Highmark Wholecare
Pharmacy Division
Phone 800-392-1147 Fax 888-245-2049

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. 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).

3. 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).

4. 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 Dupixent (dupilumab) policy; **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;

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.

   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

1. 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.

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COPD AGENTS PRIOR AUTHORIZATION FORM *(form effective 7/6/2026)*

☐New request ☐Renewal request # of pages: _____		Prescriber name:	
Name of office contact:		Specialty:	
Contact's phone number:		NPI:	State license #:
LTC facility contact/phone:		Street address:	
Beneficiary name:		City/state/zip:	
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested:		Strength:
Directions for use:	Quantity:	Duration requested:
Diagnosis:		Dx code *(required)*:

Complete all sections that apply to the beneficiary and this request.
Check all that apply and submit documentation for each item.

INITIAL requests

1. For a PHOSPHODIESTERASE (PDE) INHIBITOR (e.g., Daliresp, Ohtuvayre):

☐**For DALIRESP (roflumilast):**
- ☐Has COPD that is severe according to current GOLD guidelines and based on medical history, physical exam findings, and lung function tests
- ☐Has chronic bronchitis with cough and sputum production for at least 3 months per year in 2 consecutive years
- ☐Does not have moderate or severe liver impairment (Child-Pugh B or C) [contraindication]

☐**For OHTUVAYRE (ensifentrine):**
- ☐Has COPD that is moderate to severe according to current GOLD guidelines and based on medical history, physical exam findings, and lung function tests
- ☐Has a score of ≥2 on the Modified Medical Research Council (mMRC) Dyspnea Scale

☐**For ALL PDE inhibitors:**
- ☐Other causes of chronic airflow limitations have been excluded, such as asthma, bronchiectasis, heart failure, tuberculosis, etc.
- ☐Tried and failed or has a contraindication or an intolerance to first-line therapies according to current GOLD guidelines:
  - ☐Inhaled long-acting beta 2 agonist (LABA)
  - ☐Inhaled long-acting anticholinergic/muscarinic antagonist (LAMA)
  - ☐Inhaled corticosteroid (unless beneficiary has an eosinophil count <100 cells/microliter – *submit documentation of lab results*)
  - ☐other:

    _____
- ☐Does not have suicidal ideations
- ☐**For a beneficiary with a history of suicide attempt(s), bipolar disorder, major depressive disorder, schizophrenia, substance use disorder(s), anxiety disorder(s), borderline personality disorder, and/or antisocial personality disorder:**
  - ☐Was evaluated and treated for this/these mental health condition(s) by a psychiatrist
  - ☐Is a candidate for treatment with the requested PDE inhibitor as determined by a psychiatrist
- ☐**For a beneficiary who does not have a history of the above mental health conditions:**
  - ☐Had a mental health evaluation performed by the prescriber
  - ☐Is a candidate for treatment with the requested PDE inhibitor

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2. For all OTHER COPD Agents:

☐ Tried and failed or has a contraindication or an intolerance to the preferred COPD Agents (*Refer to https://papdl.com/preferred-drug-list for a list of preferred and non-preferred drugs in this class.)*

RENEWAL requests

1. For a PHOSPHODIESTERASE (PDE) INHIBITOR (e.g., Daliresp, Ohtuvayre):

☐ **For DALIRESP (roflumilast):**
- ☐ Frequency of COPD exacerbations has decreased since starting Daliresp
- ☐ Does not have moderate or severe liver impairment (Child-Pugh B or C) [contraindication]

☐ **For OHTUVAYRE (ensifentrine):**
- ☐ Experienced a positive clinical response to Ohtuvayre as documented by:
  - ☐ Increased pulmonary function
  - ☐ Decreased dyspnea severity
  - ☐ Decreased use of rescue drugs
  - ☐ Decreased symptom severity

☐ **For ALL PDE inhibitors:**
- ☐ Does not have suicidal ideations
- ☐ Was evaluated for new onset or worsening symptoms of anxiety and depression
- ☐ Is a candidate for treatment with the requested PDE inhibitor

2. For all OTHER COPD Agents → complete beneficiary, prescriber, and drug fields at the top of this form and submit request with recent chart notes

PLEASE FAX COMPLETED FORM WITH REQUIRED CLINICAL DOCUMENTATION

Prescriber Signature:	**Date**:

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