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.

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<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tbody>
<tr>
<td>06/12/2017</td>
<td>New policy for Orkambi created. Not covered diagnosis added.</td>
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References: