

Daliresp (roflumilast)
Effective June 16, 2019

Plan	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		<input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Specialty Limitations	N/A		
Contact Information	Specialty Medications		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
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 when the following criteria are met:

- Patient is new to AllWays Health Partners and has been stabilized on Daliresp for the approvable indication **OR**
- Patient has a diagnosis of severe COPD associated with chronic bronchitis and a history of exacerbations **AND**
- Patient has had a documented side effect, allergy, or treatment failure with at least one orally- inhaled corticosteroid **AND**
- Patient has had a documented side effect, allergy, or treatment failure with at least one orally inhaled, long-acting anticholinergic **OR**
- Patient has had a documented side effect, allergy, or treatment failure with at least one orally- inhaled, long-acting beta agonist **AND**
- Patient will be using the requested medication in combination with at least one orally-inhaled, long-acting bronchodilator

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.

References

1. Daliresp (roflumilast) [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2018
2. Global Initiative for Chronic Obstructive Lung Disease. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease; Updated 2015. 2015 [cited 20 May 2015]. Available at: <http://www.goldcopd.org/Guidelines/guidelines-resources.html>
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.

Review History

06/25/12 – Reviewed
06/24/13 – Reviewed
06/23/14 – Reviewed
06/22/15 – Reviewed & Revised
06/27/16 – Reviewed
06/26/17 – Reviewed
06/25/18 – Reviewed
06/19/19 – Reviewed & Revised

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