



Montana Healthcare Programs
Drug Prior Authorization Drug Criteria

KALYDECO® (ivacaftor)

I. Medication Description

Kalydeco® is a cystic fibrosis transmembrane conductance regulator (CFTR) potentiator indicated for the treatment of cystic fibrosis (CF) in patients aged 4 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor, based on clinical and/or in vitro assay data.

II. Position Statement

Coverage is determined through a prior authorization process **that must include** supporting clinical documentation for each request.

III. Initial Coverage Criteria

Member must meet all the following criteria:

- Member must be at least 4 months of age
- Must be prescribed by a pulmonologist specializing in the treatment of cystic fibrosis
- Member must have one confirmed mutation of the CFTR gene responsive to ivacaftor based on clinical and/or **in vitro** assay data
- Provider attests that patient has been compliant on Kalydeco® and other cystic fibrosis maintenance medications. Non-compliance will be discussed with the prescriber.
- At six months, provider will attest patient has achieved a meaningful clinical response with one or more of the following:
 - Lung function improvement as demonstrated by improvement or stability in percent predicted expiratory volume (ppFEV1)
 - Decline in pulmonary exacerbations (decrease in intravenous therapy (IV) antibiotic use, decrease in hospitalizations)
 - Stability or increase in body mass index (BMI)

IV. Renewal Coverage Criteria

- Prescriber will be made aware of patient non-compliance to all medications to treat CF

V. Quantity Limitations

- Greater than 6 years of age: Maximum daily dose is two 150mg tablets daily
- Ages 6 months to less than 6 years of age:
 - Weight <7 kg: Maximum daily dose is two 25 mg packets daily
 - Weight 7 kg to less than 14 kg: Maximum daily dose is two 50mg packets daily
 - Weight greater than or equal to 14kg: Maximum daily dose is two 75mg packets daily
- Ages 4 months to less than 6 months:

- Weight is greater than or equal to 5 kg: Maximum daily dose is two 25 mg packets daily

VI. Coverage Duration

- Approval granted in 6-month intervals to assist prescriber in monitoring medication compliance