

Criteria-Based Consultation Prescribing Program

CRITERIA FOR DRUG COVERAGE

ivacaftor (Kalydeco)

Initiation (new start) criteria: Non-formulary **ivacaftor (Kalydeco)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- Patient is at least 1 month of age
- Patient does not have 2 copies of the F508del mutation in the CFTR gene
- At least one responsive mutation (see Table 1) in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.

Criteria for new members entering Kaiser Permanente already taking the medication who have not been reviewed previously: Non-formulary **ivacaftor (Kalydeco)** will be covered on the prescription drug benefit when the following criteria are met:

- Prescriber specializes in the treatment of cystic fibrosis
- Diagnosis of CF confirmed by a clinician with expertise in providing CF care
- Patient is at least 1 month of age
- Patient does not have 2 copies of the F508del mutation in the CFTR gene
- At least one responsive mutation (see Table 1) in the CFTR gene detected using either an FDA-cleared CF mutation test OR testing was completed by a CLIA certified laboratory.

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Table 1: CFTR Gene Mutations Responsive to Kalydeco¹

711+3A→G	F311del	I148T	R75Q	S589N
2789+5G→A	F311L	I175V	R117C	S737F
3272-26A→G	F508C	I807M	R117G	S945L
3849+10kbC→T	F508C;S1251N	I1027T	R117H	S977F
A120T	F1052V	I1139V	R117L	S1159F
A234D	F1074L	K1060T	R117P	S1159P
A349V	G178E	L206W	R170H	S1251N
A455E	G178R	L320V	R347H	S1255P
A1067T	G194R	L967S	R347L	T338I
D110E	G314E	L997F	R352Q	T1053I
D110H	G551D	L1480P	R553Q	V232D
D192G	G551S	M152V	R668C	V562I
D579G	G576A	M952I	R792G	V754M
D924N	G970D	M952T	R933G	V1293G
D1152H	G1069R	P67L	R1070Q	W1282R
D1270N	G1244E	Q237E	R1070W	Y1014C
E56K	G1249R	Q237H	R1162L	Y1032C
E193K	G1349D	Q359R	R1283M	
E822K	H939R	Q1291R	S549N	
E831X	H1375P	R74W	S549R	

1. Kalydeco [package insert]. Vertex Pharmaceuticals Incorporated; Boston, MA. May 2023.

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