CareSource

PHARMACY POLICY STATEMENT
Indiana Medicaid

DRUG NAME	Strensiq (asfotase alfa)
BILLING CODE	Must use valid NDC
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) QUANTITY LIMIT— up to 9 mg/kg per week
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Strensiq (asfotase alfa) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HYPOPHOSPHATASIA (HPP)

For **initial** authorization:

1. Medication must be prescribed by or in consultation with an endocrinologist or other specialist in metabolic bone disease; AND
2. Member has a diagnosis of hypophosphatasia (HPP) with perinatal/infantile- or juvenile-onset (**before** 18 years of age) with ALL of the following documented:
   a) Serum alkaline phosphatase (ALP) below age-adjusted normal range;
   b) Plasma pyridoxal 5'-phosphate (PLP) elevation;
   c) Radiographic evidence of skeletal abnormality.
3. **Dosage allowed:**
   Perinatal/Infantile-Onset HPP: 2 mg/kg administered subQ three times per week, or 1 mg/kg administered six times per week. The dose may be increased to 3 mg/kg three times per week for insufficient efficacy (e.g., no improvement in respiratory status, growth, or radiographic findings).
   Juvenile-Onset HPP: 2 mg/kg administered subQ three times per week, or 1 mg/kg administered six times per week.

If member meets all the requirements listed above, the medication will be approved for 6 months.

For **reauthorization**:

1. Chart notes must document improvement in clinical signs and symptoms of hypophosphatasia, such as respiratory status, growth, or radiographic (skeletal healing) findings.

If member meets all the reauthorization requirements above, the medication will be approved for an additional 12 months.

CareSource considers Strensiq (asfotase alfa) not medically necessary for the treatment of the following disease states based on a lack of robust clinical controlled trials showing superior efficacy compared to currently available treatments:

- Pseudohypophosphatasia

DATE	ACTION/DESCRIPTION
09/13/2018	New policy for Strensiq created.
04/23/2021	Updated references. Emphasized disease onset must be before age 18 years. Amended diagnostic criteria to be more simplified: Removed pain, growth components; Removed genetic testing requirement; Added PLP measure. Specified renewal criteria.

References:

1. Strensiq [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; June 2020.
2. Mornet E, Nunes ME. Hypophophatasia. 2007 Nov 20 [Updated 2016 Feb 4]. In: Adam MP, Ardinger HH, Pagon RA, et al., editors. GeneReviews® [Internet]. Seattle (WA): University of Washington, Seattle; 1993-2018. Available from: https://www.ncbi.nlm.nih.gov/books/NBK1150/.
3. Whyte MP, Greenberg CR, Salman NJ, et al. Enzyme-Replacement Therapy in Life-Threatening Hypophosphatasia. N Engl J Med 2012; 366:904-913. Available at: http://www.nejm.org/doi/full/10.1056/NEJMoa1106173.
4. Rush ET. Childhood hypophosphatasia: to treat or not to treat. Orphanet J Rare Dis. 2018 Jul 16;13 (1):116.
5. Whyte MP, Madson KL, Phillips D, et al. Asfotase alfa therapy for children with hypophosphatasia. *JCI Insight*. 2016;1(9):e85971. Published 2016 Jun 16. doi:10.1172/jci.insight.85971
6. Whyte MP. Hypophosphatasia - aetiology, nosology, pathogenesis, diagnosis and treatment. *Nat Rev Endocrinol*. 2016;12(4):233-246. doi:10.1038/nrendo.2016.14
7. Kishnani PS, Rockman-Greenberg C, Rauch F, et al. Five-year efficacy and safety of asfotase alfa therapy for adults and adolescents with hypophosphatasia. *Bone*. 2019;121:149-162. doi:10.1016/j.bone.2018.12.011
8. Shapiro JR, Lewiecki EM. Hypophosphatasia in Adults: Clinical Assessment and Treatment Considerations. *J Bone Miner Res*. 2017;32(10):1977-1980. doi:10.1002/jbmr.3226

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