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, May 16, 2019, November 19, 2019, September 17, 2021

KALYDECO® (ivacaftor)

LENGTH OF AUTHORIZATION: Up to 6 months

INITIAL REVIEW CRITERIA:

- Patient must be ≥ 4 months old.
- Patient must have a diagnosis of Cystic Fibrosis confirmed via "health conditions" or medical records.
- Patient must have documentation of one mutation in the cystic fibrosis transmembrane conductance regulator (CFTR) gene that is responsive to ivacaftor based on clinical and/or *in vitro* assay data.
- Patient must have baseline liver function tests prior to initiating therapy, every 3 months during the first year, then annually.
- Pediatric patients must have undergone a baseline ophthalmic examination to monitor lens opacities/cataracts.
- Patient must have baseline documented percent predicted FEV1 within the previous 30 days.

CONTINUATION OF THERAPY:

- Disease response as indicated by two or more of the following:
  - Decreased pulmonary exacerbations compared to pretreatment baseline.
  - Improvement or stabilization of lung function (as measured by percent predicted FEV_1) compared to baseline or decrease in the rate of decline of lung function.
  - Weight gain
  - Clinical notes documenting improvement of patient symptoms.
- Patient must not have received a lung transplant.
- Patient must not have experienced unacceptable toxicity from the drug.
- Patient must have submission of liver function tests (every three months), then one liver function test annually thereafter.
- Pediatric patients should have a follow up ophthalmic examination at least annually.

DOSING and ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 25mg, 50mg, 75mg granule packets; 150 mg tablets.