Pharmacy Medical Necessity Guidelines:
Strensiq™ (asfotase alfa)

Effective: May 12, 2026

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RXUM
These pharmacy medical necessity guidelines apply to the following: ☒ Tufts Health RITogether – A Rhode Island Medicaid Plan		**Fax Numbers:** RXUM: 617.673.0939	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Strensiq (asfotase alfa) is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile-onset and juvenile-onset hypophosphatasia.

COVERAGE GUIDELINES

The plan may authorize coverage of **Strensiq (asfotase alfa)** for Members, when **ALL** of the following criteria are met:

Initial Authorization Criteria

1. Documented diagnosis of perinatal/infantile-onset or juvenile-onset hypophosphatasia (HPP)

AND

2. The Member was 18 years of age or less at disease onset

AND

3. The Member has clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, respiratory problems, hypercalcemia, seizures)

AND

4. The diagnosis is supported by one of the following:
    a. Molecular genetic testing (mutation[s] in the ALPL gene)

    OR

    b. Documentation of **ALL** of the following:
        i. An elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])
        ii. Findings on radiographic imaging support the diagnosis of hypophosphatasia (e.g., infantile rickets, alveolar bone loss, osteoporosis, low bone mineral content for age [as detected by DEXA])
        iii. A low baseline ALP activity (age adjusted)

Reauthorization Criteria

1. The Member has a documented diagnosis of perinatal/infantile-onset or juvenile-onset hypophosphatasia (HPP)

AND

2. The Member was 18 years of age or less at disease onset

AND

3. The Member has clinical manifestations consistent with hypophosphatasia (e.g., skeletal abnormalities, respiratory problems, hypercalcemia, seizures)

AND

4. The diagnosis is supported by one of the following:
    a. Molecular genetic testing (mutation[s] in the ALPL gene)
    b. Documentation of **ALL** of the following:
        i. An elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (i.e., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])
        ii. Findings on radiographic imaging support the diagnosis of hypophosphatasia (e.g., infantile rickets, alveolar bone loss, osteoporosis, low bone mineral content for age [as detected by DEXA])

iii. A low baseline ALP activity (age adjusted)

AND

5. Documentation the patient has responded to treatment as evidenced by improvement in respiratory status, growth, or radiographic findings

LIMITATIONS

- Initial coverage of Strensiq will be authorized for six (6) months. Reauthorization of Strensiq will be provided in 12-month intervals.
- Members new to the plan stable on Strensiq should be reviewed against Reauthorization Criteria.
- The FDA-approved labeling allows for Strensiq to be injected three times per week or six times per week. Strensiq is only covered as a three times per week injection. Coverage is limited to 24 single-use vials per 28 days.

CODES

Medical billing codes may not be used for this medication. This medication must be obtained via the Member's pharmacy benefit.

REFERENCES

1. Hoffman C, Rockman-Greengerg C, Harmatz P, et al. 7th International Conference on Children's Bone Health. Improvement in bone manifestations and respiratory status in infants and young children with HPP treated with asfotase alfa: an update on the ENB-010-10 trial. Salzburg, Austria; 2015 June 27-30.
2. National Institute of Health. Genetic and Rare Disease Information Center: Hypophosphatasia. July 2013. URL: rarediseases.info.nih.gov/gard/6734/hypophosphatasia/resources/8. Available from internet. Accessed 2016 March 21.
3. Strensiq Prescribing Information. New Haven, CT: Alexion Pharmaceuticals Inc.; July 2024.
4. United States National Library of Medicine. Genetics Home Reference: Hypophosphatasia. September 2007. URL: ghr.nlm.nih.gov/condition=hypophosphatasia. Available from internet. Accessed 2016 March 21.
5. Whyte MP, Greenberg CR, Salman NJ, et al. Enzyme-Replacement Therapy in Life-Threatening Hypophosphatasia. *N Engl J Med*. 2012; 366:904-13.
6. Whyte MP, Mahuren JD, Vrabel LA, Coburn SP. Markedly increased circulating pyridoxal-5'-phosphate levels in hypophosphatasia. *J Clin Invest*. 1985;76(2):752-756A

APPROVAL HISTORY

September 13, 2022: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. August 8, 2023: Effective September 1, 2023, administrative update: moved reauthorization criteria from limitations section to the coverage guidelines section.
2. July 9, 2024: Clarified that members new to the plan stable on Strensiq should be reviewed against Reauthorization Criteria. Minor wording updates (eff 8/1/2024).
3. May 13, 2025: No changes (eff 5/13/25)
4. May 12, 2026: No changes (eff 5/12/26).

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated.

Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

Provider Services