elexacaftor/tezacaftor/ivacaftor (Trikafta)

Initiation (new start) criteria: Formulary elexacaftor/tezacaftor/ivacaftor (Trikafta) will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis (CF)
- AND-
- Patient is at least 12 years of age
- AND-
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- AND-
- At least one F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.
- AND-
- Patient does not have either of the following:
  - Severe liver impairment (Child-Pugh Class C); OR
  - Prior solid organ or hematological transplantation, unless use of the medication is approved by transplant center.

Criteria for current Kaiser Permanente members already taking the medication who have not been reviewed previously: Formulary elexacaftor/tezacaftor/ivacaftor (Trikafta) will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis (CF)
- AND-
- Patient is at least 12 years of age
- AND-
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- AND-
- At least one F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.
- AND-
- Patient does not have either of the following:
  - Severe liver impairment (Child-Pugh Class C); OR
  - Prior solid organ or hematological transplantation, unless use of the medication is approved by transplant center.
Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Formulary elexacaftor/tezacaftor/ivacaftor (Trikafta) will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis (CF)
- Patient is at least 12 years of age
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- At least one F508del mutation in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.
- Patient does not have either of the following:
  - Severe liver impairment (Child-Pugh Class C); OR
  - Prior solid organ or hematological transplantation, unless use of the medication is approved by transplant center.