



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1024-9
Program	Prior Authorization/Notification
Medication	Daliresp® (roflumilast)
P&T Approval Date	11/2011, 11/2012, 10/2013, 10/2014, 10/2015, 10/2016, 10/2017, 10/2018, 10/2019, 10/2020, 11/2021
Effective Date	2/1/2022; Oxford only: 2/1/2022

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:

A. Initial Authorization

1. Daliresp will be approved based on all of the following criteria:

a. Diagnosis of severe to very severe COPD (i.e., FEV₁ less than or equal to 50% of predicted)

-AND-

b. COPD is associated with chronic bronchitis

-AND-

c. History COPD exacerbation(s)

Authorization will be issued for 12 months

B. Reauthorization

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 Programs:

- 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). 2021.

Program	Prior Authorization/Notification - Daliresp
Change Control	
Date	Change
10/2013	Removed \leq and replaced with text of less than or equal to. Updated reauthorization language to documentation of positive clinical response to therapy. Updated references.
10/2014	Updated references.
10/2015	Updated background and references.
10/2016	Aligned criteria with indications and usage section of the prescribing information and with the GOLD guidelines. Updated references.
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.
11/2021	Annual Review. Updated references.