MEDICAL MUTUAL®

Drug Policy

Policy:	Daliresp (roflumilast)	Annual Review Date: 02/15/2024 Last Revised Date: 02/15/2024

OVERVIEW

Roflumilast tablets (Daliresp, generic), a selective phosphodiesterase-4 inhibitor, 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. Limitations of use: Roflumilast is not a bronchodilator and is not indicated for the relief of acute bronchospasm.

POLICY STATEMENT

This policy involves the use of roflumilast. Prior authorization is recommended for pharmacy benefit coverage of roflumilast. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of roflumilast is recommended in those who meet the following criteria:

1. Chronic Obstructive Pulmonary Disease (COPD)

Criteria. *Patient must meet the following criteria (A, B, C, and D):*

- **A.** The patient has severe COPD or very severe COPD (FEV_1 < 50% predicted); AND
- **B.** The patient has a history of exacerbations which required the use of systemic corticosteroids, antibiotics, or hospital admission; AND
- **C.** Patient meets ONE of the following (i or ii):
  - **a.** Patient has chronic bronchitis AND has tried an inhaled long-acting $beta_2$-agonist, an inhaled long-acting muscarinic antagonist, and an inhaled corticosteroid concomitantly; OR
    Note: Use of a combination inhaler containing multiple agents from the medication classes listed would fulfil the requirement. Refer to **Appendix** for examples of inhaled therapies used for COPD.
  - **b.** Patient has tried an inhaled long-acting muscarinic antagonist and long-acting $beta_2$-agonist concomitantly AND has a blood eosinophil level < 100 cells/microliter.

Note: Use of a combination inhaler containing multiple agents from the medication classes listed would fulfil the requirement. Refer to **Appendix** for examples of inhaled therapies used for COPD.

D. If brand Daliresp is being requested, the patient meets both of the following criteria (a and b):

- **a.** Patient has tried generic roflumilast; AND
- **b.** Brand Daliresp is being requested due to a formulation difference in the inactive ingredient(s) [e.g., difference in dyes, fillers, preservatives] between the Brand and the corresponding generic product which, per the prescriber, would result in a significant allergy or serious adverse reaction.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Roflumilast has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Asthma.** The efficacy of roflumilast (formulation not specified) in patients with asthma, allergic asthma, and exercise-induced asthma has been evaluated. More data are needed to define the place in therapy of roflumilast in the treatment of asthma. Current asthma guidelines do not address roflumilast as a recommended therapy for asthma management.

2. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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Appendix

Brand (Generic Name)	Mechanism of Action
Arcapta® Neohaler® (indacaterol inhalation powder)	LABA
Serevent® Diskus® (salmeterol xinafoate inhalation powder)	LABA
Striverdi® Respimat® (olodaterol inhalation spray)	LABA
Brovana® (arformoterol tartrate inhalation solution)	LABA
Perforomist® (formoterol fumarate inhalation solution)	LABA
Incruse® Ellipta® (umeclidinium inhalation powder)	LAMA
Seebri™ Neohaler® (glycopyrrolate inhalation powder)	LAMA
Spiriva® HandiHaler® (tiotropium bromide inhalation powder)	LAMA
Spiriva® Respimat® (tiotropium bromide inhalation spray)	LAMA
Tudorza® Pressair® (aclidinium bromide inhalation powder)	LAMA
Lonhala® Magnair® (glycopyrrolate inhalation solution)	LAMA
Yupelri® (revefenacin inhalation solution)	LAMA
Alvesco® (ciclesonide inhalation aerosol)	ICS
ArmonAir® Digihaler® (fluticasone propionate inhalation powder)	ICS
Arnuity® Ellipta® (fluticasone furoate inhalation powder)	ICS
Asmanex® HFA (mometasone inhalation aerosol)	ICS
Asmanex® Twisthaler® (mometasone inhalation powder)	ICS
Flovent® Diskus® (fluticasone propionate inhalation powder)	ICS
Flovent® HFA (fluticasone propionate inhalation aerosol)	ICS
Pulmicort Flexhaler® (budesonide inhalation powder)	ICS
Qvar® RediHaler™ (beclomethasone HFA inhalation aerosol)	ICS
Pulmicort Respules® (budesonide inhalation suspension, generic)	ICS/LABA
Advair Diskus® (fluticasone propionate/salmeterol inhalation powder, generic [including Wixela Inhub®])	ICS/LABA
Breo® Ellipta® (fluticasone furoate/vilanterol inhalation powder)	ICS/LABA
Symbicort® (budesonide/formoterol fumarate inhalation aerosol, generic)	ICS/LABA
Anoro® Ellipta® (umeclidinium and vilanterol inhalation powder)	LAMA/LABA
Bevespi Aerosphere® (glycopyrrolate and formoterol fumarate inhalation aerosol)	LAMA/LABA
Duaklir® Pressair® (aclidinium bromide and formoterol fumarate inhalation powder)	LAMA/LABA
Stiolto® Respimat® (tiotropium bromide and olodaterol inhalation spray)	LAMA/LABA
Utibron® Neohaler® (indacaterol and glycopyrrolate inhalation powder)	LAMA/LABA
Breztri Aerosphere™ (budesonide, glycopyrrolate, and formoterol fumarate inhalation aerosol)	ICS/LAMA/LABA
Trelegy™ Ellipta® (fluticasone furoate, umeclidinium, and vilanterol inhalation powder)	ICS/LAMA/LABA

LABA – Long-acting beta2-agonist; LAMA – Long-acting muscarinic antagonist; ICS – Inhaled corticosteroid.