Updated: 10/2018
PARP Approved: 10/2018

Gateway Health
Prior Authorization Criteria
Strensiq (Asfotase Alfa)

All requests for Strensiq (Asfotase Alfa) require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Strensiq (Asfotase Alfa) Prior Authorization Criteria:

For all requests for Strensiq (Asfotase Alfa) all of the following criteria must be met:

- Must provide laboratory documentation of **ALL** the following:
  - Baseline serum alkaline phosphatase (ALP) activity below the age and gender-adjusted normal range
  - Presence of a tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing recognized to be deleterious with this condition
  - Baseline laboratory documentation confirming elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate, urinary inorganic pyrophosphate, serum or urine phosphoethanolamine) without B6 or other MVI supplementation.
- The requested dose and frequency is in accordance with FDA-approved labeling, nationally recognized compendia, and/or evidence-based practice guidelines
- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders

Coverage may be provided with a diagnosis of perinatal, infantile-onset, or juvenile-onset hypophosphatasia and the following criteria is met:

- Documentation of at least **ONE** of the following prior to the age of 18:
  - Symptoms:
    - Vitamin B6-dependent seizures
    - Respiratory insufficiency
    - Hypotonia
    - Loss of deciduous teeth before the age of four
    - Low trauma or non-traumatic fractures, with supporting historical documentation and radiographic evidence of the fracture.
    - Gait disturbance such as delayed walking or waddling gait. Must provide results of a recent (within 12 months) 6 minute walk test showing lower than expected results.
    - Osteopenia, osteoporosis, or low bone mineral content for age attributable to hypophosphatasia
  - Radiographic evidence:
    - Knock knees
    - Rachitic chest
    - Bowing of leg(s)
    - Craniosynostosis

        - Infantile rickets
        - Osteochondral spurs
- **Initial Duration of Approval:** 6 months
- **Reauthorization criteria**
    - Must provide laboratory documentation confirming a decrease in level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g. serum pyridoxal 5'-phosphate, urinary inorganic pyrophosphate, serum or urine phosphoethanolamine)
    - Must have claims history or chart documentation supporting adherence to medication
    - Must provide documentation of annual renal ultrasound and retinal exam for calcium deposition
    - Must provide chart documentation of one or more of the following that were originally utilized to support initial medical necessity for this medication:
        - Radiographic evidence of improvement in skeletal deformities or growth
        - Improvement in 6 minute walk test
        - Improvement in bone density
        - Reduction in fractures
- **Reauthorization Duration of Approval:** 12 months

Coverage may be provided for any non-FDA labeled indication if it is determined that the use is a medically accepted indication supported by nationally recognized pharmacy compendia or peer-reviewed medical literature for treatment of the diagnosis(es) for which it is prescribed. These requests will be reviewed on a case by case basis to determine medical necessity.

When criteria are not met, the request will be forwarded to a Medical Director for review. The physician reviewer must override criteria when, in their professional judgment, the requested medication is medically necessary.

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STRENSIQ (ASFOTASE ALFA)
PRIOR AUTHORIZATION FORM

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health℠ Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

REQUESTED DRUG INFORMATION

Medication:	Strength:
Frequency:	Duration:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:

Billing Information

This medication will be billed: ☐ at a pharmacy **OR**
☐ medically (if medically please provide a JCODE:_____

Place of Service: ☐ Hospital ☐ Provider's office ☐ Member's home ☐ Other

Place of Service Information

Name:	NPI:
Address:	Phone:

MEDICAL HISTORY (Complete for ALL requests)

Does the member have a tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation? ☐ Yes ☐ No
If Yes, please provide ALPL genomic testing documentation.

Does the member have at least one the following symptoms prior to the age of 18:

☐ Vitamin B6-dependent seizures
☐ Hypotonia
☐ Low trauma or non-traumatic fractures
☐ Osteopenia, osteoporosis, or low bone mineral content for age
☐ Respiratory insufficiency
☐ Premature loss of deciduous teeth
☐ Gait disturbance

Does the member have radiographic evidence of at least one of the following prior to the age of 18:

☐ Knock knees
☐ Bowing of leg(s)
☐ Infantile rickets
☐ Rachitic chest
☐ Craniosynostosis
☐ Osteochondral spurs

CURRENT or PREVIOUS THERAPY

Medication Name	Strength/ Frequency	Dates of Therapy	Status (Discontinued & Why/Current)

Gateway Health

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STRENSIQ (ASFOTASE ALFA)
PRIOR AUTHORIZATION FORM (CONTINUED) – PAGE 2 OF 2

Please complete and fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable to Gateway Health[SM] Pharmacy Services. **FAX:** (888) 245-2049
If needed, you may call to speak to a Pharmacy Services Representative.
PHONE: (800) 392-1147 Monday through Friday 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:
Health Options ID:	Member weight: _____pounds or _____kg

REFERENCE VALUES

Lab	Initial (Pre-Treatment) Value	Reference Range	Date	Post-Therapy Value (Reauthorization only)	Reference Range	Date
Serum Alkaline Phosphatase (ALP)		**(adjusted for age and gender)**		**N/A**		
Serum Pyridoxal 5'-Phosphate						
Urinary Inorganic Pyrophosphate						
Serum or Urine Phosphoethanolamine						
Other Tissue Non-Specific Alkaline Phosphate (TNSALP) Substrate [Please specify type and source:] _____ _____						

REAUTHORIZATION

Has the member been adherent to the medication? ☐ Yes ☐ No
If Yes, please provide documentation.

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date