



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1024-11
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, 11/2022, 11/2023
Effective Date	2/1/2024

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:

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

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

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). 2023.

Program	Prior Authorization/Notification – Daliresp
Change Control	
Date	Change
10/2013	Removed ≤ 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.
11/2022	Annual Review. Added state mandate language. Updated references.
11/2023	Annual review. Updated references.