Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Trikafta™ (Elexacaftor/ivacaftor/tezacaftor; ivacaftor) PA

Trikafta is indicated for the treatment of cystic fibrosis (CF) in patients aged 6 years and older who have at least one F508del mutation in the CFTR gene or a mutation in the CFTR gene that is responsive based on *in vitro* data.

CRITERIA:

Select the diagnosis:

☐ Cystic fibrosis (CF); ICD-10 code(s): _____

Initial authorization: 6 months

Prior authorization will be considered for patients when **ALL** the following criteria are met:

☐ Yes ☐ No Age of patient is within the age range as recommended by the FDA label; ***AND***

☐ Yes ☐ No Diagnosis of CF; ***AND***

☐ Yes ☐ No Prescribed by or in consultation with a CF specialist/pulmonologist specializing in treating CF patients.

a. Name of CF treating or consulting specialist/pulmonologist:
_____

b. Provide chart documentation from consulting provider including name, strength and dosing instructions of CF drug:
_____

AND

☐ Yes ☐ No Patient has a diagnosis of CF with a CFTR mutation* responsive to Trikafta.

- If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to confirm the presence of a CFTR mutation.
- Submission upon request of laboratory results documenting ONE of the following:

a. Patient has at least one F508del mutation in the CFTR gene.

OR

b. The patient has at least one of the following mutations in the CFTR gene that is responsive to Trikafta based on *in vitro* data.

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*CFTR Mutations Responsive to Trikafta:

List of *CFTR* Gene Mutations that are Responsive to TRIKAFTA					
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*	

* *F508del* is a responsive *CFTR* mutation based on both clinical and *in vitro* data
† here a single allele of the *CFTR* gene has multiple mutations; these exist independent of mutations on the other allele.

☐ Yes ☐ No Trikafta is not prescribed concurrently with other CFTR modulators (e,g., Orkambi®, Kalydeco®, Symdeko®); ***AND***

☐ Yes ☐ No Baseline measures submitted by provider of **ALL** of the following:

a. For age appropriate patients, percent predicted expiratory volume in 1 second (ppFEV1):_____

b. Body mass index (BMI):_____

c. Pulmonary exacerbations- number in preceding 6 months: _____

AND

☐ Yes ☐ No Dose does not exceed elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300mg (2 tablets elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg and 1tablet ivacaftor 150 mg) per day

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<u>Reauthorization</u>: 12 months with evidence of appropriate clinical response to therapy

☐ Yes ☐ No Prescribed by or in consultation with a CF specialist/ pulmonologist who specializes in treating CF patients.

a. Name of CF treating/consulting specialist/pulmonologist:

_____

b. Provide chart documentation from consulting provider including name, strength, and dosing instruction of CF drug:

AND

☐ Yes ☐ No Trikafta is not prescribed concurrently with other CFTR modulators (e,g., Orkambi®, Kalydeco®, Symdeko®);

_____

AND

☐ Yes ☐ No Provider attests that the patient has achieved a clinically meaningful response while on Trikafta based on **ALL** of the following:

a. For age appropriate patients, improved or stable lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1): _____

b. Body mass index (BMI):_____

c. Pulmonary exacerbations- number of exacerbations compared to number of exacerbations prior to medication initiation:_____

AND

☐ Yes ☐ No If request is for a dose increase, new dose does not exceed elexacaftor 200 mg/tezacaftor 100 mg/ivacaftor 300 mg (2 tablets elexacaftor 100 mg/tezacaftor 50 mg/ivacaftor 75 mg and 1 tablet ivacaftor 150 mg) per day.

<u>How Supplied:</u>

84-count tablet carton

(4 wallets, each wallet containing 14 tablets of elexacaftor, tezacaftor and ivacaftor and 7 tablets of ivacaftor)