## Prior Authorization Review Panel

**CHC-MCO Policy Submission**

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

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| **Plan: PA Health & Wellness** | **Submission Date: N/A** |
| **Policy Number: PHW.PDL.098** | **Effective Date: 01/01/2020**<br>**Revision Date: 07/2020** |
| **Policy Name: Chronic Obstructive Pulmonary Disease (COPD) Agents** | |

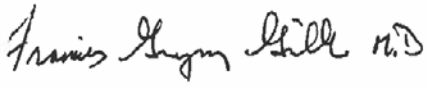
**Type of Submission – Check all that apply:**

- ☐ **New Policy**
- ☐ **Revised Policy***
- ✓ **Annual Review - No Revisions**
- ✓ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

**Please provide any changes or clarifying information for the policy below:**

Q3 2020 annual review: no changes.

| | |
|---|---|
| **Name of Authorized Individual (Please type or print):**<br><br>**Francis G. Grillo, MD** | **Signature of Authorized Individual:**<br>  |

# Clinical Policy: Chronic Obstructive Pulmonary Disease (COPD) Agents

Reference Number: PHW.PDL.098
Effective Date: 01/01/2020
Last Review Date: 07/2020

Revision Log

**Policy/Criteria**
*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of health plans affiliated with PA Health and Wellness® that Chronic Obstructive Pulmonary Disease (COPD) Agents are **medically necessary** when the following criteria are met:

## I. Requirements for Prior Authorization of Chronic Obstructive Pulmonary Disease (COPD) Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for COPD Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred COPD Agent.

2. A COPD Agent when there is a record of a recent paid claim for another drug in the same therapeutic class of drugs (therapeutic duplication).

3. A prescription for tiotropium for a diagnosis of asthma.

4. A COPD Agent with a prescribed quantity that exceeds the quantity limit.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a COPD Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Daliresp (roflumilast), **all** of the following:

   a. Has a diagnosis of severe COPD as documented by medical history, physical exam findings, and lung function testing (forced expiratory volume (FEV1) <50% of predicted) that are consistent with severe COPD according to the current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines on the diagnosis and management of COPD,

b. Has a diagnosis of chronic bronchitis as documented by cough and sputum production for at least 3 months in each of 2 consecutive years,

c. Had other causes of their chronic airflow limitations excluded,

d. Continues to experience more than 2 exacerbations of COPD per year requiring emergency department visits, hospitalization, or oral steroid use despite maximum therapeutic doses of, intolerance, or contraindication to regular scheduled use of **all** of the following:

   i. Long-acting inhaled beta 2 agonist,
   ii. Preferred long-acting inhaled anticholinergic,
   iii. Inhaled corticosteroid,

e. Does not have moderate to severe liver impairment (Child-Pugh B or more severe),

f. Will not be taking strong cytochrome P450 enzyme inducers such as but not limited to rifampin, phenobarbital, carbamazepine, and phenytoin,

g. Does not have suicidal ideations,

h. **One** of the following:

   i. Was evaluated, treated, and determined to be a candidate for treatment with Daliresp by a psychiatrist if the beneficiary has a history of prior suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance use disorders, anxiety disorders, borderline personality disorder and antisocial personality disorder
   ii. For all others, had a mental health evaluation performed by the prescriber and determined to be a candidate for treatment with Daliresp;

**AND**

2. For all other non-preferred COPD Agents, whether the beneficiary has a documented history of therapeutic failure, intolerance, or contraindication of the preferred COPD Agents; **AND**

3. For therapeutic duplication, **one** of the following:

   a. Is being titrated to, or tapered from, a drug in the same class
   b. Supporting peer-reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested;

**AND**

4. For tiotropium when prescribed for a diagnosis of asthma, **both** of the following:

    a. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature

    b. **One** of the following:

        i. Is currently receiving optimally tolerated doses of **both** of the following:

            a) Inhaled glucocorticoids
            b) Long acting beta agonists

        ii. Has a contraindication or intolerance to optimally titrated doses of **both** of the following:

            a) Inhaled glucocorticoids
            b) Long acting beta agonists;

    **AND**

5. If a prescription for a COPD Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

    NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**FOR RENEWALS OF PRESCRIPTIONS FOR DALIRESP (ROFLUMILAST)**:
The determination of medical necessity of a request for renewal of a prior authorization for a prescription for Daliresp (roflumilast) that was previously approved will take into account whether the beneficiary:

1. Has documented improvement in the $FEV_1$ and $FEV_1$/forced vital capacity (FVC) ratio and a decrease in the frequency of COPD exacerbations; **AND**

2. Will not be taking strong cytochrome P450 enzyme inducers such as but not limited to rifampin, phenobarbital, carbamazepine, and phenytoin; **AND**

3. Does not have suicidal ideations; **AND**

4. Was reevaluated and treated for new onset or worsening symptoms of anxiety and depression and determined to continue to be a candidate for treatment with Daliresp; **AND**

5. If a prescription for Daliresp (roflumilast) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in PA.CP.PMN.59 Quantity Limit Override.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a COPD Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

**D. Dose and Duration of Therapy: 12 months**

E. References

1. Daliresp package insert. Forest Pharmaceuticals, Inc. St. Louis, MO, 2010.
2. 2010 Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the diagnosis, management and prevention of Chronic Obstructive Pulmonary Disease.
3. American Psychiatric Association Practice Guideline for the Assessment and Treatment of Patients with Suicidal Behaviors, November 2003.
4. Busse WW et.al. National Heart Lung and Blood Institute Guidelines for the Diagnosis and Management of Asthma (EPR-3).
5. Peters, S. et.al. Treatment of moderate persistent asthma in adolescents and adults. Up To Date. Accessed October 9, 2015.
6. Wenzel, S. Treatment of severe asthma in adolescents and adults. Accessed October 9, 2015.
7. Martin, R.J. Alternative and experimental agents for the treatment of asthma. Up To Date. Accessed October 9, 2015.
8. Spiriva package insert. Boehringer Ingelheim Pharmaceuticals, Inc. Ridgefield, CT, February 2017.

| Reviews, Revisions, and Approvals | Date |
|---|---|
| Policy created | 01/01/2020 |
| Q3 2020 annual review: no changes. | 07/2020 |