Reference number(s)
3374-A

SPECIALTY GUIDELINE MANAGEMENT

TRIKAFTA (elexacaftor/tezacaftor/ivacaftor)

POLICY

I. 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
Trikafta is indicated for the treatment of patients with cystic fibrosis (CF) aged 12 years and older who have at least one F508del mutation in the CFTR gene. 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.

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

II. REQUIRED DOCUMENTATION

The following information is necessary to initiate the prior authorization review: genetic testing report confirming the presence of the appropriate *CFTR* gene mutation.

III. CRITERIA FOR INITIAL APPROVAL

Cystic Fibrosis [1]
Authorization of 12 months may be granted for treatment of cystic fibrosis when all of the following criteria are met:
A. Genetic testing was conducted to detect a mutation in the CFTR gene.
B. The member is positive for at least one F508del mutation in the CTFR gene.
C. The member is at least 12 years of age.
D. Trikafta will not be used in combination with other ivacaftor containing medications.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in FEV1 from baseline).

V. REFERENCES

1. Trikafta [package insert]. Boston, MA: Vertex Pharmaceuticals Inc; October 2019.