

### Clinical Pharmacy Program Guidelines for Daliresp

Program	Prior Authorization
Medication	Daliresp (roflumilast)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	6/2011
Pharmacy and Therapeutics Approval Date	10/2020
Effective Date	12/2020

**1. Background:**

Daliresp (roflumilast) is a phosphodiesterase-4 inhibitor indicated for reducing the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

**2. Coverage Criteria:**

<p><b>A. <u>Initial Authorization</u></b></p> <p>1. <b>Daliresp</b> will be approved based on <b>all</b> of the following criteria:</p> <p style="padding-left: 40px;">a. Diagnosis of severe to very severe COPD (i.e., FEV<sub>1</sub> less than or equal to 50% of predicted)</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">b. COPD is associated with chronic bronchitis</p> <p style="text-align: center;"><b>-AND-</b></p> <p style="padding-left: 40px;">c. History of COPD exacerbation(s)</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><b>B. <u>Reauthorization</u></b></p>
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1. **Daliresp** will be approved for **continuation** of therapy based on the following criterion:

a. Documentation of positive clinical response to Daliresp therapy

**Authorization will be issued for 12 months.**

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4. References:**

1. Daliresp [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2019.
2. Global strategy for the diagnosis, management, and prevention of COPD. Global Initiative for Chronic Obstructive Lung Disease (GOLD). 2019.

Program	Prior Authorization –Daliresp
<b>Change Control</b>	
Date	Change
6/2011	New drug policy
6/2012	Annual Review
6/2013	<ul style="list-style-type: none"> <li>• Converted policy to new UHC enterprise wide formatting</li> <li>• No changes to clinical criteria</li> </ul>
6/2014	<ul style="list-style-type: none"> <li>• Annual Review</li> </ul>
12/2015	<ul style="list-style-type: none"> <li>• Removed from initial therapy criteria: History of at least 1 COPD exacerbation in the previous year.</li> <li>• Changed trial and failure of other COPD medications requirement to “one prior therapy for COPD”. Previously individual COPD medications were listed.</li> </ul>
9/2016	Updated policy template.
7/2017	Updated background, criteria, and references to align with Employer and Individual’s policy.
10/2017	Annual Review. Administrative updates. Updated references.
10/2018	Annual review. Updated references.
10/2019	Annual review. Updated references.

10/2020	Annual review. Updated references. Added Additional Clinical Rules section.
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