Health Alliance™

Pharmacy Drug Policy & Procedure

Policy Name:	Trikafta (elexacaftor-tezacaftor-ivacaftor)	Policy#:	2754P

Purpose of the Policy

The purpose of this policy is to define the criteria for coverage of Trikafta.

Statement of the Policy

Health Alliance Medical Plans will approve the use of Trikafta for the following mutations under the specialty pharmacy benefit, when the following criteria have been met.

List of CFTR gene mutations that produce CFTR protein and are responsive to elexacaftor/tezacaftor/ivacaftor include (this is not an all-inclusive list and is subject to change): 2789+5G----+A, 3272-26A +G, 3849+10kbC----+T, L138, 711+3A----+G, Al006E, A1067T, A120T, A234D, A349V, A455E, A554Ec, Dll0E, Dll0H, Dl152H, D1270N, D192G, D443Y, D579G, D614G, D836Y, D924N, D979V, E116K, E193K, E403D, E56K, E588V, E60K, E822K, E831X, E92K, F1016S, F1052V, F1074L, Fl099L, F191V, F311del or F312del, F311L, F508Ca, F508C;S1251N, F508del, F575Y, G1069R, G1244E, G1249R, G126D, G1349D, G178E, G178R, G194R, G194V, G314E, G551D, G551S, G576A, G622D, G970D, H1054D, H1375P, H939R, I1027T, Il 139V, I1269N, I1366N, I148T, I175V, I336K, I601F, I618T, I807M, I980K, K1060T, L1324P, Ll335P, Ll480P, LISP, L206W, L320V, L346P, L967S, L997F, Ml52V, M265R, M952I, M952T, P205S, P5L, P67L, Q1291R, Q237E, Q237H, Q359R, Q98R, R1066H, R1070Q, R1070W, Rl 162L, Rl 17C, Rl 17G, Rl 17H, Rl 17L, Rl 17P, R1283M, Rl283Sc, RI 70H, R258G, R31L, R334L, R334Q, R347H, R347L, R347P, R352Q, R352W, R553Q, R668C, R74Q, R74W, R751L, R75Q, R792G, R933G, S1159F, S1159P, S1251N, S1255P, S549N, S549R, S589N, S737F, S912L, S945L, S977F, T1036N, T1053I, T338I, Vl 153E, V1240G, V1293G, V201M, V232D, V562I, V754M, W1282R, Y1014C, Y1032C, Y109N, Y161S.

Criteria

1. Coverage Criteria

1.1 Documented diagnosis of cystic fibrosis

1.2 Documentation that the member has at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene responsive to Trikafta based on clinical and/or in vitro assay data

1.3 Age 2 years or older

1.4 Prescribed by a provider specializing in the treatment of cystic fibrosis

1.5 Documentation supporting baseline liver function tests have been obtained

1.6 For **Trikafta granules:** patient must be less than 12 years old or prescriber may submit justification why tablets cannot be used

1.7 Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Trikafta by both a pharmacist and a medical director

2. Approval Period

2.1 Initial Approval: 12 months

2.2 Subsequent Approvals: 2 years

References

1. Trikafta (elexacaftor/tezacaftor/ivacaftor) [prescribing information]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2024.
2. Heijerman HGM, McKone EF, Downey DG, et al. Efficacy and safety of the elexacaftor plus tezacaftor plus ivacaftor combination regimen in people with cystic fibrosis homozygous for the F508del mutation: a doubleblind, randomised, phase 3 trial. Lancet 2019; 394:1940.
3. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Pulmonary Guidelines: Use of CFTR Modulator Therapy in Patients with Cystic Fibrosis. Ann Am Thorac Soc. 2018 Mar.

4. Southern KW, Castellani C, Lammertyn E, et al. Standards of care for CFTR variant-specific therapy (including modulators) for people with cystic fibrosis. J Cyst Fibros. 2023 Jan;22(1):17-30
5. Kapnadak SG, Dirnango E, Hempstead SE, et al. Cystic Fibrosis Foundation consensus guidelines for the care of individuals with advanced cystic fibrosis lung disease. J Cyst Fibros. 2020 May;19(3):344-354

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