



Manual Prior Authorization

Kalydeco (ivacaftor)

Prior authorization is required for Kalydeco (ivacaftor). Payment will be considered for patients when the following criteria are met:

1. Patient is 2 years of age or older; and
2. Has a diagnosis of cystic fibrosis with a *G551D, G1244E, G1349D, G178R, G551S, R117H, S1251N, S1255P, S549N, or S549R* mutation in the CFTR gene as detected by a FDA-cleared CF mutation test; and
3. Prescriber is a CF specialist or pulmonologist; and
4. Patient does not have one of the following infections: *Burkholderia cenocepacia, dolosa, or Mycobacterium abscessus*

Here are the important DDIs/dosing considerations for this drug; review of these considerations should be part of the PA and re-review process and should be considered for DDI/max dose edits given the extreme costs involved.

Moderate hepatic impairment: Child-Pugh Class B or worse: 150 mg **daily** max

Do **NOT** co-administer with strong CYP3A inducers: **carbamazepine, phenobarbital, phenytoin, rifabutin, rifampin, St. John's Wort**

Strong CYP3A inhibitors: **REDUCE** dose to 150 mg **twice weekly**: **ketoconazole, itraconazole, posaconazole, voriconazole, telithromycin, clarithromycin**

Moderate CYP3A inhibitors: **REDUCE** dose to 150 mg **daily**: **fluconazole, erythromycin**

