor) 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. Mutation testing indicates individual has two copies of the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene; **AND**
- IV. A copy of the CF mutation analysis test result must be provided.

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

State Specific Mandates		
CA	9/26/2015	Request from California Children's Services to have all requests for Orkambi in individuals less than 21 years of age to be reviewed by the health plan.

### Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2016. URL: <http://www.clinicalpharmacology.com>. Updated periodically.

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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Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	NA

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

DrugPoints System [Internet Database]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2016; Updated periodically.

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