

**Pharmacy Policy**

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**ACEIs and ARBs**

**Policy Number:** 9.601

**Version Number:** 2

**Version Effective Date:** 3/1/2022

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|---|--|
| <p><b>Product Applicability</b>    <input type="checkbox"/> <b>All Plan+ Products</b></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:**

- **Enalapril Oral Solution (Epaned)**
- **Qbrelis (lisinopril)**

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

|                                     |   |
|-------------------------------------|---|
| <b>Covered Use</b>                  | All FDA approved indications unless otherwise excluded  |
| <b>Exclusion Criteria</b>           | None  |
| <b>Required Medical Information</b> | <p><b><u>Enalapril Oral Solution (Epaned)</u></b></p> <p>Documentation of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of hypertension, heart failure, or left ventricular dysfunction; <b>AND</b></li> </ol> |

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|                               |  |
|-------------------------------|--|
|                               | <p>2. Inability to take an oral tablet or capsule due to difficulty swallowing</p> <p><b>Qbrelis</b><br/>Documentation of the following:</p> <ol style="list-style-type: none"> <li>1. Diagnosis of hypertension, heart failure, or acute myocardial infarction ; <b>AND</b></li> <li>2. Inability to take an oral tablet or capsule due to difficulty swallowing</li> </ol> |
| <b>Age Restrictions</b>       | Qbrelis: 6 years and over  |
| <b>Prescriber Restriction</b> | None   |
| <b>Coverage Duration</b>      | 12 months  |
| <b>Other criteria</b>         | <p>Reauthorization:</p> <ol style="list-style-type: none"> <li>1. Continued inability to take an oral tablet or capsule due to difficulty swallowing</li> </ol>  |

## Clinical Background Information and References

1. Matchar DB, McCrory DC, Orlando LA, et al. Systematic review: Comparative effectiveness of angiotensin-converting enzyme inhibitors and angiotensin II receptor blockers for treating essential hypertension. *Ann Intern Med.* 2008;148:16-29.
2. Kunz R, Friedrich C, Wolbers M, Mann JFE. Meta-analysis: Effect of monotherapy and combination therapy with inhibitors of the renin angiotensin system on proteinuria in renal disease. *Ann Intern Med.* 2008;148:30-48.
3. Angiotensin II Receptor Antagonists. Facts and Comparisons 4.0 (online), 2009. Available from Woltres Kluwer Health, Inc. Accessed April, 2012.
4. Benowitz NL. Antihypertensive Agents. In: Katzung BG, Ed. *Basic and Clinical Pharmacology, 10<sup>th</sup> Ed.* McGraw-Hill; 2007: 175-177.
5. American College of Obstetricians and Gynecologists. Hypertension in pregnancy: report of the American College of Obstetricians and Gynecologists' Task Force on Hypertension in Pregnancy. *Obstet Gynecol.*2013;122:1122-1131.
6. FDA Drug Safety Communication: FDA approves label changes to include intestinal problems (sprue-like enteropathy) linked to blood pressure medicine olmesartan medoxomil. Last updated 7/11/2013.
7. FDA. ACE Inhibitors: Dual Blockade of the RAS. Available: <http://www.fda.gov/Safety/MedWatch/SafetyInformation/ucm418829.htm>. Accessed April, 2014.
8. Epaned® (enalapril) prescribing information. Silvergate Pharmaceuticals, Inc. Greenwood, CO 80111. January 2016.
9. Qbrelis™(lisinopril) prescribing information. Silvergate Pharmaceuticals, Inc. Greenwood, CO 80111. July 2016.

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| Original Approval Date | Original Effective Date | Policy Owner      | Approved by                             |
|------------------------|-------------------------|-------------------|---|
| 12/1/2020              | 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                | 9.131 ACEIs and ARBs Policy retired, new policy created                        | 1/1/2021                | P&T Committee |
| 11/11/2021               | Annual Review: Generic Epaned added to policy to reflect generic availability. | 3/1/2022                | P&T Committee |

### Next Review Date

11/2022

### 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.

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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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