



Prior Authorization Criteria

ORKAMBI (ivacaftor/lumacaftor) PA CRITERIA:

Select the diagnosis:

Cystic fibrosis (CF) ICD-10 code(s): _____

Initial Authorization: 6 months

Prior authorization approval will be considered when **ALL** of the following criteria are met:

Yes No Age of patient is within the age range as recommended by the FDA label*;
AND

Yes No Prescribed by or in consultation with a CF specialist/ pulmonologist who specializes in treating CF patients; **AND**

a. Name of CF treating or consulting specialist/pulmonologist

b. For consults, provide chart documentation including name of drug

Yes No Patient has a diagnosis of cystic fibrosis is homozygous for the F508del mutation (F508del/F508del) in the cystic fibrosis transmembrane regulator (CFTR) gene. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of the F508del mutation on both alleles of the CFTR gene. Submission, upon request, of laboratory results documenting responsive CFTR mutation; **AND**

Yes No Baseline measures submitted by provider of ALL of the following:

a. For age appropriate patients, percent predicted expiratory volume in 1 second (ppFEV1): _____

b. Body mass index (BMI): _____

c. Pulmonary exacerbations- number in preceding 6 months: _____

Reauthorization: 12 months with evidence of appropriate clinical response to therapy

Yes No Prescribed by or in consultation with a CF specialist/pulmonologist who specializes in treating CF patients.

a. Name of CF treating/consulting specialist/pulmonologist

b. For consults, provide chart documentation including name of drug

AND

Yes No Provider attests that the patient has achieved a clinically meaningful response while on Orkambi based on **ALL** of the:

- a. For age appropriate patients, improved or stable lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1)_____
- b. Body mass index (BMI):_____
- c. Pulmonary exacerbations- number of exacerbations compared to number of exacerbations prior to medication initiation:_____

How Supplied:

Orkambi (lumacaftor 100mg/ivacaftor 125 mg) tablets

112-count tablet box containing a 4-week supply (4 weekly cartons of 7 daily blister strips with 4 tablets per strip). 28 day supply

Orkambi (lumacaftor 200mg/ivacaftor 125mg) tablets

112-count tablet box containing a 4-week supply (4 weekly cartons of 7 daily blister strips with 4 tablets per strip). 28 day supply

Orkambi (lumacaftor 100 mg /ivacaftor) oral granules (for use in children age less than 6 years

- ***Use of granules for children age equal to or greater than 6 years requires clinical justification**

56 count carton (contains 56 unit dose packets of lumacaftor 100 mg/ivacaftor 125 mg per packet)

56 count carton (contains 56 unit dose packets of lumacaftor 150 mg/ivacaftor 188 mg per packet)