CareSource

PHARMACY POLICY STATEMENT **Marketplace**	
DRUG NAME	Orkambi (lumacaftor/ivacaftor)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT— 112 tablets per 28 days or 56 unit-dose packets per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Orkambi (lumacaftor/ivacaftor) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

CYSTIC FIBROSIS

For **initial** authorization:

1. Member must be 2 years of age or older; AND
2. Member has a diagnosis of cystic fibrosis; AND
3. Medication must be prescribed by a pulmonologist or an infectious disease specialist; AND
4. Member has had genetic testing documented in chart notes with two copies (homozygous) of the F508del mutation (F508del/F508del) in their CFTR gene; AND
5. If member is 6 years or older, must have a trial and failure of Symdeko, unless not tolerated or contraindicated.
6. **Dosage allowed:** Adults and pediatric members age 12 years and older: two tablets (each containing lumacaftor 200 mg/ivacaftor 125 mg) taken orally every 12 hours. Pediatric members age 6 through 11 years: two tablets (each containing lumacaftor 100 mg/ivacaftor 125 mg) taken orally every 12 hours. Pediatric members age 2 through 5 years < 14 kg: one packet of granules (each containing lumacaftor 100 mg/ivacaftor 125 mg), ≥ 14 kg or greater: one packet of granules (each containing lumacaftor 150 mg/ivacaftor 188 mg).

If member meets all the requirements listed above, the medication will be approved for 3 months.

For **reauthorization**:

1. Member must be in compliance with all other initial criteria; AND
2. Member's adherence to medication is confirmed by claims history; AND
3. Chart notes submitted with any of the following:
   a) Improved FEV1 and/or other lung function tests;
   b) Improvement in sweat chloride;
   c) Decrease in pulmonary exacerbations;
   d) Decrease in pulmonary infections;
   e) Increase in weight-gain;
   f) Decrease in hospitalizations.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

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CareSource considers Orkambi (lumacaftor/ivacaftor) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
06/12/2017	New policy for Orkambi created. Not covered diagnosis added.
03/14/2019	Age coverage expanded (approved for 2 years old members and older).
12/30/2020	Diagnosis of cystic fibrosis added to initial criteria. Reauthorization criteria updated to ask for evidence of disease improvement. Added trial of Symdeko for members 6 years and older.
11/17/2021	Annual review, no changes

References:

1. Orkambi [package insert]. Boston, MA: Vertex Pharmaceuticals Inc; August, 2018.
2. Orkambi. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: http://www.micromedexsolutions.com.
3. National Guideline Clearinghouse (NGC). Guideline summary: Cystic fibrosis pulmonary guidelines. Chronic medications for maintenance of lung health. In: National Guideline Clearinghouse (NGC) [Web site]. Rockville (MD): Agency for Healthcare Research and Quality (AHRQ); 2013 Apr 01. Available: https://www.guideline.gov.

Effective date: 01/01/2022
Revised date: 11/17/2021