

## Pharmacy Policy

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### Step Therapy – Pulmonary Agents

**Policy Number:** 9.138

**Version Number:** 2

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

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

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

## Prior Authorization Policy

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### POLICY STATEMENT:

A step therapy program has been developed to encourage the use of Step-1 products prior to the use of a Step-2 product, without interrupting existing therapy. If the step therapy rule is not met for a Step-2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

### Standard Criteria:

The Plan May Authorize Coverage Of The Products in Appendix A For Members Meeting The Following Criteria When Step Therapy Is Not Met At Point Of Sale From Claims History:

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1. Prescribers must provide documentation (including dates of trial and outcome) that the member has tried and failed the appropriate number of Step 1 agents as indicated in Appendix A and in the coverage criteria requirements; OR
2. Prescriber must provide documentation that the member has a contraindication to or other clinical rationale preventing the use of ALL Step 1 agents indicated in Appendix A

**Appendix A: Step Therapy Details**

<b>Bronchodilators, Sympathomimetic</b>		
<b>Step 1</b>	<b>Step 2</b>	<b>Coverage Criteria</b>
Albuterol Nebulization Solution	Levalbuterol HCl Nebulization Solution	Prescription claims indicating that the member has had at least 1 prescription for albuterol nebulizer solution in the past 130 days

<b>MISC.</b>		
<b>Step 1</b>	<b>Step 2</b>	<b>Coverage Criteria</b>
Montelukast (generic Singulair) Zafirlukast (generic Accolate)	Zileuton ER (generic Zflo CR) Zflo (Zileuton)	A Step 2 Agent will be covered when prescription claims are present indicating a trial of ALL Step 1 Agents in the last 365 days OR at least a 90 day supply of a Step 2 Agent in the last 130 days

<b>Original Approval Date</b>	<b>Original Effective Date</b>	<b>Policy Owner</b>	<b>Approved by</b>
9/10/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

**Policy Revisions History**

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## Policy Revisions History

Review Date	Summary of Revisions	Revision Effective Date	Approved by
9/10/2020	P&T Committee Review. Discontinued Step Therapy Policy 9.087 and created separate policy for each drug class for all lines of business. Updated policy to align with 2021 formulary. Changed approval duration from 2 to 1 year. Changed trial duration from 120 to 130 days	1/1/2021	P&T Committee
8/12/2021	Annual P&T Review: Aligned standard criteria.	1/1/2022	P&T Committee

### Next Review Date

8/2022

### Other Applicable Policies

### Reference to Applicable Laws and Regulations, If Any

### 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.

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

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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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