

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

DRUG NAME	Orkambi (lumacaftor/ivacaftor)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Preferred Product) QUANTITY LIMIT – 120 tablets per 30 days
LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY	<a href="#">Click Here</a>

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 6 years of age or older; AND
2. Medication must be prescribed by a pulmonologist or an infectious disease specialist; AND
3. Member has had genetic testing documented in chart notes with two copies (homozygous) of the F508del mutation (F508del/F508del) in their CFTR gene.
4. **Dosage allowed:** Adults and pediatric patients age 12 years and older: two tablets (each containing lumacaftor 200 mg/ivacaftor 125 mg) taken orally every 12 hours. Pediatric patients age 6 through 11 years: two tablets (each containing lumacaftor 100 mg/ivacaftor 125 mg) taken orally every 12 hours.

***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.

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

**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.

References:

1. Orkambi [package insert]. Boston, MA: Vertex Pharmaceuticals Inc; 2016. Accessed March 6, 2017.
2. Orkambi. Micromedex Solutions. Truven Health Analytics, Inc. Ann Arbor, MI. Available at: <http://www.micromedexsolutions.com>. Accessed March 6, 2017.
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>. Accessed March 6, 2017.



Effective date: 08/09/2017  
Revised date: 06/12/2017