
Prior Authorization DRUG Guidelines

KALYDECO (ivacaftor)

Effective Date: 4/24/12

Date Developed: 3/20/12 by Albert Reeves MD

Last Approval Date: 1/26/16, 1/24/17, 1/23/18, 1/22/19

(Archived 1/22/19)

KALYDECO is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator.

Pre-Authorization Criteria: treatment of cystic fibrosis (CF) in patients aged 2 years and older who have the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene:
G551D,G1244E,G1349D,G178R,G551S,S1251N,S1255P,S549N,S549R, R117H

VCHCP requires that KALYDECO be prescribed by a pulmonologist or a CF-related physician.

Dosing: Adults and pediatrics patients age 6 years and older

One 150 mg tablet taken orally every 12 hours with fat-containing food.

Dosing: Pediatric patients age 2 to <6 years:

<14 kg: 50 mg packet every 12 hours

≥14 kg: 75 mg packet every 12 hours

Dosing: Hepatic Impairment: Reduce dose in patients with moderate and severe hepatic impairment.

Dosing: Geriatric

See adult dosing. No dosage adjustment is required in elderly patients.

Dosage Forms: U.S.

KALYDECO is available in tablet form, in 150 mg strength.

Administration

Always take KALYDECO with fatty food.

Patient should avoid food containing grapefruit or Seville oranges while taking KALYDECO.

WARNINGS / PRECAUTIONS

- Elevated transaminases (ALT or AST). Transaminases (ALT and AST) should be assessed regularly.
- Concomitant use with strong CYP3A inducers (e.g., rifampin, St. John's Wort) substantially decreases exposure which may diminish effectiveness.
- Avoid foods containing grapefruit or Seville oranges

ADVERSE REACTIONS

- The most common adverse drug reactions to KALYDECO (occurring $\geq 8\%$ of patients with CF who have a G551D mutation in the CFTR gene) were headache, oropharyngeal pain, upper respiratory tract infection, nasal congestion, abdominal pain, nasopharyngitis, diarrhea, rash, nausea, and dizziness.

REFERENCES

Vertex pharmacy/drug insert, issued January 2012

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