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)

1. Does the patient have a diagnosis of cystic fibrosis (CF) and meet **ALL** of the following criteria?
   - Documentation of one of the following mutations in the CFTR gene:

2789+5G→A	*D1152H*	*G1069R*	*P67L*	*S1251N*
3272-26A→G	*D1270N*	*G1244E*	*R1070Q*	*S1255P*
3849+10kbC→T	*D579G*	*G1349D*	*R1070W*	*S549N*
711+3A→G	*E193K*	*G178R*	*R117C*	*S549R*
A1067T	*E56K*	*G551D*	*R117H*	*S945L*
A455E	*E831X*	*G551S*	*R347H*	*S977F*
D110E	*F1052V*	*K1060T*	*R352Q*	
D110H	*F1074L*	*L206W*	*R74W*	

   - The patient is 6 months of age or older
   - The patient is NOT homozygous for the F508del mutation in the CFTR gene
   - The medication is prescribed by or given in consultation with a pulmonologist or CF expert

   If yes, continue to #2.
   If no, do not approve.
   DENIAL TEXT: See the initial denial text at the end of the guideline.

2. Is the patient 6 years of age or older?

   If yes, **approve Kalydeco 150mg tablets for 12 months by GPID or GPI-14 with a quantity limit of #2 tablets per day.**
   APPROVAL TEXT: Renewal requires the patient has shown improvement compared to baseline in clinical status 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, continue to #3.

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INITIAL CRITERIA (CONTINUED)

3. Does the patient weigh less than 14kg (documentation of weight required)?

   If yes, **approve for 12 months by GPID or GPI-14 for all strengths below as follows:**
   - **Kalydeco 25mg packets: #2 packets per day.**
   - **Kalydeco 50mg packets: #2 packets per day.**

   If no, **approve Kalydeco 75mg packets for 12 months by GPID or GPI-14 with a quantity limit of #2 packets 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.

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 are 6 months of age or older
B. You have a diagnosis of cystic fibrosis (life-threatening disorder that damages lungs and digestive system)
C. If you are between 6 months and less than 6 years of age, **Ivacaftor packets** will be approved. Documentation of your weight is required
D. You have documentation of one of the following mutations in the CFTR (Cystic fibrosis transmembrane conductance regulator) gene:

2789+5G→A	*D1152H*	*G1069R*	*P67L*	*S1251N*
3272-26A→G	*D1270N*	*G1244E*	*R1070Q*	*S1255P*
3849+10kbC→T	*D579G*	*G1349D*	*R1070W*	*S549N*
711+3A→G	*E193K*	*G178R*	*R117C*	*S549R*
A1067T	*E56K*	*G551D*	*R117H*	*S945L*
A455E	*E831X*	*G551S*	*R347H*	*S977F*
D110E	*F1052V*	*K1060T*	*R352Q*	
D110H	*F1074L*	*L206W*	*R74W*	

E. You are **NOT** homozygous (have 2 copies of the same gene) for the F508del mutation in the CFTR (Cystic fibrosis transmembrane conductance regulator) gene
F. The medication is prescribed by or given in consultation with a pulmonologist (lung doctor) 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 #2 (tablets/packets) 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: 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 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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IVACAFTOR

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. April 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 02/12
Client Approval: 02/20
P&T Approval: 01/20

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