Kalydeco® (ivacaftor capsules) – Prior Authorization Criteria

Kalydeco® is FDA approved for the treatment of cystic fibrosis (CF) in patients 2 years of age and older with one of the following mutations in the cystic fibrosis transmembrane conductance regulator (CFTR) gene: G551D, G1244E, G1349D, G178R, G551S, S1251N, S1255P, S549N, S549R, or R117H.1 The mechanism of action involves potentiation of the epithelial cell CFTR protein resulting in improved regulation of salt and water balance in various tissues including the lungs. Clinical studies have demonstrated a positive impact on forced expiratory volume (FEV1), pulmonary exacerbations, weight gain, and quality of life.27 Kalydeco® is not effective in patients with CF who are homozygous for the F508del mutation in the CFTR gene.1

Initial Approval Criteria

An initial approval for a period of 3 months will be granted if the following criteria are met:

1. Client is ≥ 2 years of age.
3. Prescriber specializes in pulmonology or is from a CF center accredited by the Cystic Fibrosis Foundation.
4. If appropriate, patient is receiving and/or has had adequate trials of the following medications:
   - Dornase alfa
   - Hypertonic saline
   - Inhaled or oral antibiotics
5. Baseline liver function tests (ALT/AST) are provided.
6. Baseline FEV1 in clients ≥ 6 years is provided
7. Goals of therapy are provided.

Renewal Criteria

Additional approvals, beyond the initial 3 month approval, will be granted for 6 months at a time if the following criteria are met:

1. Adherence to Kalydeco® therapy is confirmed.
2. Response to therapy is documented (e.g. improved FEV1, weight gain, decreased exacerbations, etc.).
3. Documentation of continued use of standard therapies previously initiated, if appropriate/tolerated, is provided.
4. Liver functions tests (ALT/AST) are provided with each renewal during the first year of treatment and annually thereafter.

Kalydeco 10.2014, 4.2015
References