

Generic Name:

Elexacaftor/tezacaftor/ivacaftor and Ivacaftor

Therapeutic Class or Brand Name: Trikafta®**Applicable Drugs (if Therapeutic Class):** N/A**Preferred:** N/A**Non-preferred:** N/A**Date of Origin:** 8/25/2022**Date Last Reviewed / Revised:** 1/12/2024**PRIOR AUTHORIZATION CRITERIA**

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

- I. Documented diagnosis of Cystic Fibrosis (CF).
- II. Documentation that an FDA-cleared CF mutation test has detected at least one *F508del* mutation in the *CFTR* gene or a mutation in the *CFTR* gene that is responsive based on in vitro data (extensive list may be reviewed in package insert)
- III. 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.
- IV. Minimum age requirement: 6 years old.
- V. Treatment must be prescribed by or in consultation with a pulmonologist or a physician who specializes in the treatment of cystic fibrosis.

EXCLUSION CRITERIA

- Concomitant use of Trikafta® with strong CYP3A inducers (i.e. rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, St. John's wort).

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Up to 84 tablets 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. Trikafta. Prescribing Information. Boston, MA: Vertex Pharmaceuticals Incorporated; 2023. Accessed January 12, 2024. https://pi.vrtx.com/files/uspi_elexacaftor_tezacaftor_ivacaftor.pdf.
2. Ren C, Morgan R, et al. Cystic Fibrosis Foundation Pulmonary Guidelines: Use of Cystic Fibrosis Transmembrane Conductance Regulator Modulator Therapy in Patients with Cystic Fibrosis. *American Thoracic Society*. 2017; 15 (3); 271 – 280. DOI: 10.1513/AnnalsATS.201707-539OT

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.