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
This policy involves the use of Daliresp. Prior authorization is recommended for pharmacy benefit coverage of Daliresp. Approval is recommended for those who meet the conditions of coverage in the Criteria and Initial/Extended Approval for the diagnosis provided. Conditions Not Recommended for Approval are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Daliresp as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Daliresp be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

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

1. **Chronic Obstructive Pulmonary Disease (COPD)**
Criteria. Patient must meet the following criteria

A. The patient has severe COPD or very severe COPD (FEV\textsubscript{1} < 50\% predicted); AND
B. The patient has chronic bronchitis; AND
C. The patient has a history of exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission; AND
D. The patient has failed on, experienced intolerance, or has a contraindication to ALL of the following medications in combination (Note: use of a combination inhaler containing multiple of the below medication classes would fulfill the requirement for the respective classes):
   a. An inhaled long-acting beta\textsubscript{2}-agonist (LABA) [e.g. salmeterol, formoterol, indacaterol, olodaterol]; AND
   b. An inhaled long-acting muscarinic antagonist (LAMA) [e.g. tiotropium, umeclidinium, alclidinium, glycopyrrolate]; AND
   c. An inhaled corticosteroid (ICS) [e.g. fluticasone]

Initial Approval/ Extended Approval.
A) Initial Approval: 1 year
B) Extended Approval: 1 year

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

Documentation Requirements:
The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.
REFERENCES