Trikafta (elexacaftor/tezacaftor/ivacaftor)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Trikafta (elexacaftor/tezacaftor/ivacaftor) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Initial requests for Trikafta (elexacaftor/tezacaftor/ivacaftor) may be approved if the following are met:

I. Individual has a diagnosis of cystic fibrosis (CF); **AND**
II. Individual is 2 years of age or older; **AND**
III. A copy of the CF mutation analysis test result must be provided; **AND**
IV. Individual has a mutation-positive result in the cystic fibrosis transmembrane conductance regulator (CFTR) gene with **one** of the following mutation types:

3141del9	E822K	G1069R	L967S	R117L	S912L
546insCTA	F191V	G1244E	L997F	R117P	S945L
A46D	F311del	G1249R	L1077P	R170H	S977F
A120T	F311L	G1349D	L1324P	R258G	S1159F
A234D	F508C	H139R	L1335P	R334L	S1159P
A349V	F508C; S1251N	H199Y	L1480P	R334Q	S1251N
A455E	F508del	H939R	M152V	R347H	S1255P
A554E	F575Y	H1054D	M265R	R347L	T338I
A1006E	F1016S	H1085P	M952I	R347P	T1036N
A1067T	F1052V	H1085R	M952T	R352Q	T1053I
D110E	F1074L	H1375P	M1101K	R352W	V201M
D110H	F1099L	I148T	P5L	R553Q	V232D
D192G	G27R	I175V	P67L	R668C	V456A
D443Y	G85E	I336K	P205S	R751L	V456F
D443Y; G576A; R668C	G126D	I502T	P574H	R792G	V562I
D579G	G178E	I601F	Q98R	R933G	V754M
D614G	G178R	I618T	Q237E	R1066H	V1153E
D836Y	G194R	I807M	Q237H	R1070Q	V1240G
D924N	G194V	I980K	Q359R	R1070W	V1293G
D979V	G314E	I1027T	Q1291R	R1162L	W361R
D1152H	G463V	I1139V	R31L	R1283M	W1098C

D1270N	G480C	I1269N	R74Q	R1283S	W1282R
E56K	G551D	I1366N	R74W	S13F	Y109N
E60K	G551S	K1060T	R74W; D1270N	S341P	Y161D
E92K	G576A	L15P	R74W; V201M	S364P	Y161S
E116K	G576A; R668C	L165S	R74W; V201M; D1270N	S492F	Y563N
E193K	G622D	L206W	R75Q	S549N	Y1014C
E403D	G628R	L320V	R117C	S549R	Y1032C
E474K	G970D	L346P	R117G	S589N	
E588V	G1061R	L453S	R117H	S737F	

Continuation requests for Trikafta (elexacaftor/tezacaftor/ivacaftor) may be approved if the following is met:

I. There is clinically significant improvement or stabilization in clinical signs and symptoms of disease (including but not limited to improvement in FEV1, decrease in pulmonary exacerbations, improvement in BMI or improvement of respiratory symptoms [cough, sputum production, difficulty breathing]).

Trikafta (elexacaftor/tezacaftor/ivacaftor) may not be approved for the following:

I. In combination with Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor) or Symdeko (tezacaftor/ivacaftor); **OR**
II. Individual with severe hepatic impairment (Child-Pugh Class C).

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: March 19, 2023.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
4. Simon RH. Cystic fibrosis: Overview of the treatment of lung disease. Last updated: February 13, 2023. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: March 17, 2023.
5. Simon RH. Cystic fibrosis: Treatment with CFTR modulators. Last updated: November 29, 2022. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. Accessed: March 17, 2023.