HIGHMARK HEALTH OPTIONS

Updated: 09/2025
DMMA Approved: 09/2025

Request for Prior Authorization for Strensiq (asfotase alfa)
Website Form – www.highmarkhealthoptions.com
Submit request via: Fax - 1-855-476-4158

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:

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.

Drugs are authorized in generic form unless the branded product is on the preferred drug list or the prescriber has indicated in writing that the branded product is medically necessary. If only the branded product is on the preferred drug list, the generic form will be considered non-preferred and shall not require the prescriber to indicate in writing that the branded product is medically necessary.

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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 Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

PROVIDER INFORMATION

Requesting Provider:	NPI:
Provider Specialty:	Office Contact:
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:	

Is this medication being used for a chronic or long-term condition for which the medication may be necessary for the life of the patient? ☐ Yes ☐ No

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			

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: _____

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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 Highmark Health Options Pharmacy Services. **FAX: (855) 476-4158**
If needed, you may call to speak to a Pharmacy Services Representative. **PHONE**: (844) 325-6251 Mon – Fri 8 am to 7 pm

MEMBER INFORMATION

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

REAUTHORIZATION (continued)

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