

Kalydeco (ivacaftor)

Coverage Criteria:

1. Patient has a diagnosis of cystic fibrosis; and,
2. Patient has at least one mutation in the CFTR gene that is responsive to the prescribed drug based on clinical and/or in vitro assay data; and,
3. Prescribed and managed by a specialist from a cystic fibrosis treatment center; and,
4. Prescribed within the FDA approved dosing regimen.

Renewal Criteria:

1. Patient has been seen at the cystic fibrosis treatment center in the past 12 months; and,
2. Documentation that the medication continues to be effective; and,
3. Prescribed within the FDA approved dosing regimen.

Coverage Duration:

Initial approvals and reauthorizations will be provided for twelve months.

Other Criteria:

Prescribed using the FDA-approved regimen of up to one packet or tablet twice daily.