

Daliresp (roflumilast)
Effective 08/01/2020

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	N/A		
Contact Information	Medical Benefit Pharmacy Benefit	Phone: 833-895-2611 Phone: 800-711-4555	Fax: 888-656-6671 Fax: 844-403-1029
Exceptions	N/A		

Overview

Daliresp (roflumilast) 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

Authorization may be granted for members who are currently receiving treatment with Daliresp, excluding when the product is obtained as samples or via manufacturer's patient assistance programs.

Or

Authorization may be granted when ALL the following criteria are met:

1. Patient has a diagnosis of severe COPD associated with chronic bronchitis and a history of exacerbations
2. Patient has had a documented side effect, allergy, or treatment failure with a combination long-acting beta agonist/inhaled corticosteroid or a long-acting bronchodilator (long-acting beta-agonist, long-acting anticholinergic) and an inhaled corticosteroid used concurrently as separate agents.

Continuation of Therapy

Reauthorization may be granted with improvement per physician assessment/evaluation of overall disease activity within the previous 6 months from time of recertification request.

Limitations

1. Initial approvals will be granted for 12 months.
2. Reauthorizations will be granted for 36 months.
3. The following quantity limits apply:

Daliresp 250mg	30 tablets per month
Daliresp 500mg	30 tablets per month

References

1. Daliresp (roflumilast) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; March 2019
2. Global Initiative for Chronic Obstructive Lung Disease (GOLD). Global Strategy for the Diagnosis, Management and Prevention of Chronic Obstructive Pulmonary Disease: 2020 Report. <http://www.goldcopd.org> (Accessed on January 29, 2020)
3. National Institute for Health and Clinical Excellence. Management of chronic obstructive pulmonary disease in adults in primary and secondary care (partial update). [guideline on the internet]. 2010, June; Review decision date: 2014 July [cited 20 May 2015]. Available from: www.nice.org.uk/guidance/cg101.
4. FDA panel votes against roflumilast for COPD [press release on the Internet]. New York (NY): Medscape LLC; 2010 Apr 9 [cited 2012 May]. Available from: <http://www.medscape.com/viewarticle/720010>.
5. Oba Y, Keeney E, Ghatehorde N, Dias S. Dual combination therapy versus long-acting bronchodilators alone for chronic obstructive pulmonary disease (COPD): a systematic review and network meta-analysis. *Cochrane Database Syst Rev* 2018; 12:CD012620
6. Martinez FJ, Calverley PM, Goehring UM, Brose M, Fabbri LM, Rabe KF. Effect of roflumilast on exacerbations in patients with severe chronic obstructive pulmonary disease uncontrolled by combination therapy (REACT): a multicentre randomised controlled trial. *Lancet*. 2015;385(9971):857-66.
7. Horita N, Nagashima A, Kaneko T. Long-Acting β -Agonists (LABA) Combined With Long-Acting Muscarinic Antagonists or LABA Combined With Inhaled Corticosteroids for Patients With Stable COPD. *JAMA* 2017; 318:1274.
8. Ni H, Moe S, Soe Z, et al. Combined aclidinium bromide and long-acting beta2-agonist for chronic obstructive pulmonary disease (COPD). *Cochrane Database Syst Rev* 2018

Review History

06/25/2012 – Reviewed

06/24/2013 – Reviewed

06/23/2014 – Reviewed

06/22/2015 – Reviewed & Revised

06/27/2016 – Reviewed

06/26/2017 – Reviewed

06/25/2018 – Reviewed

06/19/2019 – Reviewed & Revised

05/20/2020 – Reviewed and Updated May P&T Mtg; combined PA criteria for inhaler use into one statement; references updated; removed to be used in combination with long-acting bronchodilator (to match MH).

Effective 8/1/20.

09/22/2021- Reviewed Sept. P&T; reference updated.

