PRIOR AUTHORIZATION POLICY

POLICY: Pulmonary – Daliresp Prior Authorization Policy
- Daliresp® (roflumilast tablets – Astra Zeneca)

REVIEW DATE: 11/11/2020

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.[1] Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

Clinical Efficacy

Daliresp has been studied in patients currently receiving treatment with bronchodilators (e.g., long-acting $beta_2$-agonists [LABAs]) and inhaled corticosteroids (ICSs) with or without additional therapy with a long-acting muscarinic antagonist (LAMA).[2-7] Five placebo-controlled clinical trials evaluated the effect of Daliresp on COPD exacerbations.[1-7] Two of these studies initially included patients with severe COPD with chronic bronchitis and/or emphysema; in both studies, Daliresp did not demonstrate a significant reduction in COPD exacerbation rates. An exploratory analysis of these trials found that in the subgroup of patients with severe COPD who had chronic bronchitis and exacerbations within the previous year, Daliresp resulted in better exacerbation reduction than in the overall population. Two subsequent trials were conducted involving patients with severe COPD, chronic bronchitis, and at least one COPD exacerbation within the previous year. In both trials, Daliresp demonstrated a significant reduction in the rate of moderate or severe exacerbations compared to placebo.

Guidelines

The 2020 Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for the diagnosis, management, and prevention of COPD recommend bronchodilators and inhaled corticosteroids as initial pharmacological treatment.[8] Following initiation, therapies should be adjusted as needed based on symptom severity and exacerbation risk. Daliresp is recommended in patients who continue to experience exacerbations despite LAMA/ LABA combination therapy and have a blood eosinophil level < 100 cells/microliter. Low blood eosinophils are predictive of an insufficient response to ICS therapy, thereby making Daliresp a good option. Daliresp is also listed as a possible therapeutic option in patients receiving triple therapy with an ICS/LAMA/LABA who have an forced expiratory volume in 1 second (FEV_1) < 50% and chronic bronchitis, and continue to experience exacerbations (especially if the patient has been hospitalized for one or more COPD exacerbations in the past year).

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Daliresp. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Chronic Obstructive Pulmonary Disease (COPD).** Approve Daliresp for 3 years if the patient meets the following criteria (A, B, C, and D):
   - **A)** Patient has severe COPD or very severe COPD, according to the prescriber; AND
   - **B)** Patient has a history of exacerbations; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient has chronic bronchitis AND has tried an inhaled long-acting beta$_2$-agonist, an inhaled long-acting muscarinic antagonist, and an inhaled corticosteroid concomitantly; OR
     - **ii.** Patient has tried an inhaled long-acting muscarinic antagonist and long-acting beta$_2$-agonist concomitantly AND has a blood eosinophil level < 100 cells/microliter.

   Note: Use of a combination inhaler containing multiple agents from the medication classes listed would fulfil the requirement. Examples of an inhaled long-acting beta$_2$-agonists include Arcapta Neohaler, Serevent Diskus, Striverdi Respimat, Brovana, and Perforomist. Examples of a long-acting muscarinic antagonists include Incruse Ellipta, Seebri Neohaler, Spiriva HandiHaler, Spiriva Respimat, Tudorza Pressair, Lonhala Magnair, and Yupelri. Examples of inhaled corticosteroids include Alvesco, ArmonAir Digihaler, Arnuity Ellipta, Asmanex Twisthaler/HFA, Flovent Diskus/HFA, Pulmicort Flexhaler, Qvar RediHaler, and budesonide suspension for inhalation (Pulmicort Respules, generics). Examples of inhaled corticosteroid/long-acting beta$_2$-agonist combination inhalers include Advair Diskus (generic Wixela Inhub; authorized generics), Breo Ellipta, and Symbicort. Examples of long-acting muscarinic antagonist/long-acting beta$_2$-agonist combination inhalers include Anoro Ellipta, Bevespi Aerosphere, Duaklir Pressair, Stiolto Respimat, and Utibron Neohaler. Examples of corticosteroid/long-acting beta$_2$-agonist/long-acting muscarinic antagonist combination inhalers are Breztri Aerosphere and Trelegy Ellipta.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Daliresp is not recommended for the following situations:

1. **Asthma.** The efficacy of roflumilast (formulation not specified) in patients with asthma[9-11], allergic asthma[12,13], and exercise-induced asthma[14] has been evaluated. More data are needed to define the place in therapy of Daliresp in the treatment of asthma. Current asthma guidelines from the Global Initiative for Asthma Prevention (GINA) [2020] and the European Respiratory Society (ERS)/American Thoracic Society (ATS) [2014] Global Strategy for Asthma Management and Prevention do not address Daliresp as a recommended therapy for asthma management.[15,16]

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

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