SPECIALTY GUIDELINE MANAGEMENT

ORKAMBI (lumacaftor/ivacaftor)

POLICY

A. INDICATIONS
The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indication
- Treatment of cystic fibrosis (CF) patients age 12 years and older who are homozygous for the F508del mutation in the CFTR gene.

Limitation of use: The efficacy and safety of Orkambi have not been established in patients with CF other than those homozygous for the F508del mutation.

All other indications are considered experimental/investigational and are not covered benefits.

B. REQUIRED DOCUMENTATION
The following information is necessary to initiate the prior authorization review:
- Results of genetic testing positive for the F508del mutation on both alleles of the CFTR gene.

C. CRITERIA FOR APPROVAL
1. Cystic Fibrosis
   a. Authorization of 12 months may be granted for members prescribed Orkambi for the treatment of cystic fibrosis who meet ALL of the following criteria:
      i. The member is positive for the F508del mutation on both alleles of the CFTR gene
      ii. The member is at least 12 years of age
      iii. Orkambi will not be used in combination with Kalydeco

D. CONTINUATION OF THERAPY
All members (including new members) requesting authorization for continuation of therapy must meet ALL initial authorization criteria.

E. DOSAGE AND ADMINISTRATION
Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

The following dosing limits apply:
4 tablets per day

REFERENCES