

<b>Clinical Policy Title:</b>	lumacaftor/ivacaftor
<b>Policy Number:</b>	RxA.435
<b>Drug(s) Applied:</b>	Orkambi®
<b>Original Policy Date:</b>	03/06/2020
<b>Last Review Date:</b>	12/11/2025
<b>Line of Business Policy Applies to:</b>	All lines of business (except Medicare)

## Criteria

### I. Initial Approval Criteria

#### A. Cystic Fibrosis (must meet all):

1. Diagnosis of cystic fibrosis;
2. Member is homozygous for the F508del mutation in the CFTR gene.

#### Approval Duration

**All Lines of Business (except Medicare):** 12 months

### II. Continued Therapy Approval

#### A. Cystic Fibrosis (must meet all):

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met initial approval criteria.

**Lines of Business (except Medicare):** 12 months

## References

1. Mogayzel PJ, Naureckas ET, Robinson KA, et al. Cystic fibrosis pulmonary guidelines: Chronic medications for maintenance of lung health. Am J Respir Crit Care Med. 2013; 187(7): 680-689. Available at: <https://pubmed.ncbi.nlm.nih.gov/23540878/>. Accessed March 24, 2025.
2. Ren CL, Morgan RL, Oermann C, et al. Cystic Fibrosis Foundation pulmonary guidelines: Use of cystic fibrosis transmembrane conductance regulator modulator therapy in patients with cystic fibrosis. Ann Am Thorac Soc. 2018; 15(3): 271-280. Available at: <https://pubmed.ncbi.nlm.nih.gov/29342367/>. Accessed March 24, 2025.
3. Farrell PM, White TB, Ren CL et al. Diagnosis of cystic fibrosis: Consensus guidelines from the Cystic Fibrosis Foundation. J Pediatr. 2017; 181S: S4-15. Available at: <https://pubmed.ncbi.nlm.nih.gov/28129811/> Accessed March 24, 2025.
4. Alexander S, Alshafi K, Al-Yaghchi C, et al. Clinical Guidelines: Care of Children with Cystic Fibrosis. Royal Brompton and Harefield NHS. 2020;(8):22-23. Available at: <https://www.rbht.nhs.uk/sites/nhs/files/Corporate%20governance/CF%20guideline%202020%20FINAL.pdf>. Accessed March 24, 2025.
5. Cystic Fibrosis Foundation: Clinical Care Guidelines. Available at: <https://www.cff.org/medical-professionals/clinical-care-guidelines>. Accessed March 24, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1) Policy title was updated.</li> <li>2) Continued Therapy Approval criteria II.A.1 was rephrased.</li> <li>3) References were updated.</li> </ol>	03/06/2020	09/14/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria and Continued Therapy Approval criteria were updated to remove HIM approval duration.</li> <li>2. Continued Therapy Approval Criteria II.A.1 was rephrased to " Member is currently receiving medication that has been authorized by RxAdvance...".</li> <li>3. References were reviewed and updated.</li> </ol>	7/1/2021	9/14/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria I.A.3:Updated to add prescriber criteria.</li> <li>2. References were reviewed and updated.</li> </ol>	04/04/2022	07/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Initial Approval Criteria, I.A.7.a: Updated to include new age specific dosing criteria "Age 1 to 2 years".</li> <li>2. Continued Therapy Approval Criteria, II.A.4.a: Updated to include new age specific dosing criteria "Age 1 to 2 years".</li> <li>3. References were reviewed and updated.</li> </ol>	04/25/2023	07/13/2023
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> <li>1. Removed prescriber criteria.</li> <li>2. Removed age criteria.</li> <li>3. Removed dosing criteria.</li> <li>4. Updated continuation of therapy language.</li> <li>5. Updated approval duration verbiage.</li> <li>6. References were reviewed and updated.</li> </ol>	03/24/2025	04/10/2025
<p>Policy was reviewed.</p>	12/11/2025	12/11/2025