

## 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 when there is a record of a recent paid claim for another drug in the same therapeutic class of drugs in the Point-of-Sale Online 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 maximum therapeutic doses of or intolerance or contraindication to regular scheduled use of **all** of the following:
    - i. Long-acting inhaled beta 2 agonist,
    - ii. Long-acting inhaled anticholinergic,
    - iii. Inhaled corticosteroid,
  - e. Does not have a history of a contraindication to the prescribed medication,
  - f. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact),
  - g. Does not have suicidal ideations,

h. **One** of the following:

- i. Was evaluated, treated, and determined to be a candidate for treatment with Daliresp (roflumilast) by a psychiatrist if the beneficiary has a history of prior suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance use disorders, anxiety disorders, borderline personality disorder, and antisocial personality disorder
- 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. Is being transitioned to another drug in the same class with the intent of discontinuing one of the medications
  - b. 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 documented improvement in the FEV<sub>1</sub> and FEV<sub>1</sub>/forced vital capacity (FVC) ratio and a decrease in the frequency of COPD exacerbations; **AND**
2. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); **AND**
3. Does not have a history of a contraindication to the prescribed medication; **AND**
4. Does not have suicidal ideations; **AND**
5. 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.

### DALIRESP (roflumilast) PRIOR AUTHORIZATION FORM

|  |      |                  |                  |
|--|------|------------------|------------------|
| <input type="checkbox"/> New request <input type="checkbox"/> 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

|  |          |            |  |
|--|----------|------------|--|
| <b>Medication requested:</b> Daliresp tablet   |          | Strength:  | Directions:  |
| Quantity:  | Refills: | Diagnosis: | Dx code (required):  |
| Is the beneficiary taking a strong CYP3A4 inducer?<br><input type="checkbox"/> carbamazepine <input type="checkbox"/> efavirenz <input type="checkbox"/> oxcarbazepine <input type="checkbox"/> phenytoin<br><input type="checkbox"/> dexamethasone <input type="checkbox"/> nevirapine <input type="checkbox"/> phenobarbital <input type="checkbox"/> rifampin |          |            | <input type="checkbox"/> Yes <i>Submit documentation of beneficiary's complete current medication list.</i><br><input type="checkbox"/> No |

#### 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
- 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.**

- FEV1 and FEV1/FVC ratio have improved since starting Daliresp
- 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 GATEWAY – PHARMACY DIVISION**

|                              |              |
|------------------------------|--------------|
| <b>Prescriber Signature:</b> | <b>Date:</b> |
|------------------------------|--------------|

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

|   |      |                   |                  |  |
|---|------|-------------------|------------------|--|
| <input type="checkbox"/> New request <input type="checkbox"/> 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 <i>(submit documentation)</i> :  |  | Dx code <i>(required)</i> : |           |
| Has the beneficiary taken the requested non-preferred medication in the past 90 days? <i>(submit documentation)</i> ..... <input type="checkbox"/> Yes <input type="checkbox"/> 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 GATEWAY – PHARMACY DIVISION**

|                       |       |
|-----------------------|-------|
| Prescriber Signature: | Date: |
|-----------------------|-------|

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