CareSource

PHARMACY POLICY STATEMENT
Georgia Medicaid

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.

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: 07/01/2021
Revised date: 12/30/2020