BlueCross BlueShield Federal Employee Program

TRIKAFTA
PRIOR APPROVAL REQUEST

Send completed form to:
Service Benefit Plan
Prior Approval
P.O. Box 52080 MC 139
Phoenix, AZ 85072-2080
Attn. Clinical Services
Fax: 1-877-378-4727

Additional information is required to process your claim for prescription drugs. Please complete the patient portion, and have the prescribing physician complete the physician portion and submit this completed form.

Patient Information (required)			**Provider Information (required)**		
Date:			Provider Name:		
Patient Name:			Specialty:	NPI:	
Date of Birth:	Sex: ❑Male ❑Female		Office Phone:	Office Fax:	
Street Address:			Office Street Address:		
City:	State:	Zip:	City:	State:	Zip:
Patient ID: **R**			Physician Signature:		
PHYSICIAN COMPLETES					

Trikafta

(elexacftor/tezacaftor/ivacaftor)

****Check www.fepblue.org/formulary to confirm which medication is part of the patient's benefit**

NOTE: Form must be completed in its **entirety** for processing

Please select dosage form and indicate quantity:

❑**Tablets (blister packs) -** Will the patient need more than 252 tablets (12 blister packs) every 84 days? ❑**Yes*** ❑**No**
***If YES**, please specify the requested quantity: _____ tablets every 90 days

❑**Packets of granules (wallets) -** Will the patient need more than 168 packets of granules (12 wallets) every 84 days? ❑**Yes*** ❑**No**
***If YES**, please specify the requested quantity: _____ packets of granules every 90 days

Is this request for brand or generic? ❑Brand ❑Generic

1. Does the patient have a diagnosis of cystic fibrosis (CF)? ❑Yes ❑No
2. Does the patient have severe hepatic impairment (Child-Pugh Class C)? ❑Yes ❑No
3. Will this medication be used in combination with another *cystic fibrosis transmembrane conductance regulator (CFTR) potentiator? ❑Yes** ❑No ***If YES**, please specify the medication: _____
   CFTR Potentiators: Kalydeco (ivacaftor), Orkambi (ivacaftor/lumacaftor), Symdeko (ivacaftor/tezacaftor)
4. Has the patient been on Trikafta continuously for the last **6 months**, excluding samples? ***Please select answer below:***

   ❑**NO** – this is **INITIATION** of therapy, please answer the following questions:
   a. Does the patient have at least one *F508del* mutation in the cystic fibrosis transmembrane regulator (CFTR) gene confirmed by an FDA-cleared CF mutation test? ❑Yes ❑No*
      ***If NO**, does the patient have a *CFTR gene mutation responsive to Trikafta? ❑Yes ❑No
      See Page 2 for a list of CFTR gene mutations responsive to Trikafta
   b. **Age 6 or older**: What is the pretreatment percent predicted forced expiratory volume (ppFEV)? _____ %
   c. Will the patient's ALT, AST, alkaline phosphatase, and bilirubin levels be obtained prior to initiating Trikafta? ❑Yes* ❑No
      ***If YES**, does the prescriber agree to monitor the patient's ALT, AST, alkaline phosphatase, and bilirubin levels every month for the first 6 months of treatment, every 3 months for the next 12 months, and annually thereafter? ❑Yes ❑No
   d. Is this medication being prescribed by a pulmonologist or gastroenterologist? ❑Yes ❑No

   ❑**YES** – this is a PA renewal for **CONTINUATION** of therapy, please answer the following questions:
   a. **Age 5 or younger**: Have the patient's symptoms improved or stabilized from baseline? ❑Yes ❑No
   b. **Age 6 or older**: Has the patient been stable or has there been an improvement of ppFEV$_1$ from baseline? ❑Yes ❑No
   c. Has there been a reduction in the number of pulmonary exacerbations? ❑Yes ❑No
   d. Does the prescriber agree to monitor the patient's ALT, AST, alkaline phosphatase, and bilirubin levels annually? ❑Yes ❑No

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List of CFTR Gene Mutations Responsive to TRIKAFTA

Mutations responsive to TRIKAFTA based on clinical data*				
2789+5G→A	*D1152H†*	*L206W†*	*R1066H†*	*S945L†*
3272-26A→G	*F508del†*	*L997F†*	*R117C†*	*T338I†*
3849+10kbC→T	*G85E†*	*M1101K†*	*R347H†*	*V232D†*
A455E†	*L1077P†*	*P5L†*	*R347P†*	
Mutations responsive to TRIKAFTA based on in vitro data‡				
N1303K	*F200I*	*I1139V*	*P574H*	*S1045Y*
1507_1515del9	*F311del*	*I125T*	*P67L*	*S108F*
2183A→G	*F311L*	*I1269N*	*P750L*	*S1118F*
3141del9	*F508C*	*I1366N*	*Q1291R*	*S1159F*
546insCTA	*F508C;S1251N*	*I148N*	*Q1313K*	*S1159P*
A1006E	*F575Y*	*I148T*	*Q237E*	*S1235R*
A1067P	*F587I*	*I175V*	*Q237H*	*S1251N*
A1067T	*G1047R*	*I331N*	*Q359R*	*S1255P*
A107G	*G1061R*	*I336K*	*Q372H*	*S13F*
A120T	*G1069R*	*I502T*	*Q493R*	*S341P*
A234D	*G1123R*	*I506L*	*Q552P*	*S364P*
A309D	*G1244E*	*I556V*	*Q98R*	*S492F*
A349V	*G1247R*	*I601F*	*R1048G*	*S549I*
A46D	*G1249R*	*I618T*	*R1070Q*	*S549N*
A554E	*G126D*	*I807M*	*R1070W*	*S549R*
A62P	*G1349D*	*I980K*	*R1162L*	*S589N*
C491R	*G178E*	*K1060T*	*R117C;G576A;R668C*	*S737F*
D110E	*G178R*	*K162E*	*R117G*	*S912L*
D110H	*G194R*	*K464E*	*R117H*	*S977F*
D1270N	*G194V*	*L1011S*	*R117L*	*T1036N*
D1445N	*G27E*	*L1324P*	*R117P*	*T1053I*
D192G	*G27R*	*L1335P*	*R1283M*	*T1086I*
D443Y	*G314E*	*L137P*	*R1283S*	*T1246I*
D443Y;G576A;R668C	*G424S*	*L1480P*	*R170H*	*T1299I*
D565G	*G463V*	*L15P*	*R258G*	*T351I*
D579G	*G480C*	*L165S*	*R297Q*	*V1153E*
D614G	*G480S*	*L320V*	*R31C*	*V1240G*
D836Y	*G551A*	*L333F*	*R31L*	*V1293G*
D924N	*G551D*	*L333H*	*R334L*	*V201M*
D979V	*G551S*	*L346P*	*R334Q*	*V392G*
D993Y	*G576A*	*L441P*	*R347L*	*V456A*
E116K	*G576A;R668C*	*L453S*	*R352Q*	*V456F*
E116Q	*G622D*	*L619S*	*R352W*	*V562I*
E193K	*G628R*	*L967S*	*R516S*	*V603F*
E292K	*G970D*	*M1137V*	*R553Q*	*V754M*
E403D	*G970S*	*M150K*	*R555G*	*W1098C*
E474K	*H1054D*	*M152V*	*R668C*	*W1282R*
E56K	*H1085P*	*M265R*	*R709Q*	*W361R*
E588V	*H1085R*	*M952I*	*R74Q*	*Y1014C*
E60K	*H1375P*	*M952T*	*R74W*	*Y1032C*
E822K	*H139R*	*N1088D*	*R74W;D1270N*	*Y109N*
E92K	*H199Y*	*N1303I*	*R74W;V201M*	*Y161D*
F1016S	*H620P*	*N186K*	*R74W;V201M;D1270N*	*Y161S*
F1052V	*H620Q*	*N187K*	*R751L*	*Y301C*
F1074L	*H939R*	*N418S*	*R75L*	*Y563N*
F1099L	*H939R;H949L*	*P140S*	*R75Q*	
F1107L	*I1027T*	*P205S*	*R792G*	
F191V	*I105N*	*P499A*	*R933G*	
Mutations responsive to TRIKAFTA based on extrapolation from Trial 5§				
4005+2T→C	*2789+2insA*	*3849+40A→G*	*5T;TG13*	
1341G→A	*296+28A→G*	*3849+4A→G*	*621+3A→G*	
1898+3A→G	*3041-15T→G*	*3850-3T→G*	*711+3A→G*	
2752-26A→G	*3600G→A*	*5T;TG12*	*E831X*	

* Clinical data obtained from Trials 1, 2, and 5.
† This mutation is also predicted to be responsive by FRT assay.
‡ The N1303K mutation is predicted to be responsive by HBE assay. All other mutations predicted to be responsive with in vitro data are supported by FRT assay.
§ Efficacy is extrapolated from Trial 5 to non-canonical splice mutations because clinical trials in all mutations of this subgroup are infeasible and these mutations are not amenable to interrogation by FRT system.