



**STANDARD COMMERCIAL DRUG FORMULARY  
PRIOR AUTHORIZATION GUIDELINES**

**TEZACAFTOR/IVACAFTOR**

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
TEZACAFTOR/IVACAFTOR	SYMDEKO	44771		GPI-10 (4530990280)	

**GUIDELINES FOR USE**

**INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)**

- Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ONE** of the following criteria?
  - Documentation that the patient is homozygous for the F508del-CFTR gene mutation
  - Documentation that the patient has at least one of the following mutations in the CFTR gene:

<i>2789+5G→A</i>	<i>D110E</i>	<i>E56K</i>	<i>P67L</i>	<i>S945L</i>
<i>3272-26A→G</i>	<i>D110H</i>	<i>E831X</i>	<i>R1070W</i>	<i>S977F</i>
<i>3849+10kbC→T</i>	<i>D1152H</i>	<i>F1052V</i>	<i>R117C</i>	
<i>711+3A→G</i>	<i>D1270N</i>	<i>F1074L</i>	<i>R347H</i>	
<i>A1067T</i>	<i>D579G</i>	<i>K1060T</i>	<i>R352Q</i>	
<i>A455E</i>	<i>E193K</i>	<i>L206W</i>	<i>R74W</i>	

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

If yes, **approve for 24 weeks by HICL or GPI-10 with a quantity limit of #2 per day.**

**APPROVAL TEXT:** Renewal requires the patient have 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.

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

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PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR/IVACAFTOR

INITIAL CRITERIA (CONTINUED)

**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 **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for approval:

- A. You are 6 years of age or older
- B. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
- C. You have cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
- D. You have documentation that you are either homozygous (you have 2 copies of the same gene) for the F508del-CFTR (Cystic fibrosis transmembrane conductance regulator) gene mutation; **OR** you have documentation that you have at least one of the following mutations in the CFTR gene:

2789+5G→A	D110E	E56K	P67L	S945L
3272-26A→G	D110H	E831X	R1070W	S977F
3849+10kbC→T	D1152H	F1052V	R117C	
711+3A→G	D1270N	F1074L	R347H	
A1067T	D579G	K1060T	R352Q	
A455E	E193K	L206W	R74W	

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.

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 #2 per day.**

If no, do not approve.

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

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PRIOR AUTHORIZATION GUIDELINES

TEZACAFTOR/IVACAFTOR

RENEWAL CRITERIA (CONTINUED)

**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 **TEZACAFTOR/IVACAFTOR (Symdeko)** requires the following rule(s) be met for renewal:

- A. You have cystic fibrosis (CF: inherited life-threatening disorder that damages the 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.

**RATIONALE**

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

**REFERENCES**

- Symdeko (tezacaftor/ivacaftor) [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc., June 2019.

Library	Commercial	NSA
Yes	Yes	No

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