Strensiq (asfotase alfa)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Strensiq (asfotase alfa)

APPROVAL CRITERIA

Initial requests for Strensiq (asfotase alfa) may be approved when the following criteria are met:

I. Individual has a diagnosis of one of the following:
   A. Individual has a diagnosis of perinatal/infantile hypophosphatasia (HPP), and had onset of symptoms prior to 6 months of age; **OR**
   B. Individual has a diagnosis of juvenile-onset HPP, and had onset of disease ≤ 18 years of age;

AND

II. Documentation is provided that individual's total serum alkaline phosphatase is below the lower limit of normal for the individual's age and gender at diagnosis (Whyte 2012); **AND**

III. Documentation is provided that individual has plasma pyridoxal 5'-phosphate levels are greater than the upper limit of normal at the time of diagnosis (Whyte 2012); **AND**

IV. One or more of the following:
   A. Radiographic evidence of poor bone mineralization including flared and frayed metaphyses, severe/generalized osteopenia or widened growth plates (Whyte 2012); **OR**
   B. Genetic test results that confirm infantile HPP; **OR**
   C. One of the following:
      1. History or presence of nontraumatic postnatal fracture healing; **OR**
      2. History of elevated serum calcium; **OR**
      3. Functional craniosynostosis with decreased head circumference growth; **OR**
      4. Nephrocalcinosis; **OR**
      5. Rachitic chest deformity; **OR**
      6. Respiratory compromise; **OR**
      7. Vitamin B6-responsive seizures; **OR**
      8. Failure to thrive.

Continuation requests for Strensiq (asfotase alfa) may be approved if the following criteria are met:

I. The above criteria are met at the time of initiation; **and**

II. The individual has demonstrated clinical improvement in symptoms following asfotase alfa therapy.

Strensiq may not be approved when the above criteria are not met and for all other indications.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: November 17, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. Whyte MP, Greenberg CR, Salman NJ, et al. Enzyme-replacement therapy in life-threatening hypophosphatasia. N Engl J Med. 2012; 366(10):904-913.
6. Whyte MP, Madson KL, Phillips D, et al. Asfotase alfa therapy for children with hypophosphatasia. *JCI Insight* 2016; 1(9):e85971. Available at: https://df6sxcketz7bb.cloudfront.net/manuscripts/85000/85971/cache/85971.2-20160727111116-covered-253bed37ca4c1ab43d105aefdf7b5536.pdf
7. Whyte MP, Rockman-Greenberg C, Ozono K, et al. Asfotase alfa treatment improves survival for perinatal and infantile hypophosphatasia. J Clin Endocrinol Metab. 2016; 101(1):334-342.
8. Whyte MP, Zhang F, Wenkert D, et al. Hypophosphatasia: validation and expansion of the clinical nosology for children from 25 years experience with 173 pediatric patients. Bone. 2015; 75:229-239.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.

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