STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

LUMACAFTOR-IVACAFTOR

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
LUMACAFTOR/IVACAFTOR	ORKAMBI	42235		GPI-10 (4530990230)	

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 1 year of age or older
   - Therapy is prescribed by or in consultation with a pulmonologist or CF expert
   - There is documentation that the patient is homozygous for the F508del-CFTR gene mutation

   If yes, **approve by GPID or GPI-14 for 24 weeks for all of the formulations and strengths with the following quantity limits:**
   - **75-94 mg granule packets: #2 per day.**
   - **100-125 mg granule packets: #2 per day.**
   - **150-188 mg granule packets: # 2 per day.**
   - **100-125 mg tablets: #4 per day.**
   - **200-125 mg tablets: #4 per day.**

   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 **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:
   A. You have cystic fibrosis (a type of lung disorder)
   B. You are 1 year of age or older
   C. Therapy is prescribed by or in consultation with a pulmonologist (lung/breathing doctor) or cystic fibrosis expert
   D. There is documentation that you are homozygous (have 2 copies of the same gene) for the F508del-CFTR (type of gene: cystic fibrosis transmembrane conductance regulator) mutation

   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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LUMACAFTOR-IVACAFTOR

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of cystic fibrosis (CF) and improvement in clinical status 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 by GPID or GPI-14 for lifetime for all of the formulations and strengths with the following quantity limits:**
   - **75-94 mg granule packets: #2 per day.**
   - **100-125 mg granule packets: #2 per day.**
   - **150-188 mg granule packets: #2 per day.**
   - **100-125 mg tablets: #4 per day.**
   - **200-125 mg tablets: #4 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 **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:
   A. You have cystic fibrosis (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 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 (worsening in lung condition)

   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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LUMACAFTOR-IVACAFTOR

RATIONALE

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

REFERENCES

- Orkambi [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated, September 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 10/01/22
Created: 07/15
Client Approval: 09/22
P&T Approval: 10/22