ALASKA MEDICAID
Prior Authorization Criteria

Kalydeco® (Ivacaftor)

FDA Indication and Usage:

Treatment of cystic fibrosis (CF) in patients age 6 years and older who have *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R* mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene.

An FDA-cleared CF mutation test, along with recommended verification sequencing when appropriate, should be used to detect the presence of a *CFTR* mutation.

Dosage Form/Strength:

Tablet, 150mg

Criteria for Approval:

1. Diagnosis of Cystic Fibrosis; **AND**
2. Confirmed *G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, or S549R* mutation in the Cystic Fibrosis Transmembrane Regulator (CFTR) gene from an FDA-cleared CF mutation test; **AND**
3. Recipient is 6 years of age or older.

Criteria for Denial

- Homozygous for the *F508del* mutation in the *CFTR* gene.

Length of Authorization:

1. Initial coverage may be approved for 2 months.
2. *Re-authorization*, may be approved for up to 10 months if documentation of clinical improvement submitted

Quantity Limit:

- Maximum 2 doses per day; 30 days

Mechanism of Action:

Cystic fibrosis transmembrane conductance regulator (CFTR) potentiator

References:

Kalydeco™ [package insert]. Boston, MA; Vertex, June 2014.