# Strensiq (asfotase alfa)

**Coverage Criteria:**

Reserved for patients meeting all of the following criteria:

1. The patient has a diagnosis of Perinatal/Infantile-or juvenile-onset hypophosphatasia (HPP); AND,
2. The patient was 18 years of age or younger at disease onset; AND,
3. Diagnosis has been confirmed by:
    a. Tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing (medical chart documentation required); OR,
    b. Both of the following (medical chart documentation required):
        i. Patient had low baseline alkaline phosphatase (ALP) activity (age adjusted); AND,
        ii. Diagnosis of HPP was confirmed by presence of elevated ALP substrate levels (increased serum pyridoxal 5-phosphate (PLP) or urinary phosphoethanolamine (PEA)); AND,
4. When prescribed by a provider specializing in genetics and metabolism; AND,
5. The patient and/or guardian has attested that they will adhere to the treatment plan; AND,
6. When prescribed according to the FDA approved regimen of 6mg/kg per week (generally either 2mg/kg three times weekly or 1mg/kg six times weekly) initially and then up to 9mg/kg per week.

**Coverage Duration:**

Initial authorizations will be for 6 months.

**Renewal Criteria:**

Annual reauthorizations will require all of the following:

1. The patient has been seen by the prescriber within the past 12 months; AND,
2. There has been a clinically relevant decrease from baseline in tissue-nonspecific alkaline phosphatase (TNSALP) substrate levels (either serum pyridoxal 5-phosphate (PLP) or urinary phosphoethanolamine (PEA)). Medical chart documentation is required; AND,
3. The patient has remained adherent to Strensiq therapy; AND,
4. Strensiq is prescribed according to the FDA approved dosing regimen.

P&T Date: August 2016, February 2022, February 2023
Effective Date: 1/1/2017, 4/1/2022, 4/1/2023