AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Trikafta	Page:	1 of 3
Effective Date:	6/9/2025	Last Review Date:	5/27/2025
Applies to:	☒Illinois ☒Maryland	☒Florida Kids ☒Pennsylvania Kids	☐New Jersey ☒Virginia

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:

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 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 clinical and/or 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 indicated mutation.

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 Specialties

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

Coverage Criteria

Cystic Fibrosis[1]

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

- Genetic testing was conducted to detect a mutation in the CFTR gene.
- The member has ONE of the following mutations in the CFTR gene: 2789+5G→A, D1152H, L206W, R1066H, S945L, 3272-26A→G, F508del, L997F, R117C, T338I, 3849+10kbC→T, G85E, M1101K, R347H, V232D, A455E, L1077P, P5L, R347P, N1303K, 1507_1515del9, 2183A→G, 3141del9, 546insCTA, A1006E, A1067P, A1067T, A107G, A120T, A234D, A309D, A349V, A46D, A554E, A62P, C491R, D110E, D110H, D1270N, D1445N, D192G, D443Y, D443Y;G576A;R668C, D565G, D579G, D614G, D836Y, D924N, D979V, D993Y, E116K, E116Q, E193K, E292K, E403D, E474K, E56K, E588V, E60K, E822K, E92K, F1016S, F1052V, F1074L, F1099L, F1107L, F191V, F200I, F311del, F311L, F508C, F508C;S1251N, F575Y, F587I, G1047R, G1061R, G1069R, G1123R, G1244E, G1247R, G1249R, G126D, G1349D, G178E, G178R, G194R, G194V, G27E, G27R, G314E, G424S, G463V, G480C, G480S, G551A, G551D, G551S, G576A, G576A;R668C, G622D, G628R, G970D, G970S, H1054D, H1085P, H1085R, H1375P, H139R, H199Y, H620P, H620Q, H939R, H939R;H949L, I1027T, I105N, I1139V, I125T, I1269N, I1366N, I148N, I148T, I175V, I331N, I336K, I502T, I506L, I556V, I601F, I618T, I807M, I980K, K1060T, K162E, K464E, L1011S, L1324P, L1335P, L137P, L1480P, L15P, L165S, L320V, L333F, L333H, L346P, L441P, L453S, L619S, L967S, M1137V, M150K, M152V, M265R, M952I, M952T, N1088D, N1303I, N186K, N187K, N418S, P140S, P205S, P499A, P574H, P67L, P750L, Q1291R, Q1313K, Q237E, Q237H, Q359R, Q372H, Q493R, Q552P, Q98R, R1048G, R1070Q, R1070W, R1162L, R117C;G576A;R668C, R117G, R117H, R117L, R117P, R1283M, R1283S, R170H, R258G, R297Q, R31C, R31L, R334L, R334Q, R347L, R352Q, R352W, R516S, R553Q, R555G, R668C, R709Q, R74Q, R74W, R74W;D1270N, R74W;V201M, R74W;V201M;D1270N, R751L, R75L, R75Q, R792G, R933G, S1045Y, S108F, S1118F, S1159F, S1159P, S1235R, S1251N, S1255P, S13F, S341P, S364P, S492F, S549I, S549N, S549R, S589N, S737F, S912L, S977F, T1036N, T1053I, T1086I, T1246I, T1299I, T351I, V1153E, V1240G, V1293G, V201M, V392G, V456A, V456F, V562I, V603F, V754M, W1098C, W1282R, W361R, Y1014C, Y1032C, Y109N, Y161D, Y161S, Y301C, Y563N, 4005+2T→C, 1341G→A, 1898+3A→G, 2752-26A→G, 2789+2insA, 296+28A→G, 3041-15T→G, 3600G→A, 3849+40A→G, 3849+4A→G, 3850-3T→G, 5T;TG12, 5T;TG13, 621+3A→G, 711+3A→G, E831X.
- 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 section who are experiencing benefit from therapy as evidenced by disease stability or disease improvement (e.g., improvement in 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).

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 Incorporated; December 2024.