MEDICATION POLICY:
Strensiq (asfotase alfa)

Generic Name: asfotase alfa

Brand Name: Strensiq

Preferred: N/A

Non-Preferred: N/A

VSI-Excluded Drug: Strensiq

Date of Origin: 4/27/2026

Date Last Reviewed / Revised: 4/27/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through V are met)

I. Documented diagnosis of perinatal/infantile- and juvenile-onset hypophosphatasia (HPP) AND must meet ALL criteria listed:

   A. Diagnosis is supported by all of the following:

      i. Presence of a known pathological mutation in the ALPL gene as detected by ALPL molecular genetic testing

      ii. Age-adjusted serum levels of alkaline phosphatase (ALP) are persistently below the lower limit of normal (i.e. present on at least 2 separate measurements)

      iii. Documentation satisfying one of the following (1 or 2):

         1. Plasma pyridoxal 5'-phosphate (PLP) levels are greater than the upper limit of normal **OR**

         2. Urinary phosphoethanolamine (PEA) levels are greater than the upper limit of normal

II. Documented onset of disease at < 18 years of age

III. Treatment must be prescribed by or in consultation with an endocrinologist or specialist experienced in the treatment of metabolic bone disorders.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Adult-onset hypophosphatasia

OTHER CRITERIA

- The requested dosage must be appropriate based on the patient's weight and may be administered as divided doses three times per week or six times per week.
- For requests for the Strensiq 80 mg/0.8 mL vial, the patient's weight must be ≥ 40 kg.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantity sufficient for the appropriate weight-based dose per 28 days
    - For diagnosis of perinatal/infantile-onset hypophosphatasia, the request may not exceed a dose of 9 mg/kg per week
    - For diagnosis of juvenile-onset hypophosphatasia, the request may not exceed a dose of 6 mg/kg per week

APPROVAL LENGTH

- **Authorization:** 6 months
- **Re-Authorization:** 6 months, with an updated letter of medical necessity or progress notes showing clinically significant improvement or maintenance with treatment and that the patient is adherent to treatment and the medication is tolerated. Clinically significant improvement or maintenance may be demonstrated by ongoing improvement in clinical symptoms or by a ≥ 2-point increase from baseline in the Radiographic Global Impression of Change (RGI-C).

APPENDIX

N/A

REFERENCES

1. Strensiq. Prescribing Information. Alexion Pharmaceuticals, Inc.; July 2024. Accessed April 24, 2026. https://alexion.us/-/media/alexion_global/documents/regulatory/north-america/usa/2024/english/strensiq_uspi.pdf
2. Michigami T, Ohata Y, Fujiwara M, et al. Clinical Practice Guidelines for Hypophosphatasia. *Clin Pediatr Endocrinol*. 2020;29(1):9-24. doi: 10.1297/cpe.29.9.
3. Seefried L, Genest F, Brandi ML, et al. Diagnosis and Treatment of Hypophosphatasia. *Calcif Tissue Int*. 2025 Mar 6;116(1):46. doi: 10.1007/s00223-025-01356-y.