Pharmacy Drug Policy & Procedure

Policy Name:	Strensiq (asfotase alfa)	Policy #:	2453P

Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Strensiq (asfotase alfa).

Statement of the Policy

Health Alliance Medical Plans will approve the use of Strensiq (asfotase alfa) under the Specialty Pharmacy benefit when the following criteria have been met.

Criteria

1. 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

2. Managed Dose Limit

2.1 9 mg/kg/week for perinatal/infantile onset hypophosphatasia

2.2 6 mg/kg/week for juvenile-onset hypophosphatasia

3. Approval Period

3.1 Initial Approval: 12 months

3.2 Subsequent Approvals: 12 months with documentation of clinical response based on decrease from baseline in 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]

CPT Codes

HCPCS Codes

References

1. Strensiq (asfotase alfa) [prescribing information]. Boston, MA: Alexion Pharmaceuticals Inc; July 2024.
2. Kishnani PS, Rockman-Greenberg C, Rauch F, et al. Five-year efficacy and safety of asfotase alfa therapy for adults and adolescents with hypophosphatasia. Bone. 2019;121:149-162.
3. Whyte MP, Madson KL, Phillips D, et al: Asfotase alfa therapy for children with hypophosphatasia. JCI Insight 2016; 1(9):e85971.
4. Whyte MP, Rockman-Greenberg C, Ozono K, et al: Asfotase alfa treatment improves survival for perinatal and infantile hypophosphatasia. J Clin Endocrinol Metab 2016; 101(1):334-342.

Created Date: 02/03/16
Effective Date: 02/03/16
Posted to Website: 01/01/22
Revision Date: 10/02/24