

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)

- 1. 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 (CF)
 expert

If yes, continue to #2. If no, do not approve.

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

- 2. Does the patient meet **ONE** of the following criteria?
 - Documentation that the patient is homozygous for the 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:

546insCTA	E92K	G576A	L346P	R117G	S589N
711+3A→G	E116K	G576A; R668C	L967S	R117H	S737F
2789+5G→A	E193K	G622D	L997F	R117L	S912L
3272-26A→G	E403D	G970D	L1324P	R117P	S945L
3849+10kbC→T	E588V	G1069R	L1335P	R170H	S977F
A120T	E822K	G1244E	L1480P	R258G	S1159F
A234D	E831X	G1249R	M152V	R334L	S1159P
A349V	F191V	G1349D	M265R	R334Q	S1251N
A455E	F311del	H939R	M952I	R347H	S1255P
A554E	F311L	H1054D	M952T	R347L	T338I
A1006E	F508C	H1375P	P5L	R347P	T1036N
A1067T	F508C; S1251N	I148T	P67L	R352Q	T1053I
D110E	F508del	I175V	P205S	R352W	V201M
D110H	F575Y	1336K	Q98R	R553Q	V232D
D192G	F1016S	I601F	Q237E	R668C	V562I
D443Y	F1052V	I618T	Q237H	R751L	V754M

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D443Y; G576A; R668C	F1074L	1807M	Q359R	R792G	V1153E
D579G	F1099L	1980K	Q1291R	R933G	V1240G
D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W	Y109N
D979V	G194R	I1366N	R74W; D1270N	R1162L	Y161S
D1152H	G194V	K1060T	R74W; V201M	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N	R1283S	Y1032C
E56K	G551D	L206W	R75Q	S549N	
E60K	G551S	L320V	R117C	S549R	

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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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 have cystic fibrosis (inherited life-threatening disorder that damages the 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 (lung/breathing doctor) or cystic fibrosis expert
- 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:

= 0016				
E92K	G576A	L346P	R117G	S589N
E116K	G576A; R668C	L967S	R117H	S737F
E193K	G622D	L997F	R117L	S912L
E403D	G970D	L1324P	R117P	S945L
E588V	G1069R	L1335P	R170H	S977F
E822K	G1244E	L1480P	R258G	S1159F
E831X	G1249R	M152V	R334L	S1159P
F191V	G1349D	M265R	R334Q	S1251N
F311del	H939R	M952I	R347H	S1255P
F311L	H1054D	M952T	R347L	T338I
F508C	H1375P	P5L	R347P	T1036N
F508C; S1251N	I148T	P67L	R352Q	T1053I
F508del	I175V	P205S	R352W	V201M
F575Y	1336K	Q98R	R553Q	V232D
F1016S	I601F	Q237E	R668C	V562I
F1052V	I618T	Q237H	R751L	V754M
F1074L	1807M	Q359R	R792G	V1153E
F1099L	1980K	Q1291R	R933G	V1240G
	E116K E193K E403D E588V E822K E831X F191V F311del F311L F508C F508C; S1251N F508del F575Y F1016S F1052V F1074L	E116K G576A; R668C E193K G622D E403D G970D E588V G1069R E822K G1244E E831X G1249R F191V G1349D F311del H939R F311L H1054D F508C H1375P F508C; S1251N I148T F508del I175V F575Y I336K F1016S I601F F1052V I618T F1074L I807M	E116K G576A; R668C L967S E193K G622D L997F E403D G970D L1324P E588V G1069R L1335P E822K G1244E L1480P E831X G1249R M152V F191V G1349D M265R F311del H939R M952I F311L H1054D M952T F508C H1375P P5L F508C; S1251N I148T P67L F508del I175V P205S F575Y I336K Q98R F1016S I601F Q237E F1052V I618T Q237H F1074L I807M Q359R	E116K R668C L997S R117H E193K G622D L997F R117L E403D G970D L1324P R117P E588V G1069R L1335P R170H E822K G1244E L1480P R258G E831X G1249R M152V R334L F191V G1349D M265R R334Q F311del H939R M952I R347H F311L H1054D M952T R347L F508C H1375P P5L R347P F508C; S1251N I148T P67L R352Q F508del I175V P205S R352W F575Y I336K Q98R R553Q F1016S I601F Q237E R668C F1052V I618T Q237H R751L F1074L I807M Q359R R792G

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D614G	G126D	I1027T	R31L	R1066H	V1293G
D836Y	G178E	I1139V	R74Q	R1070Q	W1282R
D924N	G178R	I1269N	R74W	R1070W	Y109N
D979V	G194R	I1366N	R74W; D1270N	R1162L	Y161S
D1152H	G194V	K1060T	R74W; V201M	R1283M	Y1014C
D1270N	G314E	L15P	R74W; V201M; D1270N	R1283S	Y1032C
E56K	G551D	L206W	R75Q	S549N	
E60K	G551S	L320V	R117C	S549R	

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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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 [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Inc.; December 2020.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A Created: 02/18

Commercial Effective: 02/01/21 Client Approval: 01/21 P&T Approval: 01/21

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