AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Strensiq (asfotase alfa)	Page:	1 of 4
Effective Date:	3/23/2026	Last Review Date:	2/9/2026
Applies to:	☒Illinois ☒Florida Kids ☒Maryland ☒Pennsylvania Kids ☒Virginia		

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Strensiq under the patient's prescription drug benefit.

Description:

Strensiq is indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

All other indications are considered experimental/investigational and not medically necessary.

Applicable Drug List:

Non-Formulary: Strensiq

Policy/Guideline:

Prescriber Specialties
This medication must be prescribed by or in consultation with an endocrinologist, geneticist, or a physician specializing in the treatment of metabolic bone disorders

Documentation:
Submission of the following information is necessary to initiate the prior authorization review:

Initial Requests:
- Members who are 18 years of age or older at the time of the request: Chart notes or medical record documentation of presence of condition before 18 years of age
- Chart notes or medical record documentation confirming diagnosis by EITHER of the following:
  - Genetic test results confirming a pathogenic variant in the ALPL gene
  - Submission of ALL of the following:
    - Radiographic imaging demonstrating skeletal abnormalities (see Appendix B)
    - Serum alkaline phosphatase (ALP) level below the gender and age-specific reference range of the laboratory performing the test
    - Elevated tissue non-specific alkaline phosphatase (TNSALP) substrate level (e.g., serum pyridoxal 5-phosphate [PLP] level, urine phosphoethanolamine [PEA] level, or urinary or plasma inorganic pyrophosphate [PPi] level)
    - Chart notes, medical record documentation, or laboratory reports of ophthalmology examination and renal ultrasound at baseline)

Continuation Requests:
- Chart notes or medical record documentation showing benefit to therapy by ONE of the following:

  - Radiographic Global Impression of Change (RGI-C) rating
  - Height and weight measurements as measured by z-scores
  - Modified Performance Oriented Mobility Assessment-Gait (MPOMA-G) score
  - Distance walked in the 6 Minute Walk Test (6MWT)
  - Timed Up & Go (TUG) Test
  - Chair Rise Test
  - Lower Extremity Function Scale (LEFS)
- Chart notes, medical record documentation, or laboratory reports of ophthalmology examination and renal function assessment

Coverage Criteria:

Perinatal/Infantile- and Juvenile-Onset Hypophosphatasia (HPP)
Authorization of 12 months may be granted for treatment of HPP when ALL of the following criteria are met:

- Member has clinical signs and/or symptoms of hypophosphatasia (see Appendix A)
  The onset of the disease was perinatal/infantile or juvenile (prior to 18 years of age)
  Diagnosis is confirmed by EITHER of the following criteria:
  - Presence of a known pathogenic variant in the ALPL gene as detected by molecular genetic testing
  - Member meets ALL of the following criteria:
    - Radiographic imaging demonstrating skeletal abnormalities (see Appendix B)
    - Serum alkaline phosphatase (ALP) level below the gender- and age-specific reference range of the laboratory performing the test
    - Elevated tissue-nonspecific alkaline phosphatase (TNSALP) substrate level (e.g., serum PLP level, urine PEA level, or urinary or plasma PPi level) as defined by the laboratory performing the test
- Member has had an ophthalmology examination and renal ultrasound at baseline
- Member's weekly dose will not exceed EITHER of the following:
  - 9 mg/kg weekly in a member with perinatal/infantile-onset HPP
  - 6 mg/kg weekly in a member with juvenile-onset HPP

Continuation of Therapy:

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria who are currently receiving the requested medication through a paid pharmacy or medical benefit when ALL of the following criteria are met:

- Member is experiencing benefit from therapy as demonstrated by improvement in ONE of the following from baseline:
  - Skeletal manifestations as assessed by the Radiographic Global Impression of Change (RGI-C) scale

- Height and weight as measured by z-scores, and member is less than 18 years of age
- Step length by at least one point in either foot based on the Modified Performance Oriented Mobility Assessment-Gait (MPOMA-G) scale
- Six Minute Walk Test (6MWT)
- Timed Up & Go (TUG) Test
- Chair Rise Test
- Lower Extremity Function Scale (LEFS)

- Member is monitored for signs and symptoms of ophthalmic and renal ectopic calcifications and for changes in vision or renal function
- Member's weekly dose will not exceed EITHER of the following:
  - 9 mg/kg weekly in a member with perinatal/infantile-onset HPP
  - 6 mg/kg weekly in a member with juvenile-onset HPP

Approval Duration and Quantity Restrictions:

Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

Appendix

Appendix A. Examples of Signs and Symptoms of HPP

Perinatal/Infantile-Onset HPP

- Generalized hypomineralization with rachitic features, chest deformities and rib fractures
- Skeletal abnormalities (e.g., short limbs, abnormally shaped chest, soft skull bone)
- Respiratory problems (e.g., pneumonia)
- Hypercalcemia
- Failure to thrive
- Severe muscular hypotonia and weakness
- Nephrocalcinosis secondary to hypercalciuria
- Swallowing problems
- Seizures

Juvenile-Onset HPP

- Premature loss of deciduous teeth
- Failure to thrive with anorexia, nausea, and gastrointestinal problems
- Short stature with bowed legs or knock knees
- Skeletal deformities (e.g., enlarged wrist and ankle joints, abnormal skull shape)
- Bone and joint pain
- Rickets

- Fractures
- Delayed walking
- Waddling gait

Appendix B. Examples of Radiographic Findings that Support HPP Diagnosis

- Infantile rickets
- Alveolar bone loss
- Focal bony defects of the metaphyses
- Metatarsal stress fractures or metaphyseal fractures
- Osteomalacia with lateral pseudofractures
- Osteopenia, osteoporosis, or low bone mineral content for age (as detected by dual-energy x-ray absorptiometry [DEXA])
- Prenatal long bone bowing with osteochondral spurs

References:

1. Strensiq [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; July 2024.
2. Bianchi ML. Hypophosphatasia: an overview of the disease and its treatment. Osteoporos Int. 2015; 26(12):2743-57.
3. Dahir KM, Nunes ME. Hypophosphatasia. GeneReviews [Internet]. Available at http://www.ncbi.nlm.nih.gov/books/NBK1150. Updated March 27, 2025. Accessed August 13, 2025.
4. Whyte, MP. Hypophosphatasia: An overview for 2017. Bone. 2017;102:15-25.