HIGHMARK WHOLECARE

Updated: 9/2024
PARP Approved: 10/2024

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.

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

- Must be prescribed by or in consultation with a physician who specializes in the treatment of inherited metabolic disorders
- Documentation of at least **ONE** of the following prior to the age of 18:
    - Clinical signs and symptoms of HPP:
        - 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 of HPP:
        - Knock knees
        - Rachitic chest
        - Bowing of leg(s)
        - Craniosynostosis
        - Infantile rickets
        - Osteochondral spurs
- 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
- **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 – PAGE 1 of 2

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

PROVIDER INFORMATION

Requesting Provider:	Provider NPI:
Provider Specialty:	Office Contact:
State license #:	Office NPI:
Office Address:	Office Phone:
	Office Fax:

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REQUESTED DRUG INFORMATION

Medication:	Strength:	
Directions:	Quantity:	Refills:
Is the member currently receiving requested medication? ☐ Yes ☐ No	Date Medication Initiated:	

Billing Information

This medication will be billed: ☐ at a pharmacy **OR** ☐ medically, 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)

Diagnosis:	ICD Code:

Does the member have a tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation? ☐ Yes (documentation is required) ☐ No

Which of the following symptoms were present prior to the age of 18 (check all that apply):

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

Does the member have radiographic evidence of any of the following prior to the age of 18 (check all that apply):

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

PRE-TREATMENT LAB VALUES

Lab	Value	Reference Range	Date
Serum Alkaline Phosphatase (ALP)			
Serum Pyridoxal 5'-Phosphate			
Urinary Inorganic Pyrophosphate			
Serum or Urine Phosphoethanolamine			

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

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If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (800) 392-1147 Mon – Fri 8:30am to 5:00pm

MEMBER INFORMATION

Member Name:	DOB:	
Member ID:	Member weight:	Height:

REAUTHORIZATION

Has the member been adherent to treatment regimen? ☐ Yes ☐ No

Has a renal ultrasound and retinal exam been done in the past year? ☐ Yes ☐ No

Has there been a decrease in any of the following? If so, please specify the current value and date of the test:
- ☐ Serum Pyridoxal 5'-Phosphate Lab value: _____ Date: _____
- ☐ Urinary Inorganic Pyrophosphate Lab value: _____ Date: _____
- ☐ Serum or Urine Phosphoethanolamine Lab value: _____ Date: _____

What improvements have been experienced since starting therapy (check all that apply and provide chart documentation):
- ☐ Radiographic evidence of improvement in skeletal deformities or growth
- ☐ Improvement in 6 minute walk test
- ☐ Improvement in bone density
- ☐ Reduction in fractures
- ☐ Other: _____

SUPPORTING INFORMATION or CLINICAL RATIONALE

Prescribing Provider Signature	Date