RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title: **Roflumilast (Daliresp®)**
Policy Number: **RxA.101**
Drug(s) Applied: **Roflumilast (Daliresp®)**
Last Review Date: **05/2020**
Line of Business: **Commercial**

Background

Roflumilast (Daliresp®) is a selective phosphodiesterase 4 inhibitor. Roflumilast 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(s) of use:

- Roflumilast is not a bronchodilator and is not indicated for the relief of acute bronchospasm.
- Roflumilast 250 mcg is a starting dose for the first 4 weeks of treatment only and is not the effective (therapeutic) dose.

Indication	Dosing Regimen	Maximum Dose
COPD	500 mcg PO QD (starting treatment with 250 mcg QD for 4 weeks and increasing to 500 mcg QD thereafter may reduce the rate of discontinuation in some patients)	500 mcg/day

Tablets: 250 mcg, 500 mcg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

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

1. Diagnosis of COPD;
2. Age 18 years of age or older;
3. Current (within the past 30 days) forced expiratory volume in one second (FEV_1) < 50% predicted;
4. Member meets one of the following (a or b):
   a. Failure of triple inhaled therapy consisting of a combination of a long-acting $beta_2$-agonist (LABA), long-acting antimuscarinic antagonist (LAMA), and inhaled corticosteroid (ICS) at up to maximally indicated doses;
   b. Both i and ii:
      i. Failure of dual inhaled therapy consisting of a combination of a LABA and LAMA at up to maximally indicated doses;
      ii. Current (within the past 30 days) blood eosinophil count < 100 cells/uL;
5. Daliresp is prescribed concurrently with a long-acting bronchodilator (i.e., LABA or LAMA);
6. Dose does not exceed 500 mcg per day (1 tablet per day).

Approval duration: 12 months

II. Continued Therapy

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

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 500 mcg per day (1 tablet per day).

Approval duration: 12 months

III. Appendices

Appendix A: Abbreviation/Acronym Key

COPD: chronic obstructive pulmonary disease
FDA: Food and Drug Administration
FEV_1: forced expiratory volume in one second
ICS: inhaled corticosteroid
LABA: long-acting $beta_2$-agonist
LAMA: long-acting antimuscarinic antagonist

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
ICS/LABA Combinations		
fluticasone/salmeterol (Advair Diskus®)	Refer to prescribing information	Refer to prescribing information
Breo Ellipta® (fluticasone/ vilanterol)	Refer to prescribing information	Refer to prescribing information
Symbicort® (budesonide/ formoterol)		
Dulera®**(mometasone/ formoterol)	Doses of 10 mcg formoterol/400 mcg mometasone and 10 mcg formoterol/ 200 mcg mometasone, each inhaled BID, have been studied	The optimal dose has not been established
LABA/LAMA Combinations		
Bevespi Aerosphere® (formoterol/glycopyrrolate)	Refer to prescribing information	Refer to prescribing information
Utibron Neohaler® (indacaterol/glycopyrrolate)		
Anoro Ellipta® (vilanterol/umeclidinium)		
Stiolto Respimat® (olodaterol/tiotropium)		
LAMAs		
Tudorza Pressair® (aclidinium bromide)	Refer to prescribing information	Refer to prescribing information
Seebri Neohaler® (glycopyrrolate)		
Spiriva Respimat®/ HandiHaler® (tiotropium)		

Incruse Ellipta (umeclidinium)		
LABAs		
Brovana® (arformoterol)	Refer to prescribing information	Refer to prescribing information
Arcapta Neohaler® (indacaterol)		
Striverdi Respimat® (olodaterol)		
Serevent Diskus® (salmeterol)		
ICS/LABA/LAMA Combinations		
Trelegy™ Ellipta® (fluticasone/umeclidinium/ vilanterol)	1 inhalation by mouth QD	1 inhalation/day

*Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic. *Off-label*

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): moderate to severe liver impairment (Child-Pugh B or C)
- Boxed warning(s): none reported

References

1. Daliresp Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals; January 2018. Available at: https://www.daliresp.com/. Accessed May 1, 2020.
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD): Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease (2019 report). Available from: http://www.goldcopd.org/. Accessed May 1, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com/. Accessed May 1, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Updated References	05/01/2020	05/21/2020