



wellsense.org | 877-957-1300

Pharmacy Policy

Strensiq™

Policy Number: 9.312

Revision Number: R0

Version Effective Date: 1/1/2021

Product Applicability All Plan+ Products

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth ACO

MassHealth MCO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

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

Prior Authorization Policy

Products Affected:

- Strensiq™(asfotase alfa)

The Plan may authorize coverage of the above product(s) for members meeting the following criteria:

| | |
|-------------------------------------|---|
| Covered Use | All FDA approved indication unless otherwise excluded. |
| Exclusion Criteria | None |
| Required Medical Information | Documentation of the following: 1. Diagnosis of perinatal/infantile-onset hypophosphatasia (HPP) OR juvenile-onset HPP; AND 2. Documented history of clinical manifestations consistent with HPP (e.g. skeletal |

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| | <p>abnormalities, respiratory problems, hypercalcemia, seizures); AND</p> <p>3. Member has a documented tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation AND serum alkaline phosphatase (ALP) level below the age-adjusted normal range AND plasma pyridoxal-5-phosphate (PLP) above the upper limit of normal at baseline (documentation must be provided); AND</p> <p>4. The request is for dosing regimen of 2 mg/kg three times per week; AND</p> <p>5. Member's current weight is provided; AND</p> <p>6. For children weighing less than 40 kg: the 80 mg/0.8 mL concentration vial will not be used</p> |
| Age Restrictions | None |
| Prescriber Restriction | Prescribed by an endocrinologist or other provider who specializes in the treatment of perinatal/infantile HPP or juvenile onset HPP |
| Coverage Duration | Initial: 6 months Reauthorization: 12 months |
| Other criteria | <p>Reauthorization:</p> <ol style="list-style-type: none"> 1. Initial criteria are met; AND 2. There has been a clinically significant improvement in the member's condition without adverse effects. |

Clinical Background Information and References

1. Mornet, Etienne. "Hypophosphatasia." Orphanet Journal of Rare Diseases 2 (2007): 40. PMC. Web. 29 June 2016.
2. Strensiq™ (asotase alfa). Prescribing information. Alexion Pharmaceuticals, Inc. Cheshire, CT. October 2015.
3. Strensiq drug information. UpToDate. Waltham, MA: UpToDate Inc. <https://www.uptodate.com> (Accessed on March 28, 2019.)

| Original Approval Date | Original Effective Date | Policy Owner | Approved by |
|------------------------|-------------------------|-------------------|---|
| 12/1/2020 | 1/1/2021 | Pharmacy Services | Pharmacy & Therapeutics (P&T) Committee, NH DHHS |

Policy Revisions History

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Policy Revisions History

| Review Date | Summary of Revisions | Revision Effective Date | Approved by |
|-------------|---|-------------------------|------------------------|
| 12/1/2020 | 9.068 Strensiq Policy retired, new policy created | 1/1/2021 | P&T Committee, NH DHHS |

Next Review Date

2021

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 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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