

ALASKA MEDICAID  
Prior Authorization Criteria

**Strensiq™  
(asfotase alfa)**

**FDA INDICATIONS AND USAGE**<sup>1</sup>

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

**APPROVAL CRITERIA**<sup>1,2,3</sup>

1. Medication is being prescribed by or in consultation with an endocrinologist or a specialist experienced in treating metabolic disorders **AND;**
2. Patient has a documented diagnosis of perinatal/infantile- or juvenile- onset hypophosphatasia confirmed by elevated urine concentration of phosphoethanolamine (PEA), elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior, or elevated urinary inorganic pyrophosphate (PPi) **AND;**
3. The patient was less than 18 years of age at onset **AND;**
4. The patient has clinical manifestations of hypophosphatasia (I.E. skeletal abnormalities, respiratory problems, failure to thrive, rickets, etc.) **AND;**
5. The patient has had a low baseline ALP activity adjusted for age **AND;**
6. Patient has at least one variant in the ALPL gene.

**DENIAL CRITERIA**<sup>1,2</sup>

1. Failure to meet approval criteria **OR;**
2. The provider has failed to provide the patients weight for dosing.
3. The formulation is inappropriate for the patient's weight.
  - The 80mg/0.8ml formulation is limited to patients  $\geq 40$ kg due to significant differences in bioavailability relative to the other concentrations.

**CAUTIONS**<sup>1</sup>

- Hypersensitivity reactions have occurred including anaphylaxis.
- Lipodystrophy has been observed and is recommended to rotate injection sites.
- Monitor for Ectopic Calcifications in the eye and kidney using ophthalmologic examinations and renal ultrasounds at baseline and periodically during treatment.

**DURATION OF APPROVAL**

- Approval: Up to 3 months
- Reauthorization: Up to 12 months

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**QUANTITY LIMITS**

- Up to a maximum of 9mg/kg per week

**REFERENCES / FOOTNOTES:**

1. Strensiq™ [Package Insert]. Boston, MA. Alexion Pharmaceutical, INC; June 2020. Available at: [https://alexion.com/documents/strensiq\\_uspi](https://alexion.com/documents/strensiq_uspi) Accessed: July 15, 2020.
2. Hypophosphatasia. U.S.National Library of Medicine. September 2017. Published January 2018. Accessed: July 15, 2020.
3. Whyte MP, Mahuren JD, Vrabel LA, Coburn SP. Markedly increased circulating pyridoxal-5'-phosphate levels in hypophosphatasia. J Clin Invest. 1985;76(2):752-756.