Pennsylvania
Department of Human Services

Medical Assistance BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
June 30, 2026	July 6, 2026	*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.pa.gov/agencies/dhs/resources/for-providers/provider-enrollment-information/provider-enrollment-documents

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 and managed care delivery systems. Providers rendering services to MA beneficiaries in the managed care delivery system should address any questions related to the prior authorization of COPD Agents to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Drug Utilization Review (DUR)

*01-26-61	09-26-61	27-26-47	33-26-50
02-26-47	11-26-46	30-26-46	
03-26-47	14-26-50	31-26-62	
08-26-61	24-26-60	32-26-46	

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

Fee-for-Service Provider Service Center: 1-800-537-8862

Visit the Office of Medical Assistance Programs website at:
https://www.pa.gov/agencies/dhs/departments-offices/omap-info

Board meets to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through the Department's Prospective DUR and Retrospective DUR programs.

DISCUSSION:

During the May 12, 2026, meeting, the DUR Board recommended revisions to the medical necessity guidelines for COPD Agents to add guidelines for all phosphodiesterase 3 and phosphodiesterase 4 inhibitors and to align the guidelines with current Global Initiative for Chronic Obstructive Lung Disease guidelines for the diagnosis and management of COPD.

The revisions to the guidelines to determine medical necessity of prescriptions for COPD Agents submitted for prior authorization, as recommended by the DUR Board, 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 and products 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.pa.gov/agencies/dhs/resources/pharmacy-services/pharmacy-prior-authorization-general-requirements

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
https://www.pa.gov/agencies/dhs/resources/pharmacy-services/clinical-guidelines

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.pa.gov/agencies/dhs/resources/pharmacy-services/quantity-limits-daily-dose-limits.

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 Dupixent (dupilumab), see the prior authorization guideline related to Dupixent (dupilumab); **OR**

2. For a phosphodiesterase 3 (PDE3) or phosphodiesterase 4 (PDE4) inhibitor, **all** of the following:

   a. **One** of the following:

      i. For Daliresp (roflumilast), **both** of the following:

a) Has a diagnosis of severe COPD as documented by medical history, physical exam findings, and lung function testing that are consistent with severe COPD according to the current Global Initiative for Chronic Obstructive Lung Disease (GOLD) COPD guidelines
b) Has a diagnosis of chronic bronchitis as documented by cough and sputum production for at least three months in each of two consecutive years

ii. For Ohtuvayre (ensifentrine), **both** of the following:

a) Has a diagnosis of moderate to severe COPD as documented by medical history, physical exam findings, and lung function testing that are consistent with moderate to severe COPD according to the current GOLD COPD guidelines
b) Has a score of greater than or equal to 2 on the Modified Medical Research Council (mMRC) Dyspnea Scale,

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

c. Has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) according to current GOLD COPD guidelines,

d. Does not have a contraindication to the prescribed drug,

e. Does not have suicidal ideations,

f. **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 the requested drug by a psychiatrist
ii. For all other beneficiaries, had a mental health evaluation performed by the prescriber and determined to be a candidate for treatment with the requested drug;

AND

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

4. 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 drugs that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

5. If a prescription for a COPD Agent is for 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 A PDE3 OR PDE4 INHIBITOR: The determination of medical necessity of a request for renewal of a prior authorization for a prescription for a PDE3 or PDE4 inhibitor that was previously approved will take into account whether the beneficiary:

1. **One** of the following:

   a. For Daliresp (roflumilast), has a documented decrease in the frequency of COPD exacerbations
   b. For Ohtuvayre (ensifentrine), has documentation of a positive clinical response to the prescribed drug (i.e., increased pulmonary function, decrease in the severity of dyspnea, decrease in the use of rescue medications, or decreased symptom severity);

   AND

2. Does not have a contraindication to the prescribed drug; **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 the requested drug; **AND**

5. If a prescription for a PDE3 or PDE4 inhibitor is for 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. Ohtuvayre [package insert]. Raleigh, NC: Verona Pharma, Inc; July 2025.
3. 2026 Global Initiative for Chronic Obstructive Lung Disease. Global Strategy for the diagnosis, management and prevention of Chronic Obstructive Pulmonary Disease.