Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 13, 2025

Strensiq® (asfotase alfa)

LENGTH OF AUTHORIZATION: Initial therapy: 6 months
Continuation of therapy: Up to 1 year

REVIEW CRITERIA:

- Patient must be < 18 years of age; **AND**
- Patient must have a documented diagnosis of one of the following:
  Perinatal/infantile-onset hypophosphatasia (HPP) characterized by, but not limited to:
  - Failure to thrive
  - Hypercalcemia, hyperphosphatemia and hypercalciuria
  - Brittle bones and lack of muscular development
  - Bone malformation
  - Rachitic chest deformity
  - Vitamin B6-dependent seizures
  - Failure to thrive
  - Short, bowed arms and legs

  -OR-

  Juvenile-onset hypophosphatasia (HPP) characterized by, but not limited to:
  - Premature deciduous tooth loss
  - Rickets
  - Bone and joint pain
  - Hypotonia and muscle weakness
  - Short stature
  - Skeletal malformations
  - Walking delay
  - Waddling gait
- Molecular genetic testing results confirming mutations in the ALPL gene.
- Serum alkaline phosphatase (ALP) test results confirming low or loss of activity (adjusted for gender and age).
- Test results demonstrating elevated tissue-nonspecific alkaline phosphatase (TNSALP) substrate levels (e.g., inorganic pyrophosphate [PPi], pyridoxal 5'-phosphate [PLP], or phosphoethanolamine [PEA]).
- Radiographic findings consistent with hypophosphatasia (e.g., alveolar bone loss, bone deformation, fractures, metaphyseal defects, osteomalacia, reduced bone mineral density, widened bones in the wrists and ankles).
- Documentation that an ophthalmologic examination and renal ultrasound were performed at baseline.

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	August 13, 2025

- Medication must be prescribed by or in consultation with a physician who specializes in the treatment of HPP or a related specialist (e.g., endocrinologist, geneticist).

CONTINUATION OF THERAPY:

- Patient met initial review criteria; **AND**
- Documentation of improved clinical response (e.g., improvement in radiologic findings from baseline, improved respiratory function, decreased plasma TNSALP substrate levels); **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., patient does not have any signs or symptoms of ophthalmic or renal ectopic calcifications); **AND**
- Follow-up ophthalmologic examination and renal ultrasound have been performed periodically during the treatment course; **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 18 mg/0.45 mL, 28 mg/0.7 mL, 40 mg/mL, and 80 mg/0.8 mL solution in single-dose vials for subcutaneous injection.