MEDICATION POLICY:

Orkambi®

Generic Name: Lumacaftor/Ivacaftor

Therapeutic Class or Brand Name: Orkambi®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 453099023003

Preferred: N/A

Non-preferred: N/A

Date of Origin: 7/23/2015

Date Last Reviewed / Revised: 1/17/2020

Prior Authorization Criteria

(May be considered medically necessary when criteria I through VI are met)

I. Insert Documented diagnosis of Cystic Fibrosis (CF).

II. Documented diagnosis of Cystic Fibrosis (CF).

III. 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).

IV. Documentation the patient's liver function tests (AST and ALT) and bilirubin are not above 3 x the upper limit of normal prior to starting treatment.

V. Minimum age requirement: 2 years old.

VI. 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

- Tablets: 112–count box per 28 days
- Granules: 56-units per 28 days

Approval Length

- **Authorization:** 6 months

- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective, including documentation liver function tests and bilirubin are not above 3 x the upper limit of normal.

APPENDIX

N/A

REFERENCES

1. https://pi.vrtx.com/files/uspi_lumacaftor_ivacaftor.pdf.
2. Medi-Span.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/17/2020	1. **Added** "IV. Documentation the patient's liver function tests (AST and ALT) and bilirubin are not above 3 x the upper limit of normal prior to starting treatment" under **Prior Authorization criteria and under Reauthorization Criteria.** 2. **Removed** "https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru544reg.pdf" and "https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/kalydeco-commercial-direct" **under References.**
11/26/2018	3. **Changed** "IV. Minimum age requirement: 6 years old" to "Minimum age requirement: 2 years old" **under Prior Authorization criteria**. 4. **Added "**Granules: 56-units per 28 days" under **Quantity/Days Supply Restrictions** 5. **Removed** "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/Orkambi_Criteria.pdf." and "https://d1tpfj3hind0fx.cloudfront.net/Media/Documents/UMC/0134KalydecoPriorAuth.pdf" (Links no longer valid) and **Added** "https://regence.myprime.com/content/dam/prime/memberportal/forms/AuthorForms/Cambia/Program_Summaries/dru544reg.pdf" and https://tuftshealthplan.com/documents/providers/guidelines/pharmacy-medical-necessity-guidelines/kalydeco-commercial-direct" **under References**
12/28/2017	1. **Removed** "https://shp.nctreasurer.com/Pharmacy%20Documents/orkambi.pdf" **from References** (link no longer valid).
10/7/2016	2. Changed "Orkambi™" to "Orkambi®" throughout policy. 3. **Changed** "III. Minimum age requirement: 12 years old" **to** "III. Minimum age requirement: 6 years old" **under Prior Authorization Criteria**.

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 judgement in providing the most appropriate care for their patients.