Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	November 19, 2019 September 17, 2021; January 24, 2024; August 19, 2024; March 24, 2025

TRIKAFTA™ (elexacaftor, tezacaftor and ivacaftor tablets)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 2 years old.
- Patient must have a diagnosis of Cystic Fibrosis confirmed via "health condition" or medical records.
- Patient must have at least one *F508del* mutation in the *CFTR* gene or a mutation in the CFTR gene that is responsive based on *in vitro* data.
- If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of at least one *F508del* mutation or a mutation that is responsive based on *in vitro* data.
- Patient must have baseline liver function tests prior to initiating therapy.
- Patients ages 2 to < 18 must have undergone a baseline ophthalmic examination to monitor lens opacities/cataracts.
- Patients ≥ 6 years old must have baseline documented percent predicted FEV_1 within the previous 90 days.

CONTINUATION OF THERAPY:

- Disease response as indicated by two or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline.
  - Improvement or stabilization of lung function (as measured by percent predicted FEV_1) compared to baseline or decrease in the rate of decline of lung function
  - Improvement towards patient's target BMI or maintenance of target BMI
  - Clinical notes documenting improvement of patient symptoms.
- Patient must not have received a lung transplant.
- Patient must not have experienced unacceptable toxicity from the drug.
- Submission of liver function tests (every three months) with initial reauthorization is required, then one liver function test annually thereafter.
- Patients ages 2 to < 18 should have a follow up ophthalmic examination at least annually.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as:
  - Fixed dose tablets combination containing elexacaftor 50 mg, tezacaftor 25 mg and ivacaftor 37.5 mg; co-packaged with ivacaftor 75 mg tablets.
  - Fixed dose tablets combination containing elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg; co-packaged with ivacaftor 150 mg tablets.
  - Unit-dose oral granule packets of elexacaftor 100 mg, tezacaftor 50 mg and ivacaftor 75 mg; co-packaged with unit dose packets of ivacaftor 75 mg tablets.

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- Unit-dose oral granule packets of elexacaftor 80 mg, tezacaftor 40 mg and ivacaftor 60 mg; co-packaged with unit dose packets of ivacaftor 59.5 mg tablets.