Pharmacy Medical Necessity Guidelines: Daliresp® (roflumilast)
Effective: January 9, 2018

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

This pharmacy medical necessity guideline applies to the following:

**Tufts Health Plan Commercial Plans**
- Tufts Health Plan Commercial Plans – large group plans
- Tufts Health Plan Commercial Plans – small group and individual plans

**Tufts Health Public Plans**
- Tufts Health Direct – Health Connector
- Tufts Health Together – A MassHealth Plan
- Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan

**Tufts Health Freedom Plan products**
- Tufts Health Freedom Plan - large group plans
- Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617-673-0988

**OVERVIEW**

**FDA-APPROVED INDICATIONS**
Roflumilast (Daliresp®) 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. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) COPD guidelines consider roflumilast an add-on option in patients treated with a long-acting beta-agonist, a long-acting muscarinic antagonist, and an inhaled corticosteroid who are still having exacerbations with a forced expiratory volume in the first second (FEV₁) < 50% predicted and chronic bronchitis.

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

**LIMITATIONS**
None

**CODES**
None

**REFERENCES**
2. FDA approves new drug to treat chronic obstructive pulmonary disease. [Access June 2011].
   fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm244989.htm

**APPROVAL HISTORY**
February 10, 2015: Reviewed by Pharmacy & Therapeutics Committee; approval limited to one year.

Subsequent endorsement date(s) and changes made:
- September 16, 2015: Approval duration approved for life of plan.
- January 1, 2016: Administrative change to rebranded template.
- January 12, 2016: No changes.
- January 10, 2017: Added exception language for Members new to the plan and stable on Daliresp prior to enrollment. Updated criteria to require trial and failure with a long-acting bronchodilator and an inhaled corticosteroid.
- May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
- January 9, 2018: 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. They are used in conjunction with a member's benefit document and in coordination with the member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan members or to certain delegated service arrangements. Unless otherwise noted in the member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.