

Clinical Pharmacy Program Guidelines for Daliresp

Program	Prior Authorization
Medication	Daliresp (roflumilast)
Issue Date	6/2011
Pharmacy and Therapeutics Approval Date	10/2017
Effective Date	12/2017

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>A. <u>Initial Authorization</u></p> <p>1. Daliresp will be approved based on all of the following criteria:</p> <p>a. Diagnosis of severe to very severe COPD (i.e., FEV₁ less than or equal to 50% of predicted)</p> <p style="text-align: center;">-AND-</p> <p>b. COPD is associated with chronic bronchitis</p> <p style="text-align: center;">-AND-</p> <p>c. History of COPD exacerbation(s)</p> <p>Authorization will be issued for 12 months.</p> <p>B. <u>Reauthorization</u></p> <p>1. Daliresp will be approved for continuation of therapy based on the following criterion:</p>

- a. Documentation of positive clinical response to Daliresp therapy

Authorization will be issued for 12 months.

3. References:

1. Daliresp prescribing information. AstraZeneca Pharmaceuticals LP. Wilmington, DE. April 2017.
2. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease; updated 2017.

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