

Orkambi (lumacaftor/ivacaftor)

Coverage Criteria:

1. Patient has a diagnosis of cystic fibrosis; and,
2. Patient is homozygous for the F508del mutation in the CFTR gene; and,
3. Prescribed and managed by a specialist from a cystic fibrosis treatment center; and,
4. Prescribed within FDA approved dosing.

Renewal Criteria:

1. Patient has been seen within the last 12 months at the cystic fibrosis treatment center; and,
2. Patient continues to benefit from therapy; and,
3. Prescribed within FDA approved dosing regimen.

Coverage Duration:

Initial approvals and reauthorizations will be provided for 12 months.

Other Criteria:

Prescribed using the FDA-approved regimen of up to two tablets/packets twice daily.