

Clinical Policy: Roflumilast (Daliresp)
Reference Number: CP.PMN.46
Effective Date: 11/11
Last Review Date: 08/17
[Line of Business: Medicaid](#)

[Coding Implications](#)
[Revision Log](#)

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See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Roflumilast (Daliresp[®]) is a selective phosphodiesterase 4 inhibitor.

FDA approved indication

Daliresp is indicated as a treatment to reduce the risk of chronic obstructive pulmonary disease (COPD) exacerbations in patients with severe COPD associated with chronic bronchitis and a history of exacerbations.

Limitation of use: Daliresp is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

Policy/Criteria

Provider must submit documentation (~~which may include including~~ office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation[®] that Daliresp is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chronic Obstructive Pulmonary Disease (must meet all):

1. Diagnosis of chronic obstructive pulmonary disease (COPD);
- ~~2. Age ≥ 18 years;~~
- ~~3.2~~ Member is non-smoker or is being treated for smoking cessation;
- ~~a.~~ Current forced expiratory volume in one second (FEV₁) < 50% predicted (dated within 30 days);
- ~~3.~~
- ~~4.~~ Member meets one of the following criteria (a or b):
 - ~~a.~~ Failure of ≥ 3 months of adherent use of triple inhaled therapy consisting of a combination of inhaled corticosteroid (ICS) and long-acting beta₂-agonist (LABA), long-acting antimuscarinic antagonist (LAMA), and inhaled corticosteroid (ICS) therapy within the last 6 months;
 - ~~b.~~ Failure of ≥ 3 months of adherent use of long-acting anticholinergic for COPD within the last 6 months;
5. Daliresp will be used concurrently with a ~~LABA or long-acting anticholinergic~~ long-acting bronchodilator (i.e., LABA or LAMA);
6. Request does not exceed ~~FDA approved maximum recommended dose and health plan approved daily quantity limit.~~ Dose does not exceed 500 mcg per day (1 tablet per day).

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Approval duration: 6 months

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B. Other diagnoses/indications

1. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chronic Obstructive Pulmonary Disease (must meet all):

- ~~1.~~ Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
- ~~2.~~ Documentation of positive response to therapy (e.g., improvement in lung function, symptoms/dyspnea; reduction in COPD exacerbations, etc.)
- ~~3.~~ Daliresp is used concurrently with a LABA or long-acting anticholinergic long-acting bronchodilator as evidenced by pharmacy claims history; ~~or documentation from the prescriber;~~
- ~~4.~~ If request is for a dose increase, new dose does not exceed 500 mcg per day (1 tablet per day). Request does not exceed FDA approved maximum recommended dose and health plan approved daily quantity limit.

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Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy; or
2. Refer to CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

Approval duration: Duration of request or 12 months (whichever is less)

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – CP.PMN.53 or evidence of coverage documents;

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease

FDA: Food and Drug Administration

FEV₁: forced expiratory volume in one second

ICS: inhaled corticosteroid

LABA: long-acting beta₂-agonist

LAMA: long-acting antimuscarinic antagonist

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
COPD	500 mcg PO once daily (1 tablet per day)	500 mcg per day

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VI. Product Availability

Tablets: 500 mcg

VII. Workflow Document

N/A

VIII. References

1. Daliresp Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals; November 2015. Available at: <https://www.daliresp.com/>. Accessed March 10, 2017.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD) 2017: Global Strategy for the Diagnosis, Management, and Prevention of COPD. Available from: <http://goldcopd.org>. Accessed March 10, 2017.

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
Added a requirement for documented reduction of COPD exacerbations for continued approval. Updated reference section to reflect current literature search.	11/12	11/12
Updated continued approval to include both reduction of exacerbations and compliance with Daliresp with long- acting inhaled corticosteroid with long- acting beta2 agonist and/or long- acting anti-cholinergic and added requirements for patient to be a non-smoker or be undergoing smoking cessation treatment per GOLD guideline. Standardized wording and formatting to mirror guideline templates. Removal of required spirometry and chart notes regarding documentation of FEV status, chronic bronchitis, and number of exacerbations allowing prescribers to provide information only since prescribers have the responsibility of interpreting the test results. Updated reference section to reflect current literature search.	11/13	11/13
No change.	12/14	12/14
Guideline converted to new template Modified criteria to require failure adherent use of ICS/LABA or anticholinergic with use for ≥ 3 months within the previous 6 months; Added criteria for concurrent use of a long acting bronchodilator; Added requirement that FEV1 must be within the last 30 days; Changed renewal criteria to only required concurrent use of a long acting bronchodilator	08/15	08/15
Removed option for contraindication to ICS/LABA and long acting anticholinergics as Daliresp should always be used in	05/16	08/16

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Reviews, Revisions, and Approvals	Date	P&T Approval Date
combination with at least one long-acting bronchodilator per GOLD guideline; Modified specific max quantity limit to generalized FDA max recommended dose and health plan approved QL statement; Modified continued approval to require claims of LABA and LANA or provider’s documentation as evidence of concurrent use; Updated background section. Updated reference section to reflect current literature search.		
Converted to new template. Initial: modified requirement related to failure of either a long-acting anticholinergic agent or ICS/LABA to failure of triple inhaled therapy consisting of a combination of long-acting beta₂-agonist (LABA), long-acting antimuscarinic antagonist (LAMA), and inhaled corticosteroid (ICS) per GOLD 2017 guideline Per new template update: Removed age restriction as age - age is not an absolute contraindication and COPD does not normally occur in children per PI; updated generalized FDA max recommended dose and health plan approved QL statement to include specific max dose and QL; added documentation of positive response to therapy in continuation criteria. Updated references.	03/17	08/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of

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insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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