

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

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 prescription for a non-preferred COPD Agent. See the most recent version of the PDL which includes the list of preferred COPD Agents at:
www.providersynergies.com/services/documents/PAM_PDL.pdf
2. A prescription for either a preferred or non-preferred COPD Agent when there is a record of a recent paid claim for another drug in the same therapeutic class of drugs in PROMISe, the Department's 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 non-preferred COPD Agent, the determination of whether the requested prescription is medically necessary will take into account the following:

1. For Daliresp (roflumilast), whether the recipient:
 - 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 most current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines on the diagnosis and management of COPD

AND

- 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

AND

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- c. Had other causes of their chronic airflow limitations excluded

AND

- 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, intolerance, or contraindication to regular scheduled use of a:

- i. Long-acting inhaled beta 2 agonist

AND

- ii. Preferred long-acting inhaled anticholinergic

AND

- iii. Inhaled corticosteroid

AND

- e. Does not have moderate to severe liver impairment (Child-Pugh B or more severe)

AND

- f. Will not be taking strong cytochrome P450 enzyme inducers such as but not limited to rifampin, phenobarbital, carbamazepine, and phenytoin

AND

- g. Does not have suicidal ideations

AND

- h. Was evaluated, treated, and determined to be a candidate for treatment with Daliresp by a psychiatrist if the recipient has a history of prior suicide attempt, bipolar disorder, major

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depressive disorder, schizophrenia, substance use disorders, anxiety disorders, borderline personality disorder and antisocial personality disorder

OR

- i. For all others, had a mental health evaluation performed by the prescriber and determined to be a candidate for treatment with Daliresp

In evaluating a request for a renewal of prior authorization of a prescription for Daliresp, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

- a. Has documented improvement in the forced expiratory volume (FEV₁) and FEV₁/forced vital capacity (FVC) ratio, and a decrease in the frequency of COPD exacerbations

AND

- b. Will not be taking strong cytochrome P450 enzyme inducers such as but not limited to rifampin, phenobarbital, carbamazepine, and phenytoin

AND

- c. Does not have suicidal ideations

AND

- d. 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
2. For all other non-preferred COPD Agents , whether the recipient has a documented history of therapeutic failure, intolerance or contraindication of the preferred COPD Agents
 3. For therapeutic duplication, whether:

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- a. The recipient is being titrated to, or tapered from, a drug in the same class

OR

- b. Supporting peer-reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested

OR

4. The recipient does not meet the clinical review guidelines listed above, but in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

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 the request for 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 recipient.

D. Dose and Duration of Therapy

Requests for prior authorization of Daliresp will be approved for up to 12 months.

References:

1. Daliresp package insert. Forest Pharmaceuticals, Inc. St. Louis, MO, 2010.
2. 2010 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