Pharmacy Drug Policy Checklist

POLICY NAME	Strensiq (asfotase alfa)	POLICY #	2453P

Criteria

Coverage Criteria

☐ **1.1** Documented diagnosis of Juvenile-Onset Hypophosphatasia or Perinatal or Infant-Onset Hypophosphatasia defined ONE of the following:

- Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 years (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures) OR
- Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., craniosynostosis, infantile rickets, nontraumatic fractures)

☐ **1.2** Prescribed by a geneticist (gene doctor), endocrinologist (hormone doctor), or specialist in the treatment of hypophosphatasia or related disorders

☐ **1.3** Documentation of ONE of the following:

- Low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-adjusted normal range AND an elevated level of tissue non-specific alkaline phosphatase (TNSALP) substrate (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level]) OR
- Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing

☐ **1.4** Review of chart notes documenting diagnosis and confirming that patient has met all of the above requirements for treatment with Strensiq by both a pharmacist and medical director