Pharmacy Medical Necessity Guidelines: Strensiq™ (asfotase alfa)

Effective: November 10, 2020

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:

Commercial Products

☒ Tufts Health Plan Commercial products – large group plans
☒ Tufts Health Plan Commercial products – small group and individual plans
☒ Tufts Health Freedom Plan products – large group plans
☒ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☒ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

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:

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

- Initial approval will be limited to 6 months.
- 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.
- 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. Food and Drug Administration. FDA News Release. 2015. URL: fda.gov/newsevents/newsroom/pressannouncements/ucm468836.htm. Available from internet. Accessed 2016 March 21.
2. 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.
3. 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.
4. Strensiq Prescribing Information. New Haven, CT: Alexion Pharmaceuticals Inc.; June 2020.
5. 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.
6. Whyte MP, Greenberg CR, Salman NJ, et al. Enzyme-Replacement Therapy in Life-Threatening Hypophosphatasia. *N Engl J Med*. 2012; 366:904-13.
7. 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:

1. November 15, 2016: Updated criteria to allow for diagnosis to be confirmed by molecular genetic testing or clinical findings (defined in 4bi-4biii).
2. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
3. November 14, 2017: No changes.
4. November 13, 2018: Administrative update to the template.
5. December 10, 2019: No changes.
6. November 10, 2020: No changes.

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.