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

Updated: 02/03/2020 V7
☐ 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)