OVERVIEW
Daliresp, a selective phosphodiesterase-4 (PDE-4) inhibitor, is indicated as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations. Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm. Daliresp has been studied in patients currently receiving treatment with short-acting bronchodilators, long-acting beta2-agonists (LABAs), and/or inhaled corticosteroids (ICSs); it has also been studied as add-on therapy to ICS/LABA therapy with or without a long-acting muscarinic antagonist (LAMA). In the two primary pivotal studies of Daliresp, eligible patients had a clinical diagnosis of COPD (confirmed with a post-bronchodilator forced expiratory volume in 1 second [FEV1]/forced vital capacity [FVC] ratio ≤ 70%), chronic cough and sputum production, and a post-bronchodilator FEV1 of ≤ 50% of the predicted value. All patients had at least one recorded COPD exacerbation requiring systemic glucocorticosteroids and/or treatment in a hospital in the previous year. Patients could continue using short-acting beta2-agonists (SABAs) as needed and LABAs or short-acting anticholinergics at stable doses. In two add-on studies, eligible patients had a post-bronchodilator FEV1 of 40% to 70% of predicted, postbronchodilator FEV1/FVC ratio ≤ 70%, and fixed airway obstruction (defined as an increase in baseline FEV1 of ≤ 12% or ≤ 200 mL post-bronchodilator).

POLICY STATEMENT
Prior authorization is recommended for prescription benefit coverage of Daliresp. All approvals are provided for 1 year in duration unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA
Coverage of Daliresp is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. Chronic Obstructive Pulmonary Disease (COPD). Approve if the patient meets the following criteria (a, b, c, d, e, and f):
   a) Patient has severe COPD or very severe COPD according to the prescribing physician; AND
   b) Patient has chronic bronchitis; AND
   c) Patient has a history of exacerbations; AND
   d) Patient has tried a long-acting beta2-agonist (LABA) [e.g., salmeterol, formoterol]; AND
   e) Patient has tried a long-acting anticholinergic (e.g., tiotropium); AND
   f) Patient has tried an inhaled corticosteroid (ICS) [e.g., fluticasone].
Conditions Not Recommended for Approval
Daliresp has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

1. **Asthma.** The efficacy of roflumilast (formulation not specified) in patients with asthma, allergic asthma, and exercise-induced asthma has been evaluated. More data are needed to define the place in therapy of Daliresp in the treatment of asthma.

2. **Allergic Rhinitis.** A small study (n = 25) concluded that roflumilast (formulation not specified) effectively controls symptoms of allergic rhinitis. More data are needed to define the place in therapy of Daliresp in the treatment of allergic rhinitis.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

**Approval Duration:** 365 days (1 year)

**References**