Asfotase alfa (Strensiq™)	Place of Service **Self-Administration** (*May be covered under the pharmacy benefit)* **HCPCS: J3590** **NDC:** • 18 mg/0.45 mL (single dose vial): o NDC 25682-0010-01 (1 vial) o NDC 25682-0010-12 (12 vials) • 28 mg/0.7 mL (single dose vial): o NDC 25682-0013-01 (1 vial) o NDC 25682-0013-12 (12 vials) • 40 mg/mL (single dose vial): o NDC-25682-0016-01 (1 vial) o NDC-25682-0016-12 (12 vials) • 80 mg/0.8 mL (single dose vial): o NDC 25682-0019-01 (1 vial) o NDC 25682-0019-12 (12 vials)

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

- Perinatal/infantile-onset or Juvenile-onset hypophosphatasia (HPP)

AHFS therapeutic class: Enzymes

Mechanism of action: Tissue nonspecific alkaline phosphatase

(1) Special Instructions and Pertinent Information

Strensiq is managed under the Outpatient Pharmacy Benefit. Please contact the member's Pharmacy Benefit for information on how to obtain this drug.

To submit a request to the Medical Benefit, please submit clinical information for prior authorization review and include medical rationale why the patient cannot self-administer this drug in the home.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Strensiq™ (asfotase alfa) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Perinatal/infantile-onset or Juvenile-onset hypophosphatasia (HPP)

1. Prescribed by a pediatric specialist, **AND**
2. Patient's onset of symptoms occurred at ≤ 12 years of age, **AND**
3. 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), **and**
    b. Laboratory evidence of low ALP activity for age and gender (below lower limit of laboratory normal)

Covered Dose

Perinatal/infantile-onset or Juvenile-onset: Up to 9 mg/kg SC per week (symptoms documented ≤ 6 months of age)
Juvenile-onset: Up to 6 mg/kg SC per week

Coverage Period
Indefinite

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

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Strensiq™ (asfotase alfa) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Blue Shield's research indicates there is inadequate clinical evidence to support off-label use of this drug for the following conditions (Health and Safety Code 1367.21):

- Odonto-HPP (dental abnormalities without other complications)
- Adult onset HPP

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied:

- 18 mg/0.45 mL, 28 mg/0.7 mL, 40 mg/mL, or 80 mg/0.8 mL (solution in single-use vials)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- 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.
- DrugDex®. Available by subscription at http://www.micromedexsolutions.com/home/dispatch
- Strensiq® (asfotase alfa) [Prescribing information]. Boston, MA: Alexion Pharmaceuticals, Inc.; 6/2020.

(7) Policy Update

Date of last revision: 1Q2022
Date of next review: 3Q2022
Changes from previous policy version:

- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee