**PRIORITY PARTNERS**
7231 Parkway Dr., Suite 100
Hanover, MD 21076

JOHNS HOPKINS
HEALTH PLANS

# Prior Authorization

JOHNS HOPKINS HEALTH PLANS (MEDICAID)

Orkambi - Priority Partners MCO

This fax machine is located in a secure location as required by HIPAA regulations.
Complete/review information, sign and date. Fax signed forms to Johns Hopkins Health Plans at **1-410-424-4607**. Please contact Johns Hopkins Health Plans at **1-888-819-1043** with questions regarding the Prior Authorization process.
When conditions are met, we will authorize the coverage of Orkambi - Priority Partners MCO.

Drug Name (select from list of drugs shown)
Orkambi (lumacaftor-ivacaftor)

Quantity Frequency Strength

Route of Administration Expected Length of Therapy

Patient Information
Patient Name: _____
Patient ID: _____
Patient Group No.: _____
Patient DOB: _____
Patient Phone:

Prescribing Physician
Physician Name: _____
Physician Phone: _____
Physician Fax: _____
Physician Address: _____
City, State, Zip: _____

**Diagnosis:** _____ **ICD Code:** _____

Comments: _____

**Please circle the appropriate answer for each question.**

1. Has the plan authorized this medication in the past for this patient (i.e., previous authorization is on file under this plan)? Y N

[If yes, skip to question 10.]

2. Is there documentation confirming a diagnosis of cystic fibrosis? Y N _____

NOTE: Documentation must be submitted.

[If no, no further questions.]

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| 3. | Is the patient 2 years of age or older? | Y N | |
| | [If no, no further questions.] | | |
| 4. | Has the patient been determined to be homozygous for the F508del mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene as confirmed by a Food and Drug Administration (FDA)-approved cystic fibrosis (CF) mutation test? | Y N | |
| | NOTE: If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. \ NOTE: Documentation must be submitted. | | |
| | [If no, no further questions.] | | |
| 5. | Is there documentation of baseline liver function tests? | Y N | |
| | NOTE: Documentation must be submitted. | | |
| | [If no, no further questions.] | | |
| 6. | Is there documentation of percent predicted forced expiratory volume (FEV)-1, within the previous 30 days? | Y N | |
| | NOTE: Documentation must be submitted. | | |
| | [If no, no further questions.] | | |
| 7. | Is the patient less than 18 years of age? | Y N | |
| | [If no, skip to question 9.] | | |
| 8. | Has a baseline ophthalmic examination been performed to monitor for lens opacities/cataracts? | Y N | |
| | NOTE: Documentation must be submitted. | | |
| | [If no, no further questions.] | | |
| 9. | Does the patient have any of the following exclusions to therapy: A) Request for indication that is not Food and Drug Administration (FDA)-approved or guideline-supported, B) Patients has cystic fibrosis that is NOT homozygous for the F508del mutation, C) Pediatric cystic fibrosis patient less than 2 years of age, D) Concurrent use with another cystic fibrosis transmembrane conductance regulator (CFTR) agent? | Y N | |
| | [No further questions.] | | |
| 10. | Is there documentation showing that the patient is having a beneficial patient response, evidenced by two or more of the following: A) Improvement or stabilization of lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1), B) Reduction in pulmonary exacerbations from baseline, C) Improvement in Quality of life as demonstrated by Cystic Fibrosis Questionnaire-Revised (CFQ-R) respiratory domain score, D) Weight gain, E) Documented improvement of patient symptoms? | Y N | |
| | NOTE: Documentation must be submitted. | | |
| | [If no, no further questions.] | | |

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| 11. Does the patient have follow-up liver function tests showing one of the following: A) Serum alanine aminotransferase (ALT) or aspartate aminotransferase (AST) less than 5 times the upper limit of normal (ULN), B) Serum ALT or AST less than 3 times the ULN with bilirubin less than 2 times the ULN? | Y N | |
| NOTE: Documentation must be submitted. | | |
| [If no, no further questions.] | | |
| 12. Has the patient received a lung transplant? | Y N | |
| [If yes, no further questions.] | | |
| 13. Is the patient less than 18 years of age? | Y N | |
| [If no, skip to question 15.] | | |
| 14. Has a follow-up ophthalmic evaluation been performed? | Y N | |
| NOTE: Documentation must be submitted. | | |
| [If no, no further questions.] | | |
| 15. Does the patient have any of the following exclusions to therapy: A) Request for indication that is not Food and Drug Administration (FDA)-approved or guideline-supported, B) Patients has cystic fibrosis that is NOT homozygous for the F508del mutation, C) Pediatric cystic fibrosis patient less than 2 years of age, D) Concurrent use with another cystic fibrosis transmembrane conductance regulator (CFTR) agent? | Y N | |

I attest that the medication requested is medically necessary for this patient. I further attest that the information provided is accurate and true, and that the documentation supporting this information is available for review if requested by the claims processor, the health plan sponsor, or, if applicable a state or federal regulatory agency.

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| **Prescriber (Or Authorized) Signature and Date** |