

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.

**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 HealthSM 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? <input type="checkbox"/> Yes <input type="checkbox"/> 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:

- | | |
|--|--|
| <input type="checkbox"/> Vitamin B6-dependent seizures | <input type="checkbox"/> Premature loss of deciduous teeth |
| <input type="checkbox"/> Hypotonia | <input type="checkbox"/> Gait disturbance |
| <input type="checkbox"/> Low trauma or non-traumatic fractures | |
| <input type="checkbox"/> Osteopenia, osteoporosis, or low bone mineral content for age | |
| <input type="checkbox"/> Respiratory insufficiency | |

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

- | | |
|--|--|
| <input type="checkbox"/> Knock knees | <input type="checkbox"/> Craniosynostosis |
| <input type="checkbox"/> Bowing of leg(s) | <input type="checkbox"/> Osteochondral spurs |
| <input type="checkbox"/> Infantile rickets | |
| <input type="checkbox"/> Rachitic chest | |

CURRENT or PREVIOUS THERAPY

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

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

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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

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