Pharmacy Medical Necessity Guidelines:
Roflumilast tablet (Daliresp®)

Effective: October 13, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	RX	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FDA-APPROVED INDICATIONS

Roflumilast (Daliresp®) tablet is a phosphodiesterase-4 (PDE4) inhibitor 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. Its principal action is to reduce inflammation by inhibiting the breakdown of intracellular cyclic AMP.

Roflumilast is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

COVERAGE GUIDELINES

The plan may authorize coverage of Daliresp® (roflumilast) for Members when the following criteria are met and limitations do not apply:

1. The Member has the diagnosis of chronic obstructive pulmonary disease (COPD) or COPD associated with chronic bronchitis

AND

2. Member is new to the Plan and has been stabilized on Daliresp® for the treatment of COPD

OR

The Member has tried and failed therapy with the combination of a long-acting bronchodilator (long-acting beta agonist or a long-acting anticholinergic) and an inhaled corticosteroid or the provider submits documentation of clinical inappropriateness of treatment with a long-acting bronchodilator and an inhaled corticosteroid

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to the Brand Name criteria.

CODES

None

REFERENCES

1. Calverley P, et al. Roflumilast in symptomatic chronic obstructive pulmonary disease: Two randomized clinical trials. Lancet 2009; 374: 685-94.
2. Daliresp (roflumilast) [prescribing information]. Wilmington, DE: AstraZeneca; March 2020.
3. Fabbri L, et al. Roflumilast in moderate to severe chronic obstructive pulmonary disease treated with long acting bronchodilators: Two randomized clinical trials. Lancet 2009; 374: 695-703.
4. Mill E, et al. Pharmacotherapies for chronic obstructive pulmonary disease: a multiple treatment comparison meta-analysis. Clin Epidemiol. 2011;3:107–129.
5. Rutten-Van Mölken, et al. A 1-year prospective cost-effectiveness analysis of roflumilast for the treatment of patients with severe chronic obstructive pulmonary disease. [Abstract] Pharmacoeconomics 2007;25(8):695-711.
6. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease: 2023 report. Available at: https://goldcopd.org/2023-gold-report-2/Accessed 7 August 2023.

APPROVAL HISTORY

October 11, 2022: Reviewed by Pharmacy & Therapeutics Committee; approval limited to one year.

Subsequent endorsement date(s) and changes made:

1. September 12, 2023: Effective October 1, 2023, to reflect generic availability of Daliresp updated title of MNG to "Roflumilast tablet (Daliresp)" and added language to limitations section regarding review of brand-name products with AB-rated generics.
2. September 10, 2024: Administrative change to fax number.
3. September 9, 2025: No changes
4. October 13, 2026: No changes

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services