Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Trikafta under the patient's prescription drug benefit.

Description:

FDA-Approved Indication
Trikafta is indicated for the treatment of cystic fibrosis (CF) in patients aged 2 years and older who have at least one *F508del* mutation in the cystic fibrosis transmembrane conductance regulator *(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.

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

Applicable Drug List:

Trikafta

Policy/Guideline:

Documentation
Submission of the following information is necessary to initiate the prior authorization review: For initial requests, genetic testing report confirming the presence of the appropriate *CFTR* gene mutation.

Prescriber Specialty:
This medication must be prescribed by or in consultation with a pulmonologist.

Criteria for Initial Approval:
Cystic Fibrosis
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 has one of the following mutations in the *CFTR* gene: A46D, A120T, A234D, A349V, A455E, A554E, A1006E, A1067T, D110E, D110H, D192G, D443Y, D443Y;G576A;R668C, D579G, D614G, D836Y, D924N, D979V, D1152H, D1270N, E56K, E60K, E92K, E116K, E193K, E403D, E474K, E588V, E822K, F191V, F311del, F311L, F508C, F508C;S1251N, F508del, F575Y, F1016S, F1052V, F1074L, F1099L, G27R, G85E, G126D,

G178E, G178R, G194R, G194V, G314E, G463V, G480C, G551D, G551S, G576A, G576A;R668C, G622D, G628R, G970D, G1061R, G1069R, G1244E, G1249R, G1349D, H139R, H199Y, H939R, H1054D, H1085P, H1085R, H1375P, I148T, I175V, I336K, I502T, I601F, I618T, I807M, I980K, I1027T, I1139V, I1269N, I1366N, K1060T, L15P, L165S, L206W, L320V, L346P, L453S, L967S, L997F, L1077P, L1324P, L1335P, L1480P, M152V, M265R, M952I, M952T, M1101K, P5L, P67L, P205S, P574H, Q98R, Q237E, Q237H, Q359R, Q1291R, R31L, R74Q, R74W, R74W;D1270N, R74W;V201M, R74W;V201M;D1270N, R75Q, R117C, R117G, R117H, R117L, R117P, R170H, R258G, R334L, R334Q, R347H, R347L, R347P, R352Q, R352W, R553Q, R668C, R751L, R792G, R933G, R1066H, R1070Q, R1070W, R1162L, R1283M, R1283S, S13F, S341P, S364P, S492F, S549N, S549R, S589N, S737F, S912L, S945L, S977F, S1159F, S1159P, S1251N, S1255P, T338I, T1036N, T1053I, V201M, V232D, V456A, V456F, V562I, V754M, V1153E, V1240G, V1293G, W361R, W1098C, W1282R, Y109N, Y161D, Y161S, Y563N, Y1014C, Y1032C, 3141del9, 546insCTA.

C. The member is at least 2 years of age.
D. Trikafta will not be used in combination with other medications containing ivacaftor.

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

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit:

- Trikafta (elexacaftor/tezacaftor/ivacaftor) 50 mg/25 mg/37.5 mg tablets: 84 tablets per 28 days
- Trikafta (elexacaftor/tezacaftor/ivacaftor) 100 mg/50 mg/75 mg tablets: 84 tablets per 28 days
- Trikafta (elexacaftor/tezacaftor/ivacaftor) 80 mg/40 mg/60 mg oral granules: 56 packets per 28 days
- Trikafta (elexacaftor/tezacaftor/ivacaftor) 100 mg/50 mg/75 mg oral granules: 56 packets per 28 days

References:

1. Trikafta [package insert]. Boston, MA: Vertex Pharmaceuticals Inc; April 2023.