roflumilast (Daliresp®)

EOCCO POLICY

Policy Type: PA Pharmacy Coverage Policy: EOCCO105

Description

Roflumilast (Daliresp) is an oral phosphodiesterase 4 (PDE4) inhibitor to selectively inhibit a major cyclic-AMP (cAMP) metabolizing enzyme in the lung tissue.

Length of Authorization

- Initial: 12 months
- Renewal: 12 months

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
Roflumilast (Daliresp)	250 mcg tablet	Severe chronic obstructive pulmonary disease (COPD) with chronic bronchitis and a history of exacerbation	30 tablets/30 days
	500 mcg tablet		30 tablets/30 days

Initial Evaluation

I. Roflumilast (Daliresp) may be considered medically necessary when the following criteria below are met:
   A. Member is diagnosed with severe COPD (GOLD 3 or 4; FEV_1 < 50% predicted) associated with chronic bronchitis; **AND**
   B. Member has a history of COPD exacerbations (at least one per year) that resulted in hospitalization; **AND**
   C. Member has tried and failed, or has a contraindication to triple therapy with: long-acting beta agonist (LABA), long-acting muscarinic antagonist (LAMA), and inhaled corticosteroid (ICS); **AND**
   D. Member will be using this medication in combination with an inhaled corticosteroid (ICS)

Renewal Evaluation

I. Member has received a previous prior authorization approval for this agent through the health plan; **AND**
II. The member is <u>not</u> continuing therapy based off established therapy through samples, manufacturer coupons, or otherwise. Initial policy criteria must be met for the member to qualify for continuation through this health plan; **AND**
III. Member has exhibited improvement or stability of disease symptoms; **AND**
IV. If the request is for a dose increase, the new dose does not exceed 500 mcg per day

Supporting Evidence

I. Roflumilast (Daliresp) is FDA approved for treatment in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

II. Utilization of roflumilast (Daliresp) is reserved for members that have tried and failed a triple therapy including the following active ingredients:
- An Inhaled long-acting beta$_2$-agonist (LABA) [e.g. salmeterol, formoterol, indacaterol, olodaterol]
- An inhaled long-acting muscarinic antagonist (LAMA) [e.g. tiotropium, umeclidinium, aclidinium, glycopyrrolate]
- An inhaled corticosteroid (ICS) [e.g. fluticasone]

III. Per GOLD 2020 Guidelines, if patients treated with LABA/LAMA/ICS still have exacerbations, stopping inhaled corticosteroid (ICS) may be considered if there are adverse effects (such as pneumonia) or a reported lack of efficacy.

References

1. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2020 Report. Global strategy for prevention, diagnosis and management of chronic obstructive disease. National Institutes of Health, National Heart, Lung, and Blood Institute; Available at http://www.goldcopd.com/. Accessed November 8, 2019.
2. Daliresp [Package Insert]. Wilmington, DE. AstraZeneca Pharmaceuticals LP. Revised January, 2018.

Policy Implementation/Update:

Date Created	April 2018
Date Effective	April 2018
Last Updated	November 2019
Last Reviewed	11/2019

Action and Summary of Changes	Date
Transition from criteria to policy: In this transition process, the following updates were made: further clarification around severe COPD definition, dose limit that it does not exceed 500 mcg per day if request is for a dose increase, supporting evidence updated, and GOLD 2020 Report was updated.	11/2019
Criteria created	4/2019