pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
November 8, 2021	January 3, 2022	*See below

SUBJECT

Prior Authorization of Chronic Obstructive Pulmonary Disease (COPD) Agents – Pharmacy Services

BY

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IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: https://www.dhs.pa.gov/providers/Providers/Pages/PROMISe-Enrollment.aspx.

PURPOSE:

The purpose of this bulletin is to issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Chronic Obstructive Pulmonary Disease (COPD) Agents submitted for prior authorization.

SCOPE:

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program. The guidelines to determine the medical necessity of COPD Agents will be utilized in the fee-for-service delivery system and by the MA managed care organizations (MCOs) in Physical Health HealthChoices and Community HealthChoices. Providers rendering services in the MA managed care delivery system should address any questions related to the prior authorization of COPD Agents to the appropriate MCO.

BACKGROUND:

*01-21-27	09-21-26	27-21-18	33-21-26
02-21-14	11-21-16	30-21-21	
03-21-14	14-21-17	31-21-29	
08-21-29	24-21-24	32-21-14	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll-free number for your provider type.

Visit the Office of Medical Assistance Programs website at https://www.dhs.pa.gov/providers/Providers/Pages/Health%20Care%20for%20Providers/Contact-Information-for-Providers.aspx.

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T) Committee reviews published peer-reviewed medical literature and recommends the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the September 14, 2021, meeting, the P&T Committee recommended the following revisions to the guidelines to determine medical necessity of COPD Agents:

- Clarification of the prescriptions that require prior authorization for therapeutic duplication;
- Removal of the guideline for assessing drug interactions for requests for Daliresp (roflumilast); and
- Update to the guidelines to determine medical necessity for Daliresp (roflumilast) to reflect updated consensus treatment guidelines; and
- Removal of the guideline from the requests for renewal of the prior authorization section that the beneficiary have improvement in the FEV1 and FEV1/forced vital capacity (FVC) ratio.

The revisions to the guidelines to determine medical necessity of prescriptions for COPD Agents submitted for prior authorization, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

PROCEDURE:

The procedures for prescribers to request prior authorization of COPD Agents are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to COPD Agents) when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I
Pharmacy Prior Authorization General Requirements
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Pharmacy-Prior-Authorization-General-Requirements.aspx

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Clinical-Guidelines.aspx

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. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. An agent that contains an inhaled glucocorticoid when there is a record of a recent paid claim for another agent that contains an inhaled glucocorticoid in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. An agent that contains an inhaled long-acting anticholinergic when there is a record of a recent paid claim for another agent that contains an inhaled long-acting anticholinergic in the Point-of-Sale Online Claims Adjudication System (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 agent that contains an inhaled long-acting beta agonist in the Point-of-Sale On-Line Claims Adjudication System (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 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 **one** of the following:

   i. For a beneficiary 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 agonist,
      2. Long-acting inhaled anticholinergic,
      3. Inhaled corticosteroid

   ii. For a beneficiary 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 beneficiary with a history of suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance use disorder, anxiety disorder, borderline personality disorder, or 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 medical 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 the Quantity Limits Chapter.

   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 a documented decrease in the frequency of COPD exacerbations; **AND**

2. Does not have 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 the Quantity Limits Chapter.

   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. 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.