



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
ELEXACAFTOR/ TEZACAFTOR/ IVACAFTOR	TRIKAFTA	46112		GPI-10 (4530990340)	

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

- Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
 - The patient is 6 years of age or older
 - Therapy is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the initial denial text at the end of the guideline.

- Does the patient meet **ONE** of the following criteria?
 - Documentation that the patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
 - Documentation that the patient has at least one of the following mutations in the CFTR gene:

<i>3141delI9</i>	<i>E822K</i>	<i>G1069R</i>	<i>L967S</i>	<i>R117L</i>	<i>S912L</i>
<i>546insCTA</i>	<i>F191V</i>	<i>G1244E</i>	<i>L997F</i>	<i>R117P</i>	<i>S945L</i>
<i>A46D</i>	<i>F311del</i>	<i>G1249R</i>	<i>L1077P</i>	<i>R170H</i>	<i>S977F</i>
<i>A120T</i>	<i>F311L</i>	<i>G1349D</i>	<i>L1324P</i>	<i>R258G</i>	<i>S1159F</i>
<i>A234D</i>	<i>F508C</i>	<i>H139R</i>	<i>L1335P</i>	<i>R334L</i>	<i>S1159P</i>
<i>A349V</i>	<i>F508C; S1251N</i>	<i>H199Y</i>	<i>L1480P</i>	<i>R334Q</i>	<i>S1251N</i>
<i>A455E</i>	<i>F508del</i>	<i>H939R</i>	<i>M152V</i>	<i>R347H</i>	<i>S1255P</i>
<i>A554E</i>	<i>F575Y</i>	<i>H1054D</i>	<i>M265R</i>	<i>R347L</i>	<i>T338I</i>
<i>A1006E</i>	<i>F1016S</i>	<i>H1085P</i>	<i>M952I</i>	<i>R347P</i>	<i>T1036N</i>
<i>A1067T</i>	<i>F1052V</i>	<i>H1085R</i>	<i>M952T</i>	<i>R352Q</i>	<i>T1053I</i>
<i>D110E</i>	<i>F1074L</i>	<i>H1375P</i>	<i>M1101K</i>	<i>R352W</i>	<i>V201M</i>
<i>D110H</i>	<i>F1099L</i>	<i>I148T</i>	<i>P5L</i>	<i>R553Q</i>	<i>V232D</i>
<i>D192G</i>	<i>G27R</i>	<i>I175V</i>	<i>P67L</i>	<i>R668C</i>	<i>V456A</i>
<i>D443Y</i>	<i>G85E</i>	<i>I336K</i>	<i>P205S</i>	<i>R751L</i>	<i>V456F</i>
<i>D443Y; G576A; R668C</i>	<i>G126D</i>	<i>I502T</i>	<i>P574H</i>	<i>R792G</i>	<i>V562I</i>
<i>D579G</i>	<i>G178E</i>	<i>I601F</i>	<i>Q98R</i>	<i>R933G</i>	<i>V754M</i>
<i>D614G</i>	<i>G178R</i>	<i>I618T</i>	<i>Q237E</i>	<i>R1066H</i>	<i>V1153E</i>
<i>D836Y</i>	<i>G194R</i>	<i>I807M</i>	<i>Q237H</i>	<i>R1070Q</i>	<i>V1240G</i>
<i>D924N</i>	<i>G194V</i>	<i>I980K</i>	<i>Q359R</i>	<i>R1070W</i>	<i>V1293G</i>
<i>D979V</i>	<i>G314E</i>	<i>I1027T</i>	<i>Q1291R</i>	<i>R1162L</i>	<i>W361R</i>
<i>D1152H</i>	<i>G463V</i>	<i>I1139V</i>	<i>R31L</i>	<i>R1283M</i>	<i>W1098C</i>
<i>D1270N</i>	<i>G480C</i>	<i>I1269N</i>	<i>R74Q</i>	<i>R1283S</i>	<i>W1282R</i>

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PRIOR AUTHORIZATION GUIDELINES**

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	

If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #3 per day.**

APPROVAL TEXT: Renewal requires the patient has shown improvement in clinical status compared to baseline as shown by ONE of the following: i) patient has improved, maintained, or demonstrated less than expected decline in FEV1, ii) patient has improved, maintained, or demonstrated less than expected decline in BMI, or iii) patient has experienced a reduction in rate of pulmonary exacerbations.

If no, do not approve.

INITIAL DENIAL TEXT: **Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.*

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for approval:

- A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
- B. You are 6 years of age or older
- C. Therapy is prescribed by or given in consultation with a pulmonologist (doctor who specializes in lungs) or cystic fibrosis expert
- D. You meet ONE of the following:
 - 1. Documentation that you have at least one *F508del* mutation (a permanent change in your DNA that make up your gene) in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
 - 2. Documentation that you have at least one of the following mutations in the CFTR gene:

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



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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	

Your doctor told us [INSERT PT SPECIFIC INFO PROVIDED]. We do not have information showing you [INSERT UNMET CRITERIA]. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

ELEXACAFTOR/TEZACAFTOR/IVACAFTOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status compared to baseline as shown by **ONE** of the following?
 - The patient has improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume)
 - The patient has improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
 - The patient has experienced a reduction in rate of pulmonary exacerbations

If yes, **approve for lifetime by HICL or GPI-10 with a quantity limit of #3 per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **ELEXACAFTOR/TEZACAFTOR/IVACAFTOR (Trikafta)** requires the following rule(s) be met for renewal:

- A. You have cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
- B. You have shown improvement in clinical (medical) status compared to baseline as shown by **ONE** of the following:
 1. You have improved, maintained, or demonstrated less than expected decline in FEV1 (forced expiratory volume: amount of air you can exhale in 1 second)
 2. You have improved, maintained, or demonstrated less than expected decline in BMI (body mass index)
 3. You have experienced a reduction in rate of pulmonary exacerbations (you have less attacks of breathing problems)

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Trikafta.

REFERENCES

- Trikafta [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; June 2021.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 07/01/21

Created: 02/20

Client Approval: 06/21

P&T Approval: 07/21