

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; January 24, 2024, September 9, 2024

## **KALYDECO® (ivacaftor)**

**LENGTH OF AUTHORIZATION:** Up to 6 months

**INITIAL REVIEW CRITERIA:**

- Patient must be  $\geq 1$  month old AND weigh  $\geq 3$  kg.
- 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.
- Patients  $\geq 6$  years old must have baseline documented percent predicted FEV<sub>1</sub> within the previous 90 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<sub>1</sub>) 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 5.8mg, 13.4mg, 25mg, 50mg, 75mg granule packets; 150 mg tablets.