

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

Lumacaftor-Ivacaftor (Orkambi)

Initiation (new start) criteria and criteria for *new members* entering Kaiser

Permanente already taking the medication who have not been reviewed previously:

Non-formulary lumacaftor-ivacaftor (Orkambi) will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis
- Patient is at least 1 year of age
- Patient has two copies of delta F508 mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene
- If 6+ years of age: baseline percent predicted FEV1 (*volume of air that can be forced out of lungs in one second after taking a deep breath compared with normal reference values*) is at least 30%