Pharmacy Medical Necessity Guidelines: Strensiq™ (asfotase alfa)

Effective: June 1, 2017

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

This Pharmacy Medical Necessity Guideline applies to the following:
Tufts Health Plan Commercial Plans
✓ Tufts Health Plan Commercial Plans – large group plans
✓ Tufts Health Plan Commercial Plans – small group and individual plans
Tufts Health Public Plans
✓ Tufts Health Direct – Health Connector
✓ Tufts Health Together – A MassHealth Plan
✓ Tufts Health RITogether – A Rite Care + Rhody Health Partners Plan
Tufts Health Freedom Plan products
✓ Tufts Health Freedom Plan - large group plans
✓ Tufts Health Freedom Plan - small group plans

Fax Numbers:
RXUM: 617.673.0988

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Prior Authorization Criteria. Background, applicable product and disclaimer information can be found on the last page.

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:

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

   AND

2. The Member is ≤ 18 years of age at 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)

LIMITATIONS
1. Initial approval will be limited to 6 months.
2. Reauthorization may be given in 12 month intervals for Members with perinatal/infantile-onset or juvenile-onset hypophosphatasia (HPP) if the following criteria are met:
a. The Member meets the criteria for initial approval
b. The Member has responded to treatment with Strensiq (asfotase alfa) as evidenced by improvement in respiratory status, growth or radiographic findings.

3. 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
8. 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
April 12, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- November 15, 2016: Updated criteria to allow for diagnosis to be confirmed by molecular genetic testing or clinical findings (defined in 4bi-4biil).

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. They are used in conjunction with a Member's benefit document and in coordination with the Member's physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member's benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLink℠ Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.
For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.