



MEDICATION POLICY

Generic Name: Lumacaftor/Ivacaftor

Therapeutic Class or Brand Name: Orkambi®

Applicable Drugs (if Therapeutic Class): N/A

Date of Origin: 7/23/15

Date Last Reviewed/Revised: 10/7/16

GPI Code: 45309902300320

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

- I. Documented diagnosis of Cystic Fibrosis (CF).
- II. Documentation that patient is homozygous for the *F508del* mutation in the *CFTR* gene as detected by an FDA-cleared CF mutation test (a copy of the test must document the presence of the *F508del* mutation on both alleles of the *CFTR* gene).
- III. Minimum age requirement: 6 years old.
- IV. The prescriber is a Pulmonologist or a physician who specializes in the treatment of Cystic Fibrosis.

Exclusion Criteria:

- Patients with Cystic Fibrosis other than those homozygous for the *F508del* mutation.
- Concomitant use of Orkambi® with strong CYP3A inducers (i.e. rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, St. John's wort).

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- One 112-count tablet box per 28 days.

Approval Length:

- **Authorization:** 6 months.

Disclaimer: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgment in providing the most appropriate care for their patients.



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- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://pi.vrtx.com/files/uspi_lumacaftor_ivacaftor.pdf.
2. [Medi-Span](#).
3. http://www.bcbsnc.com/assets/services/public/pdfs/formulary/Orkambi_Criteria.pdf.
4. <https://d1tpfj3hind0fx.cloudfront.net/Media/Documents/UMC/0134KalydecoPriorAuth.pdf>.
5. <https://shp.nctreasurer.com/Pharmacy%20Documents/orkambi.pdf>.

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<i>Historical Tracking Of Changes Made To Policy</i>	
<i>10/7/2016</i>	<ol style="list-style-type: none">1. Changed “Orkambi™” to “Orkambi®” throughout policy.2. Changed “III. Minimum age requirement: 12 years old” to “III. Minimum age requirement: 6 years old” under Prior Authorization Criteria.

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