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. Member has diagnosis of hypophosphatasia (HPP) with perinatal/infantile- OR juvenile-onset; AND
2. Member was ≤ 18 years of age at onset of HPP; AND
3. Chart notes submitted with member's clinical evidence of HPP with onset prior to 18 years of age (e.g., biochemical, medical history, radiographic evidence) **and** ANY of the following:
   a) Rickets characteristically presents radiographically with metaphyseal widening and fraying, bowing of long bones, and generalized hypomineralization;
   b) Pain that does not respond to initial conservative treatments such as physical therapy, rest, NSAIDs, or acetaminophen;
   c) Poor growth that impairs function that is not caused by another etiology; AND
4. Member has documented reduced activity of unfractionated serum alkaline phosphatase (ALP) **and** presence of either one or two pathogenic variants in ALPL gene; AND
5. Medication must be prescribed by endocrinologist or other specialist in the area of the member's disease.
6. **Dosage allowed:** Perinatal/Infantile-Onset HPP: 2 mg/kg administered SQ three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen. 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 SQ three times per week, or 1 mg/kg administered six times per week. Injection site reactions may limit the tolerability of the six times per week regimen.

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

For **reauthorization**:

1. Chart notes have been provided that show the member has shown improvement of signs and symptoms of disease.

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.

References:

1. Strensiq [package insert]. New Haven, CT: Alexion Pharmaceuticals, Inc.; October, 2016.
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.

Effective date: 01/01/2019
Revised date: 09/13/2018