

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

elexacaftor/tezacaftor/ivacaftor (Trikafta)

Initiation (new start) criteria: Formulary **elexacaftor/tezacaftor/ivacaftor (Trikafta)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis (CF)
- Patient is at least 2 years of age
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- At least one responsive mutation (see Table 1) in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.
- Patient does not have either of the following:
 - Severe liver impairment (Child-Pugh Class C)
 - Prior solid organ or hematological transplantation, unless use of the medication is approved by transplant center.

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Formulary **elexacaftor/tezacaftor/ivacaftor (Trikafta)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis (CF)
- Patient is at least 2 years of age
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- At least one responsive mutation (see Table 1) in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.
- Patient does not have either of the following:
 - Severe liver impairment (Child-Pugh Class C)
 - Prior solid organ or hematological transplantation, unless use of the medication is approved by transplant center.

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Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Formulary **elexacaftor/tezacaftor/ivacaftor (Trikafta)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis (CF)
- Patient is at least 2 years of age
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- At least one responsive mutation (see Table 1) in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.
- Patient does not have either of the following:
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Table 1: CFTR Gene Mutations Responsive to elexacaftor/tezacaftor/ivacaftor (Trikafta)¹

3141del9	E92K	G622D	L206W	R170H	S549R
546insCTA	F1016S	G628R	L320V	R258G	S589N
A1006E	F1052V	G85E	L346P	R31L	S737F
A1067T	F1074L	G970D	L453S	R334L	S912L
A120T	F1099L	H1054D	L967S	R334Q	S945L
A234D	F191V	H1085P	L997F	R347H	S977F
A349V	F311del	H1085R	M1101K	R347L	T1036N
A455E	F311L	H1375P	M152V	R347P	T1053I
A46D	F508C	H139R	M265R	R352Q	T338I
A554E	F508C;S1251N	H199Y	M952I	R352W	V1153E
D110E	F508del	H939R	M952T	R553Q	V1240G
D110H	F575Y	I1027T	P205S	R668C	V1293G
D1152H	G1061R	I1139V	P574H	R74Q	V201M
D1270N	G1069R	I1269N	P5L	R74W	V232D
D192G	G1244E	I1366N	P67L	R74W;D1270N	V456A
D443Y	G1249R	I148T	Q1291R	R74W;V201M	V456F
D443Y;G576A;R668C	G126D	I175V	Q237H	R74W;V201M;D1270N	V562I
D579G	G1349D	I336K	Q359R	R751L	V754M
D614G	G178E	I502T	Q98R	R75Q	W1098C
D836Y	G178R	I601F	R1066H	R792G	W1282R
D924N	G194R	I618T	R1070Q	R933G	W361R
D979V	G194V	I807M	R1070W	S1159F	Y1014C
E116K	G27R	I980K	R1162L	S1159P	Y1032C
E193K	G314E	K1060T	R117C	S1251N	Y109N
E403D	G463V	L1077P	R117G	S1255P	Y161D
E474K	G480C	L1324P	R117H	S13F	Y161S
E56K	G551D	L1335P	R117L	S341P	Y563N
E588V	G551S	L1480P	R117P	S364P	
E60K	G576A	L15P	R1283M	S492F	
E822K	G576A;R668C	L165S	R1283S	S549N	

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

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