



**STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES**

IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
IVACAFTOR	KALYDECO	38461		GPI-10 (4530203000)	

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 1 month of age or older
 - Therapy is prescribed by or in consultation with a pulmonologist or cystic fibrosis expert
 - The patient is NOT homozygous for the F508del mutation in the CFTR gene

If yes, continue to #2.

If no, do not approve.

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

- Is there documentation (e.g., chart notes, lab results, diagnostic test results, etc.) that the patient has **ONE** of the following mutations in the CFTR gene?

<i>711+3A→G</i>	<i>F311del</i>	<i>I148T</i>	<i>R75Q</i>	<i>S589N</i>
<i>2789+5G→A</i>	<i>F311L</i>	<i>I175V</i>	<i>R117C</i>	<i>S737F</i>
<i>3272-26A→G</i>	<i>F508C</i>	<i>I807M</i>	<i>R117G</i>	<i>S945L</i>
<i>3849+10kbC→T</i>	<i>F508C; S1251N</i>	<i>I1027T</i>	<i>R117H</i>	<i>S977F</i>
<i>A120T</i>	<i>F1052V</i>	<i>I1139V</i>	<i>R117L</i>	<i>S1159F</i>
<i>A234D</i>	<i>F1074L</i>	<i>K1060T</i>	<i>R117P</i>	<i>S1159P</i>
<i>A349V</i>	<i>G178E</i>	<i>L206W</i>	<i>R170H</i>	<i>S1251N</i>
<i>A455E</i>	<i>G178R</i>	<i>L320V</i>	<i>R347H</i>	<i>S1255P</i>
<i>A1067T</i>	<i>G194R</i>	<i>L967S</i>	<i>R347L</i>	<i>T338I</i>
<i>D110E</i>	<i>G314E</i>	<i>L997F</i>	<i>R352Q</i>	<i>T1053I</i>
<i>D110H</i>	<i>G551D</i>	<i>L1480P</i>	<i>R553Q</i>	<i>V232D</i>
<i>D192G</i>	<i>G551S</i>	<i>M152V</i>	<i>R668C</i>	<i>V562I</i>
<i>D579G</i>	<i>G576A</i>	<i>M952I</i>	<i>R792G</i>	<i>V754M</i>
<i>D924N</i>	<i>G970D</i>	<i>M952T</i>	<i>R933G</i>	<i>V1293G</i>
<i>D1152H</i>	<i>G1069R</i>	<i>P67L</i>	<i>R1070Q</i>	<i>W1282R</i>
<i>D1270N</i>	<i>G1244E</i>	<i>Q237E</i>	<i>R1070W</i>	<i>Y1014C</i>
<i>E56K</i>	<i>G1249R</i>	<i>Q237H</i>	<i>R1162L</i>	<i>Y1032C</i>
<i>E193K</i>	<i>G1349D</i>	<i>Q359R</i>	<i>R1283M</i>	
<i>E822K</i>	<i>H939R</i>	<i>Q1291R</i>	<i>S549N</i>	
<i>E831X</i>	<i>H1375P</i>	<i>R74W</i>	<i>S549R</i>	

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #2 per day.**

If no, do not approve.

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

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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 **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for approval:

- A. You have cystic fibrosis (CF: a type of lung disorder)
- B. You are 1 month of age or older
- C. Therapy is prescribed by or in consultation with a pulmonologist (lung doctor) or cystic fibrosis expert
- D. You are NOT homozygous (have two copies of the same gene) for the F508del mutation (an abnormal change) in the CFTR (cystic fibrosis transmembrane conductance regulator) gene
- E. You have documentation (such as chart notes, lab results, diagnostic test results) of ONE of the following mutations in the CFTR (cystic fibrosis transmembrane conductance regulator) gene:

711+3A→G	F311del	I148T	R75Q	S589N
2789+5G→A	F311L	I175V	R117C	S737F
3272-26A→G	F508C	I807M	R117G	S945L
3849+10kbC→T	F508C; S1251N	I1027T	R117H	S977F
A120T	F1052V	I1139V	R117L	S1159F
A234D	F1074L	K1060T	R117P	S1159P
A349V	G178E	L206W	R170H	S1251N
A455E	G178R	L320V	R347H	S1255P
A1067T	G194R	L967S	R347L	T338I
D110E	G314E	L997F	R352Q	T1053I
D110H	G551D	L1480P	R553Q	V232D
D192G	G551S	M152V	R668C	V562I
D579G	G576A	M952I	R792G	V754M
D924N	G970D	M952T	R933G	V1293G
D1152H	G1069R	P67L	R1070Q	W1282R
D1270N	G1244E	Q237E	R1070W	Y1014C
E56K	G1249R	Q237H	R1162L	Y1032C
E193K	G1349D	Q359R	R1283M	
E822K	H939R	Q1291R	S549N	
E831X	H1375P	R74W	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.

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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 a less than expected decline in FEV1
 - The patient has improved, maintained, or demonstrated a less than expected decline in BMI
 - 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.

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 **IVACAFTOR (Kalydeco)** requires the following rule(s) be met for renewal:

- A. You have cystic fibrosis (CF: a type of lung disorder)
- 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 a less than expected decline in forced expiratory volume (FEV1: amount of air you can exhale in 1 second)
 2. You have improved, maintained, or demonstrated a less than expected decline in body mass index (BMI: a tool for evaluating body fat)
 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 Kalydeco.

REFERENCES

- Kalydeco [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated; May 2023.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Created: 02/12

Commercial Effective: 06/01/23

Client Approval: 05/23

P&T Approval: 01/21

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