



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)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
 - The patient is 12 years of age or older
 - Documentation that patient has at least one F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
 - The medication is prescribed by or given in consultation with a pulmonologist or cystic fibrosis expert

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 12 years of age or older
- C. 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
- D. The medication is prescribed by or given in consultation with a pulmonologist (doctor who specializes in lungs) or cystic fibrosis expert

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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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.; October 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 04/01/20

Created: 02/20

Client Approval: 02/20

P&T Approval: 01/20