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 (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 (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 (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:
            i. Long-acting inhaled beta agonist,
            ii. Long-acting inhaled anticholinergic,
            iii. 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:
    i. Long-acting inhaled beta agonist
    ii. 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 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 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)

   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.

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

DALIRESP (roflumilast) PRIOR AUTHORIZATION FORM

☐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:		Suite #:	City/state/zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

CLINICAL INFORMATION

Drug requested: Daliresp tablet		Strength:	Directions:
Quantity:	Refills:	Diagnosis:	Dx code *(required)*:

INITIAL Requests

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐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
☐Other causes of chronic airflow limitations have been excluded, such as asthma, bronchiectasis, heart failure, tuberculosis, etc.
☐Experienced more than 2 COPD exacerbations per year that required an ED visit, hospitalization, or use of oral steroids
☐Is using or cannot use maximum tolerated doses of the following (in either a single-ingredient or combination product – submit medication list):
- ☐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*)

☐Does not have moderate or severe liver impairment (Child-Pugh B or C)
☐Does not have suicidal ideations
☐Has 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 Daliresp as determined by a psychiatrist

☐Does not have a history of the above mental health conditions
- ☐Had a mental health evaluation performed by the prescriber

RENEWAL Requests

Check all of the following that apply to the beneficiary and this request and SUBMIT DOCUMENTATION for each item.

☐Frequency of COPD exacerbations has decreased since starting Daliresp
☐Does not have suicidal ideations
☐Was evaluated for new onset or worsening symptoms of anxiety and depression
- ☐If applicable, is being treated for these mental health conditions and determined to be a candidate for treatment with Daliresp

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date:

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

NON-PREFERRED MEDICATION PRIOR AUTHORIZATION FORM *(form effective 01/01/20)*

☐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:		Suite #:	City/State/Zip:
Beneficiary ID#:	DOB:	Phone:	Fax:

Please refer to https://papdl.com/preferred-drug-list for the list of preferred and non-preferred medications in each Preferred Drug List class.

Non-preferred medication name:		Dosage form:	Strength:
Directions:		Quantity:	Refills:
Diagnosis *(submit documentation)*:		Dx code (*required*):	

Has the beneficiary taken the requested non-preferred medication in the past 90 days? *(submit documentation)*..... ☐Yes ☐No

Describe all applicable medical reasons the beneficiary cannot use the preferred medication(s) in the same Preferred Drug List class. *Submit documentation (e.g., recent chart/clinic notes, diagnostic evaluations, lab results, etc.) supporting this non-preferred request.*

☐Treatment failure or inadequate response with preferred medication(s) *(include drug name, dose, and start/stop dates)*:

_____

_____

☐Unacceptable side effects, hypersensitivities, or other intolerances to preferred medication(s) *(include description and drug name(s))*:

_____

_____

☐Contraindication to preferred medication(s) *(include description and drug name(s))*:

_____

_____

☐Unique clinical or age-specific indications supported by FDA approval or medical literature *(describe)*:

_____

_____

☐Absence of preferred medication(s) with appropriate formulation *(list medical reason formulation is required)*:

_____

_____

☐Drug-drug interaction with preferred medication(s) *(describe)*:

_____

_____

☐Other medical reason(s) the beneficiary cannot use the preferred medication(s) *(describe)*:

_____

_____

☐For renewal requests of previously approved medications, submit documentation of tolerability and beneficiary's clinical response.

PLEASE FAX COMPLETED FORM TO HIGHMARK WHOLECARE – PHARMACY DIVISION

Prescriber Signature:	Date: