

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

vanzacaftor/tezacaftor/deutivacaftor (Alyftrek)

Initiation (new start) criteria and criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: non-formulary vanzacaftor/tezacaftor/deutivacaftor (Alyftrek) 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 6 years of age
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- At least one responsive mutation (per most recent Alyftrek Prescribing Information) in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.
- Patient is received prior treatment with elexacaftor/tezacaftor/ivacaftor (Trikafta), or has a mutation that is not responsive to elexacaftor/tezacaftor/ivacaftor.
- Patient does not have either of the following:
 - Severe liver impairment (Child-Pugh Class C)
 - Prior solid organ or hematological transplantation, unless use of the medication is approved by transplant center.

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