asfotase alfa (Strensiq)

Commercial Medical Benefit Drug Policy

Place of Service

Office Administration

Self-Administration *(may be covered by your Pharmacy Benefit)*

Drug Details

USP Category: GENETIC OR ENZYME OR PROTEIN DISORDER: REPLACEMENT, MODIFIERS, TREATMENT

Mechanism of Action: nonspecific alkaline phosphatase

HCPCS:

C9399:Unclassified drugs or biologicals

J3490:Unclassified drugs

J3590:Unclassified biologics

How Supplied:

18 mg/0.45 mL, 28 mg/0.7 mL, 40 mg/mL, 80 mg/0.8 mL single dose vials

Condition(s) listed in policy *(see coverage criteria for details)*

- Perinatal/Infantile-Onset or Juvenile-Onset Hypophosphatasia (HPP)

Any condition not listed in this policy requires a review to confirm it is medically necessary. For conditions that have not been approved for intended use by the Food and Drug Administration (i.e., off-label use), the criteria outlined in the Health and Safety Code section 1367.21 must be met.

Special Instructions and Pertinent Information

Provider must submit documentation (such as office chart notes, lab results or other clinical information) to ensure the member has met all medical necessity requirements.

The member's specific benefit may impact drug coverage. Other utilization management processes, and/or legal restrictions may take precedence over the application of this clinical criteria.

For billing purposes, drugs must be submitted with the drug's assigned HCPCS code (as listed in the drug policy) and the corresponding NDC (national drug code). An unlisted, unspecified, or miscellaneous code should not be used if there is a specific code assigned to the drug.

Coverage Criteria
The following condition(s) require Prior Authorization/Preservice.

Perinatal/Infantile-Onset or Juvenile-Onset Hypophosphatasia (HPP)

Meets medical necessity if all the following are met:

Initial:

1. Being prescribed by a pediatric specialist (i.e. orthopedic surgeon, pediatric endocrinologist, neonatal pediatrician, medical geneticist)
2. Patient's onset of symptoms occurred at 12 years of age or under
3. Not being used for adult-onset HPP
4. Not being used for odonto- or pseudo- HPP
5. Chart notes support the diagnosis of HPP by BOTH of the following (a and b):

a. History of one or more objective signs and symptoms consistent with HPP (e.g. radiographic evidence of skeletal hypomineralization, rickets or rachitic chest deformity, evidence of flared and/or frayed metaphyses, widened growth plates, gracile ribs, below normal Z scores for height or weight, non-healing or non-traumatic fractures, craniosynostosis, severe and generalized osteopenia)
b. Laboratory evidence of low ALP activity for age and gender (below lower limit of laboratory normal)

6. Dose does not exceed FDA-approved maximum

Reauthorization:

1. Patient is experiencing continued positive clinical response (e.g. improvement in bone mineralization, growth, and/or benefit in physical, neurologic, or respiratory function)
2. Dose does not exceed FDA-approved maximum

Coverage Period:
Yearly, based on continued response to therapy

ICD-10:
E83.30, E83.31, E83.32, E83.39

Additional Information

- Strensiq has a Boxed Warning for hypersensitivity reactions including anaphylaxis. Patients treated with enzyme replacement therapies have experienced life-threatening hypersensitivity reactions, including anaphylaxis. Anaphylaxis has occurred during the early course of enzyme replacement therapy and after extended duration of therapy. Strensiq should be initiated under the supervision of a healthcare provider with appropriate medical monitoring and support measures.
- Table 1: Serum or plasma alkaline phosphatase reference ranges

Age	Male (U/L)	Female (U/L)
0-30 days	60-320	60-320
1-11 months	70-350	70-350
1-3 years	125-320	125-320
4-6 years	150-370	150-370
7-9 years	150-440	150-440
10-11years	150-470	150-530
12-13 years	160-500	110-525
14-15 years	130-530	55-305
16-19 years	60-270	40-120
20 years +	40-120	40-120

Adapted from ARUP laboratories: http://ltd.aruplab.com/Tests/Pub/0021020

- Table 2: Weight-Based Dosing

Body weight (kg)	Mg per dose	vials per dose required	WEEKLY total # vials	Mg per dose	vials per dose required	WEEKLY total # vials

2mg/kg Three Times per Week				1 mg/kg Six Times per Week		
3	6	1 x 18 mg	3 x 18 mg	3	1 x 18 mg	6 x 18 mg
4	8	1 x 18 mg	3 x 18 mg	4	1 x 18 mg	6 x 18 mg
5	10	1 x 18 mg	3 x 18 mg	5	1 x 18 mg	6 x 18 mg
6	12	1 x 18 mg	3 x 18 mg	6	1 x 18 mg	6 x 18 mg
7	14	1 x 18 mg	3 x 18 mg	7	1 x 18 mg	6 x 18 mg
8	16	1 x 18 mg	3 x 18 mg	8	1 x 18 mg	6 x 18 mg
9	18	1 x 18 mg	3 x 18 mg	9	1 x 18 mg	6 x 18 mg
10	20	1 x 28 mg	3 x 28 mg	10	1 x 18 mg	6 x 18 mg
15	30	1 x 40 mg	3 x 40 mg	15	1 x 18 mg	6 x 18 mg
16-18	32-36	1 x 40 mg	3 x 40 mg	16-18	1 x 18 mg	6 x 18 mg
19	38	1 x 40 mg	3 x 40 mg	19	1 x 28 mg	6 x 28 mg
20	40	1 x 40 mg	3 x 40 mg	20	1 x 28 mg	6 x 28 mg
21-24	42-48	2 x 28 mg	6 x 28 mg	21-24	1 x 28 mg	6 x 28 mg
25	50	2 x 28 mg	6 x 28 mg	25	1 x 28 mg	6 x 28 mg
26-28	52-56	2 x 28 mg	6 x 28 mg	26-28	1 x 28 mg	6 x 28 mg
29	58	2 x 40 mg	6 x 40 mg	29	2 x 18 mg	12 x 18 mg
30	60	2 x 40 mg	6 x 40 mg	30	1 x 40 mg	6 x 40 mg
31-34	62-68	2 x 40 mg	6 x 40 mg	31-34	1 x 40 mg	6 x 40 mg
35	70	2 x 40 mg	6 x 40 mg	35	1 x 40 mg	6 x 40 mg
36-39	72-78	2 x 40 mg	6 x 40 mg	36-39	1 x 40 mg	6 x 40 mg
40	80	1 x 80 mg	3 x 80 mg	40	1 x 40 mg	6 x 40 mg
41-49	82-98	2 x 80 mg	6 x 80 mg	41-49	2 x 28 mg	12 x 28 mg
50	100	2 x 80 mg	6 x 80 mg	50	1 x 80 mg	6 x 80 mg
60	120	2 x 80 mg	6 x 80 mg	60	1 x 80 mg	6 x 80 mg
70	140	2 x 80 mg	6 x 80 mg	70	1 x 80 mg	6 x 80 mg
80	160	2 x 80 mg	6 x 80 mg	80	1 x 80 mg	6 x 80 mg
90				90	2 x 80 mg	12 x 80 mg
100				90	2 x 80 mg	12 x 80 mg

- Table 3: Escalated Weight-Based Dosing

Body weight (kg)	Mg per dose	Vials per dose required	WEEKLY total # vials
3mg/kg Three Times per Week			
3 -6	9-18	1 x 18 mg	3 x 18 mg
7-9	21-27	1 x 28 mg	3 x 28 mg
10	30	1 x 40 mg	3 x 40 mg
15	45	2 x 28 mg	6 x 28 mg
20	60	2 x 40 mg	6 x 40 mg
25	75	2 x 40 mg	6 x 40 mg

References

1. Strensiq (asfotase alfa). Prescribing information. Alexion Pharmaceuticals, Inc., Boston, MA. July 2024.
2. Bowden SA and Foster BL Profile of asfotase alfa in the treatment of hypophosphatasia: design, development, and place in therapy. *Drug Des Devel Ther*. 2018; 12: 3147–3161. Available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6161731/.
3. Pallais JC. Hypophosphatasia: Clinical manifestations and diagnosis. UpToDate. www.uptodate.com. Last updated Mar 24, 2025. Literature review current through May 2025.

Review History

Date of Last Annual Review: 3Q2025
Changes from previous policy version:

- New policy due to change in PI for requirement of initial dosing to be done in office.

Blue Shield of California Medication Policy to Determine Medical Necessity
Reviewed by P&T Committee