

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 2 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.

Orkambi (ivacaftor/lumacaftor) may not be approved for the following:

- I. Concurrent use with Kalydeco (ivacaftor), Symdeko (tezacaftor/ivacaftor) or Trikafta (elexacaftor/tezacaftor/ivacaftor).

***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:

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.