CareSource

| PHARMACY POLICY STATEMENT<br>**Arkansas PASSE** | |
|---|---|
| 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)<br>QUANTITY LIMIT— up to 9 mg/kg per week |
| LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY | Click Here |

Strensiq (asfotase alfa) 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. 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
3. Member has documented reduced activity of unfractionated serum alkaline phosphatase (ALP) **and** presence of either one or two pathogenic variants in ALPL gene.
4. **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. |
| **12/22/2021** | Removed age requirement and prescriber specialty requirement. |

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: 01/01/2022
Revised date: 12/22/2021