Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

KALYDECO™ (ivacaftor)

GPI CODING:

45302030000320

DESCRIPTION:

Kalydeco is FDA-approved for patients with cystic fibrosis (CF) who are 6 years of age and older with a G551D-CFTR mutation. CF is caused by mutations in the CF transmembrane conductance regulator (CFTR) gene that encode a defective chloride channel in epithelial cells. These channels are important in the regulation of airway surface liquid. Kalydeco is a CFTR potentiator that improves the function of the defective CFTR protein channels and opens them to allow chloride ions to move into and out of the cell. By allowing a proper flow of salt and fluids on the surface of the lungs, Kalydeco helps thin the thick mucus that builds up in the lungs of patients with CF.

APPROVAL DURATION:

Initial approvals: 6 months
Renewals: 12 months

CRITERIA FOR KALYDECO

I. Patient has a diagnosis of cystic fibrosis (CF) **AND**
II. Genetic testing was performed to detect the G551D mutation in the CFTR gene **AND**
III. Genetic test result was positive for the G551D mutation and this result is collected **AND**
IV. Patient is 6 years of age or older

Authorization for continued use shall be reviewed at least every 12 months to confirm that the patient has evidence of clinical improvement (eg, increase in FEV1, weight gain).