



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 17, 2012 February 27, 2014, January 6, 2015, April 30, 2015 , October 8, 2015, May 23, 2017, August 28, 2018

## KALYDECO® (ivacaftor)

LENGTH OF AUTHORIZATION: Up to 6 months

REVIEW CRITERIA:

- Patient must be  $\geq$  12 months old.
- Must have a diagnosis of Cystic Fibrosis confirmed via “health conditions” or medical records.
- Must have genetic testing confirming the presence of one cystic fibrosis transmembrane conductance regulator (CFTR) mutation.
  - (It is not effective in CF patients with two copies (homozygous) of the *F508del* mutation (*F508del/F508del*) in the CF gene and should not be approved for these patients)
- Baseline liver function tests prior to initiating therapy that are less than 3 times the upper limit of normal, then every 3 months the first year, then annually
- Baseline ophthalmic examination to monitor lens opacities/cataracts
- Baseline documented percent predicted FEV1 within the previous 30 days

CONTINUATION OF THERAPY:

- Disease response as indicated by one or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline
  - Improvement or stabilization of lung function (as measured by percent predicted FEV1) compared to baseline or decrease in the rate of decline of lung function
  - Weight gain
  - Improvement in quality of life
- Patient has not received a lung transplant
- Patient has not experienced unacceptable toxicity from the drug

DOSING and ADMINISTRATION:

- Pediatric patients 1-5 years old 7kg to <14kg: 50mg every 12 hours with fat- containing food
- Pediatric patients 1-5 years old  $\geq$ 14kg: 75mg every 12 hours with fat- containing food
- Adults and pediatric patients age 6 years and older: 150 mg tablet taken orally every 12 hours with fat-containing food.
- Dosage form: 50mg, 75mg granule packets; 150 mg tablets