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?
   - Documentation that the patient is homozygous for the F508del-CFTR gene mutation
   - The patient is 2 years of age or older
   - The medication is prescribed by or given in consultation with a pulmonologist or CF expert

   If yes, **approve by GPID or GPI-14 for 24 weeks for the requested formulation and strength with the following quantity limits:**
   For patients age 2 to 5 years old:
   - **Orkambi 100-125 mg granule packets: #2 packets per day.**
   - **Orkambi 150-188 mg granule packets: #2 packets per day.**

   For patients age 6 years and older:
   - **Orkambi 100-125 mg tablets: #4 tablets per day.**
   - **Orkambi 200-125 mg tablets: #4 tablets 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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LUMACAFTOR-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 **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for approval:

A. You are 2 years of age or older
B. You have a diagnosis of cystic fibrosis (inherited life-threatening disorder that damages the lungs and digestive system)
C. 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
D. The medication is prescribed by or given in consultation with a pulmonologist (lung/breathing 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.

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 the requested formulation and strength with the following quantity limits:**
   <u>For patients age 2 to 5 years old:</u>
   - **Orkambi 100-125 mg granule packets: #2 packets per day.**
   - **Orkambi 150-188 mg granule packets: #2 packets per day.**

   <u>For patients age 6 years and older:</u>
   - **Orkambi 100-125 mg tablets: #4 tablets per day.**
   - **Orkambi 200-125 mg tablets: #4 tablets per day.**

   If no, do not approve.
   DENIAL TEXT: See the renewal denial text at the end of the guideline.

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LUMACAFTOR-IVACAFTOR

INITIAL 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 **LUMACAFTOR-IVACAFTOR (Orkambi)** requires the following rule(s) be met for renewal:

A. You have cystic fibrosis (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 Orkambi.

REFERENCES

- Orkambi [Prescribing Information]. Boston, MA: Vertex Pharmaceuticals Incorporated, July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A
Commercial Effective: 04/01/20
Created: 07/15
Client Approval: 02/20
P&T Approval: 01/20