Clinical Policy: Chronic Obstructive Pulmonary Disease (COPD) Agents

Reference Number: PHW.PDL.098
Effective Date: 01/01/2020
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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 PA Health & 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. See the Preferred Drug List (PDL) for the list of preferred COPD Agents at: https://papdl.com/preferred-drug-list.

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

3. An agent that contains an inhaled glucocorticoid when there is a record of a recent paid claim for another product that contains an inhaled glucocorticoid (therapeutic duplication).

4. An agent that contains an inhaled long-acting anticholinergic when there is a record of a recent paid claim for another product that contains an inhaled long-acting anticholinergic (therapeutic duplication).

5. An agent that contains an inhaled long-acting beta agonist when there is a record of a recent paid claim for another product that contains an inhaled long-acting beta agonist (therapeutic duplication).

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 member:

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 **one** of the following:

   i. For a member with an eosinophil count greater than or equal to 100 cells/microliter, maximum therapeutic doses of or intolerance or contraindication to regular scheduled use of **all** of the following:

      1. Long-acting inhaled beta 2 agonist,
      2. Long-acting inhaled anticholinergic,
      3. Inhaled corticosteroid,

   ii. For a member with an eosinophil count less than 100 cells/microliter, maximum therapeutic doses of or intolerance or contraindication to regular scheduled use of **both** of the following:

      1. Long-acting inhaled beta agonist,
      2. Long-acting inhaled anticholinergic,

e. Does not have a contraindication to the prescribed medication,

f. Does not have suicidal ideations,

g. **One** of the following:

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

AND

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

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

   a. For an inhaled glucocorticoid, is being titrated to or tapered from another inhaled glucocorticoid,
   b. For an inhaled long-acting anticholinergic, is being titrated to or tapered from another inhaled long-acting anticholinergic,
   c. For an inhaled long-acting beta agonist, is being titrated to or tapered from another inhaled long-acting beta agonist,
   d. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   AND

4. 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 member 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 member, 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 member:

1. Has documented decrease in the frequency of COPD exacerbations ; **AND**

2. Does not have a history of a contraindication to the prescribed medication; **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 (roflumilast); **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 member 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 member, 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 member.

D. Dose and Duration of Therapy: 12 months

E. References

1. Daliresp [package insert]. St. Louis, MO: Forest Pharmaceuticals, Inc; March 2020.
2. 2021 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. Peters, S. et.al. Treatment of moderate persistent asthma in adolescents and adults. UpToDate. Accessed June 2, 2021.
5. Wenzel, S. Treatment of severe asthma in adolescents and adults. Accessed June 2, 2021.
6. Spiriva Handihaler [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; February 2018.
7. Spiriva Respimat [package insert]. Ridgefield, CT: Boehringer Ingelheim Pharmaceuticals, Inc.; August 2020.
8. 2019 Global Initiative for Asthma. Global Strategy for Asthma management and prevention.

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021: policy revised according to DHS revisions effective 01/05/2021	11/2020
Q1 2022: policy revised according to DHS revisions effective 01/03/2022	10/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025 annual review: no changes.	11/2024