

**Pharmacy Policy**

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**Daliresp**

**Policy Number:** 9.111

**Version Number:** 2

**Version Effective Date:** 1/1/2022

<p>Product Applicability <input type="checkbox"/> All Plan+ Products</p>	
<p><b>Well Sense Health Plan</b></p> <p><input type="checkbox"/> New Hampshire Medicaid</p>	<p><b>Boston Medical Center HealthNet Plan</b></p> <p><input checked="" type="checkbox"/> MassHealth - MCO</p> <p><input checked="" type="checkbox"/> MassHealth - ACO</p> <p><input type="checkbox"/> Qualified Health Plans/ConnectorCare/Employer Choice Direct</p> <p><input type="checkbox"/> Senior Care Options</p>

Note: Disclaimer and audit information is located at the end of this document.

**Prior Authorization Policy**

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**Products Affected:**

- Daliresp (roflumilast)

The Plan may authorize coverage of the above products for members meeting the following criteria:

<b>Covered Use</b>	All FDA approved indications not otherwise excluded
<b>Required Medical Information</b>	<ol style="list-style-type: none"> <li>1. A diagnosis of chronic obstructive pulmonary disease associated with chronic bronchitis; <b>AND</b></li> <li>2. Member has had at least 2 exacerbations in the past year OR 1 exacerbation requiring hospitalization; <b>AND</b></li> <li>3. An inadequate response or intolerance to a trial of combination regimen of a long-acting bronchodilator and an oral inhaled corticosteroid.</li> </ol>
<b>Coverage Duration</b>	12 months

\* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.

## Clinical Background Information and References

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1. Product information. Daliresp<sup>®</sup>, roflumilast. AstraZenica Pharmaceuticals LP. Wilmington, DE. January 2018.
2. Global Strategy for the Diagnosis, Management, and Prevention of Chronic Obstructive Pulmonary Disease. Global Initiative for Chronic Obstructive Lung Disease (GOLD), Inc; 2015. Accessed February 2015.
3. Ferguson GT. Management of refractory chronic obstructive pulmonary disease. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed on July 1 2021).

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

## Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.141 Daliresp Policy retired, new policy created	1/1/2021	P&T Committee
8/12/2021	Annual P&T Review: Expanded criteria to allow for 1 exacerbation requiring hospitalization	1/1/2022	P&T Committee

## Next Review Date

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8/2022

## Other Applicable Policies

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## Reference to Applicable Laws and Regulations, If Any

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### Disclaimer Information

Medical Policies are the Plan's guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member's benefit document, and when appropriate, coordinates with the Member's health care Providers to consider the individual Member's health care needs.

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Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan's service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member's benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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