Reference number(s)
6783-A

Speciality Guideline Management Alyftrek

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Alyftrek	vanzacaftor/tezacaftor/deutivacaftor

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]

Alyftrek is indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation or another responsive mutation in the cystic fibrosis transmembrane conductance regulator (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 indicated mutation.

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

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.

Reference number(s)
3374-A

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: A455E, G551D, L1077P, R352Q, S549N, V754M, D1152H, G85E, L206W, R75Q, S549R, W1098C, F508del, H1054D, M1101K, S1159F, S945L, W1282R, G1244E, I336K, R1066H, S1251N, V562I, Y563N, 1507_1515del9, 2183A→G, 3141del9, 3195del6, 3199del6, 546insCTA, A1006E, A1067P, A1067T, A107G, A120T, A234D, A309D, A349V, A46D, A554E, A559T, A559V, A561E, A613T, A62P, A72D, C491R, D110E, D110H, D1270N, D1445N, D192G, D443Y, D443Y;G576A;R 668C, D513G, 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, G1247R, G1249R, G126D, G1349D, G149R, G178E, G178R, G194R, G194V, G27E, G27R, G314E, G424S, G463V, G480C, G480S, G551A, G551S, G576A, G576A;R668C, G622D, G628R, G91R, G970D, G970S, H1085P, H1085R, H1375P, H139R, H199R, H199Y, H609R, H620P, H620Q, H939R, H939R;H949L, I1027T, I105N, I1139V, I1234Vdel6aa, I125T, I1269N, I331N, I1366N, I1398S, I148N, I148T, I175V, I502T, I506L, I506T, I556V, I601F, I618T, I807M, I980K, K1060T, K162E, K464E, L1011S, L102R, L1065P, L1324P, L1335P, L137P, L1480P, L15P, L165S, L320V, L333F, L333H, L346P, L441P, L453S, L619S, L967S, L997F, M1101R, M1137V, M150K, M152V, M265R, M952I, M952T, N1088D, N1303I, N1303K, N186K, N187K, N418S, P140S, P205S, P499A, P5L, P574H, P67L, P750L, P99L, Q1100P, Q1291R, Q1313K, Q237E, Q237H, Q359R, Q372H, Q452P, Q493R, Q552P, Q98R, R1048G, R1066C, R1066L, R1066M, R1070Q, R1070W, R1162L, R117C, R117C;G576A;R668C, R117G, R117H, R117L, R117P, R1283M, R1283S, R170H, R258G, R297Q, R31C, R31L, R334L, R334Q, R347H, R347L, R347P, R352W, R516G, R516S, R553Q, R555G, R560S, R560T, R668C, R709Q, R74Q, R74W, R74W;D1270N, R74W;V201M, R74W;V201M;D1270N, R75L, R751L, R792G, R933G, S1045Y, S108F, S1118F, S1159P, S1235R, S1255P, S13F, S341P, S364P, S492F, S549I, S589N, S737F, S912L, S977F, T1036N, T1053I, T1086I, T1246I, T1299I, T338I, T351I, T604I, V1153E, V1240G, V1293G, V201M, V232D, V392G, V456A, V456F, V520F, V603F, W361R, Y1014C, Y1032C, Y109N, Y161D, Y161S, Y301C, Y569C, Y913C, 1341G→A, 1898+3A→G, 2752-26A→G, 2789+2insA, 2789+5G→A, 296+28A→G, 3041-15T→G, 3272-26A→G, 3600G→A, 3849+10kbC→T, 3849+4A→G, 3849+40A→G, 3850-3T→G, 4005+2T→C, 5T;TG12, 5T;TG13, 621+3A→G, 711+3A→G, E831X.

- The member is at least 6 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

Alyftrek will not be used in combination with another CFTR modulator for the treatment of cystic fibrosis (e.g., Kalydeco, Trikafta).

Reference

1. Alyftrek [package insert]. Boston, MA: Vertex Pharmaceuticals Incorporated; December 2024.