Reference number(s)
3374-A

Specialty Guideline Management Trikafta

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Trikafta	elexacaftor/tezacaftor/ivacaftor

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indication[1]

Trikafta is indicated for the treatment of cystic fibrosis (CF) in adult and pediatric patients aged 2 years and older who have a clinical diagnosis of CF and who have at least one variant in the CFTR gene that is responsive based on clinical and/or in vitro data or results in the production of CFTR protein.

If the patient's genotype is unknown, an FDA-cleared CF genetic test should be used to confirm the presence of at least one variant in the CFTR gene that is either responsive based on clinical and/or in vitro data or results in the production of CFTR protein.

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Genetic testing report confirming the presence of the appropriate CFTR gene variant.
- Chart notes, laboratory values, medical records confirming a clinical diagnosis of CF.

Prescriber Specialties

This medication must be prescribed by or in consultation with a pulmonologist or a prescriber specialized in the treatment of cystic fibrosis.

Coverage Criteria

Cystic Fibrosis[1,2]

Authorization of 12 months may be granted for treatment of cystic fibrosis when all of the following criteria are met:

- The member has a confirmed clinical cystic fibrosis diagnosis (e.g., sweat chloride testing, CFTR physiological testing).
- Genetic testing was conducted to detect a variant in the CFTR gene that meets either of the following:
    - The CFTR gene variant is responsive based on clinical and/or in vitro data
    - The CFTR gene variant results in the production of CFTR protein
- The member is at least 2 years of age.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in forced expiratory volume 1 [FEV1] from baseline).

Other

Trikafta will not be used in combination with another CFTR modulator for the treatment of cystic fibrosis (e.g., Alyftrek, Kalydeco).

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Reference

1. Trikafta [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; March 2026.
2. Farrel PM, White TB, Ren CL et al. Diagnosis of cystic fibrosis: consensus guidelines from cystic fibrosis foundation. *The J of Pediatrics*. 2017; 181S: S4-S15.