Clinical Policy: Roflumilast (Daliresp)
Reference Number: PA.CP.PMN.46
Effective Date: 01/18
Last Review Date: 08/17 Revision Log
Line of Business: Medicaid

Description
Roflumilast (Daliresp®) is a selective phosphodiesterase 4 inhibitor.

FDA approved indication
Daliresp 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.

Limitation of use: Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness® that Daliresp is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Diagnosis of chronic obstructive pulmonary disease (COPD);
2. Member is non-smoker or has been referred for smoking cessation treatment;
3. Current forced expiratory volume in one second (FEV_1) < 50% predicted (
4. Failure of ≥ 3 months of adherent use of triple inhaled therapy consisting of a combination of long-acting $beta_2$-agonist (LABA), long-acting antimuscarinic antagonist (LAMA), and inhaled corticosteroid (ICS)
5. Daliresp will be used concurrently with a long-acting bronchodilator (i.e., LABA or LAMA);
6. Dose does not exceed 500 mcg per day (1 tablet per day).

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chronic Obstructive Pulmonary Disease (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy (e.g., improvement in lung function, symptoms/dyspnea; reduction in COPD exacerbations, etc.)

3. Daliresp is used concurrently with a long-acting bronchodilator as evidenced by pharmacy claims history;
4. If request is for a dose increase, new dose does not exceed 500 mcg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: Duration of request or 12 months (whichever is less)

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration
FEV_1: forced expiratory volume in one second
ICS: inhaled corticosteroid
LABA: long-acting $beta_2$-agonist
LAMA: long-acting antimuscarinic antagonist

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COPD	500 mcg PO once daily (1 tablet per day)	500 mcg per day

VI. Product Availability

Tablets: 500 mcg

VII. Workflow Document

N/A

VIII. References

1. Daliresp Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals; November 2015. Available at: https://www.daliresp.com/. Accessed March 10, 2017.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017: Global Strategy for the Diagnosis, Management, and Prevention of COPD. Available from: http://goldcopd.org. Accessed March 10, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date