

## **Trikafta (elixacaftor, tezacaftor, and ivacaftor)**

### **Coverage Criteria:**

1. Patient has a diagnosis of cystic fibrosis; and,
2. Prescribed by a specialist from a cystic fibrosis treatment center; and,  
Patient has at least one F508del mutation on the CFTR gene (homozygous or heterozygous mutation) or a mutation in the CFTR gene that is responsive based on in vitro data; and,
3. Patient will be treated with only one CFTR modulator therapy, such as Trikafta (any current CFTR modulator therapies will be discontinued prior to initiation of Trikafta); and,
4. Prescribed within FDA approved dosing.

### **Renewal Criteria:**

1. Patient has been seen by the provider in the past 12 months; and,
2. Provider attests patient continues to clinical benefit from therapy (e.g. improved FEV1 or reduction in pulmonary exacerbations); 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 one packet or two tablets of elixacaftor/tezacaftor/ivacaftor in the morning, and one packet or one tablet of ivacaftor in the evening.