Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Daliresp (roflumilast)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***April 2011 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2017*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Daliresp (roflumilast).

Daliresp (roflumilast) is a selective phosphodiesterase-4 inhibitor indicated as a treatment to reduce the risk of COPD exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

DEFINITIONS

COPD: Chronic Obstructive Pulmonary Disease

GOLD: Global Initiative for Chronic Obstructive Lung Disease

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002

Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Daliresp (roflumilast), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must have a diagnosis of severe COPD (GOLD stage III or IV) associated with chronic bronchitis
- Must have a history of COPD exacerbation within the past year
- Must have an adequate trial and failure to an inhaled long acting beta-agonist or an inhaled long acting anticholinergic or a contraindication to these agents
- Must have an adequate trial and failure to an inhaled glucocorticosteroid or a contraindication to these agents
- Must not have moderate to severe liver impairment
- Must have an evaluation by a behavioral health provided prior to the use of roflumilast (Daliresp) if the member has a diagnosis of depression and/or suicidal thoughts or behaviors AND if the member currently is undergoing treatment for depression and/or suicidal thoughts or behavior. These patients must also be followed concurrently with a behavioral health provider while on roflumilast. Documentation must be provided

Reauthorization Criteria:

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. Authorization may be extended at 1-year intervals based upon the following:

- Chart documentation from the prescriber that the member's disease has improved based upon the prescriber's assessment while on therapy.
- For members with a diagnosis of depression and/or suicidal thought or behaviors AND members with a current treatment for depression and/or suicidal thoughts or behaviors, chart documentation must be provided to show current evaluation by a behavioral health provider.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to 1 year
Reauthorization	Same as initial

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Daliresp [package insert]. St Louis, MO: Forest Pharmaceuticals, Inc.; February 2011.
2. Rabe, KF, O'Donnell D, Witte S, et al. Roflumilast-an oral anti-inflammatory treatment for chronic obstructive pulmonary disease: a randomized controlled trial. *Lancet*. 2005;366:563-571.
3. Calverley PM, Rabe KF, Goehring UM, et al. Roflumilast in symptomatic chronic obstructive pulmonary disease: two randomized clinical trials. *Lancet*. 2009;374:685-694.
4. Calverley PM, Sanchez-Toril F, McIvor A, et al. Effect of 1-Year Treatment with Roflumilast in Severe Chronic Obstructive Pulmonary Disease. *Am J Resp Crit Care Med*. 2007;176:154-161.
5. Fabbri LM, Calverley PM, Izquierdo-Alonso JL, et al. Roflumilast in moderate-to-severe chronic obstructive pulmonary disease treated with long acting bronchodilators: two randomized clinical trials. *Lancet*. 2009; 374:695-703.
6. Rutten-van Molken MP, van Nooten FE, Lindemann M, et al. A 1-year prospective cost-effectiveness analysis of roflumilast for the treatment of patients with severe chronic obstructive pulmonary disease. *Pharmacoeconomics*, 2007;25(8):695-711.
7. Cazzola M, Picciolo S, Matera MG. Roflumilast in chronic obstructive pulmonary disease: evidence from large trials. *Expert Opin. Pharmacother*. 2010;11(3):441-449.
8. Rodriguez-Roisin R, Anzueto A, Bourbeau J. et al. Global Initiative for Chronic Obstructive Lung Disease: Pocket Guide to COPD Diagnosis, Management, and Prevention. Updated 2010. www.goldcopd.org Accessed 3/16/2011.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17*