Prior Authorization Criteria

MISSISSIPPI DIVISION OF MEDICAID

Kalydeco® (*ivacaftor*) PA CRITERIA:

Select the diagnosis:

☐ Cystic fibrosis (CF) ICD-10 code(s):_____

Initial authorization: 6 months

Prior authorization approval will be considered when **ALL** of the following criteria are met:

☐ Yes ☐ No Age of patient is within the age range as recommended by the FDA label* **AND**

☐ Yes ☐ No Prescribed by or in consultation with a CF specialist/ pulmonologist who specializes in treating CF patients; **AND**

a. Name of CF treating/consulting specialist/pulmonologist
_____

b. For consults, provide chart documentation including name of drug
_____

☐ Yes ☐ No Patient has a diagnosis of cystic fibrosis (CF) and has *one* CFTR mutation responsive to Kalydeco** based on clinical and/or in vitro assay data. If the patient's genotype is unknown, an FDA-cleared CF mutation test should be used to detect the presence of a CFTR mutation followed by verification with bi-directional sequencing when recommended by the mutation test instructions for use. Submission, upon request, of laboratory results documenting responsive CTFR mutation; **AND**

**CFTR Mutations Responsive to Kalydeco

CFTR Mutations Responsive to KALYDECO[1-3]

10 Approved Prior to 2017		23 Added May 2017				5 Added July 2017
G1244E c.3731G>A	S1251N c.3752G>A	A1067T c.3199G>A	D579G c.1736A>G	K1060T c.3179A>C	R347H c.1040G>A	2789+5G→A c.2657+5G>A
G1349D c.4046G>A	S1255P c.3763T>C	A455E c.1364C>A	E193K c.577G>A	L206W c.617T>G	R352Q c.1055G>A	3272-26A→G c.3140-26A>G
G178R c.532G>A	S549N c.1646G>A	D110E c.330C>A	E56K c.166G>A	P67L c.200C>T	R74W c.220C>T	3849+10kbC→T c.3718-2477C>T
G551D c.1652G>A	S549R c.1645A>C, c.1647T>G	D110H c.328G>C	F1052V c.3154T>G	R1070Q c.3209G>A	S945L c.2834C>T	711+3A→G c.579+3A>G
G551S c.1651G>A		D1152H c.3454G>C	F1074L c.3222T>A	R1070W c.3208C>T	S977F c.2930C>T	E831X c.2491G>T
R117H c.350G>A		D1270N c.3808G>A	G1069R c.3205G>A	R117C c.349C>T		

F508del and 26 other mutations are considered not responsive to ivacaftor (see Prescribing Information for complete listing).

☐ Yes ☐ No Baseline measures submitted by provider of ALL of the following:

a. For age appropriate patients, percent predicted expiratory volume in 1 second (ppFEV1):_____
b. Body mass index (BMI):_____
c. Pulmonary exacerbations- number in preceding 6 months:_____

<u>Reauthorization</u>: 12 months with evidence of appropriate clinical response to therapy

☐ Yes ☐ No Prescribed by or in consultation with a CF specialist/ pulmonologist who specializes in treating CF patients.

a. Name of CF treating/consulting specialist/pulmonologist
_____
b. For consults, provide chart documentation including name of drug
_____

AND

☐ Yes ☐ No Provider attests that the patient has achieved a clinically meaningful response while on Kalydeco based on ALL of the following:

a. For age appropriate patients, improved or stable lung function as demonstrated by percent predicted expiratory volume in 1 second (ppFEV1):_____
b. Body mass index (BMI):_____
c. Pulmonary exacerbations- number of exacerbations compared to number of exacerbations prior to medication initiation:_____

How Supplied:

<u>Kalydeco (ivacaftor) tablets</u>

60-count bottle 150 mg tablets

56-count carton (contains 4 individual blister cards of 14 tablets per card)

<u>Kalydeco (ivacaftor) oral granules (for use in children age less than 6 years)</u>

- ***Use of granules for children equal to or greater than 6 years requires clinical justification***

56-count carton (contains 56 unit-dose packets of 25mg ivacaftor per packet)

56-count carton (contains 56 unit-dose packets of 50mg ivacaftor per packet)

56-count carton (contains 56 unit-dose packets of 75 mg ivacafator per packet)