Prior Authorization Criteria

Kalydeco® (*ivacaftor*) PA CRITERIA:

Kalydeco is indicated for the treatment of cystic fibrosis in patients age 4 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor potentiation based on clinical and/or *in vitro* assay data.

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

(Continued next page)
**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: ____________

**Reauthorization**: 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:**

*Kalydeco (ivacaftor) tablets*

- 60-count bottle 150 mg tablets
- 56-count carton (contains 4 individual blister cards of 14 tablets per card)

*Kalydeco (ivacaftor) oral granules (for use in children age less than 6 years)*

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

  - 56-count carton (contains 56 unit-dose packets of 25 mg ivacaftor per packet)
  - 56-count carton (contains 56 unit-dose packets of 50 mg ivacaftor per packet)
  - 56-count carton (contains 56 unit-dose packets of 75 mg ivacaftor per packet)