



Request for Prior Authorization
LUMACAFITOR/IVACAFITOR (ORKAMBI™)

(PLEASE PRINT – ACCURACY IS IMPORTANT)

Form with fields for IA Medicaid Member ID #, Patient name, DOB, Patient address, Provider NPI, Prescriber name, Phone, Prescriber address, Fax, Pharmacy name, Address, Phone, Pharmacy NPI, Pharmacy fax, NDC.

Prior authorization is required for Orkambi™ (lumacaftor/ivacaftor). Dual therapy with another cystic fibrosis transmembrane conductance regulator (CFTR) potentiator will not be considered. Payment will be considered for patients when the following criteria are met: 1) Patient is 12 years of age or older; and 2) Has a diagnosis of cystic fibrosis; and 3) Patient is homozygous for the F508del mutation in the CFTR gene as confirmed by a FDA-cleared CF mutation test; and 4) Baseline liver function tests (AST/ALT) and bilirubin levels are provided; and 5) Baseline percent predicted forced expiratory volume (ppFEV1) is provided and is greater than or equal to (≥) 40; and 6) Prescriber is a CF specialist or pulmonologist; and 7) Patient does not have one of the following infections: Burkholderia cenocepacia, Burkholderia dolosa, or Mycobacterium abscessus.

If the criteria for coverage are met, an initial authorization will be given for 3 months. Additional approvals will be granted for 6 months at a time if the following criteria are met: 1) Adherence to lumacaftor/ivacaftor therapy is confirmed; and 2) Response to therapy is documented by prescriber (e.g., improved ppFEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care; and 3) Liver function tests (AST/ALT) and bilirubin are assessed every 3 months during the first year of treatment and annually thereafter.

Orkambi Dosage instructions Quantity Days supply

Initial Requests. Attach the following test results:

- FDA-cleared CF mutation test documenting patient is homozygous for the F508del mutation in the CFTR gene.
Baseline liver function tests (AST/ALT) and bilirubin Result:
Baseline percent predicted forced expiratory volume (ppFEV1) Result:

Prescriber specialty: CF Specialist Pulmonologist Other (specify):

Most recent sputum culture negative for Burkholderia cenocepacia, Burkholderia dolosa, Mycobacterium abscessus: Date (please attach copy of results)

Attach lab results and other documentation as necessary. Minimal required results to be submitted are the results of the gene mutation test, lab results, and most recent sputum culture results.

Renewal Requests.

Is patient adherent to Orkambi? Yes No

Liver function tests (AST/ALT) and bilirubin will be assessed every 3 months during the first year of treatment and annually thereafter? Yes (attach most recent results) Date and result: No

Document response to therapy (e.g., improved ppFEV1 from baseline, weight increased from baseline, decreased exacerbations, improved quality of life) or rationale for continued care:

Prescriber signature (Must match prescriber listed above.) Date of submission

IMPORTANT NOTE: In evaluating requests for prior authorization the consultant will consider the treatment from the standpoint of medical necessity only. If approval of this request is granted, this does not indicate that the member continues to be eligible for Medicaid. It is the responsibility of the provider who initiates the request for prior authorization to establish by inspection of the member's Medicaid eligibility card and, if necessary by contact with the county Department of Human Services, that the member continues to be eligible for Medicaid.