Clinical Policy Title:	asfotase alfa
Policy Number:	RxA.498
Drug(s) Applied:	Strensiq®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Perinatal/Infantile and Juvenile-Onset Hypophosphatasia (HPP) (must meet all)**:**

1. Diagnosis of perinatal/infantile or juvenile-onset HPP as evidenced by the following (a, b, and c):
   a. Presence of one of the following laboratory indices (i or ii):
      i. Mutation in the ALPL gene encoding for tissue non-specific alkaline phosphatase;
      ii. Serum alkaline phosphatase below the age-adjusted normal range and either of the following (a or b):
         a) Plasma pyridoxal 5'-phosphate above the upper limit of normal (ULN);
         b) Urinary phosphoethanolamine (PEA) above the ULN;
   b. History of one of the following HPP clinical manifestations (i, ii, iii, or iv):
      i. Vitamin B6-dependent seizures;
      ii. Failure to thrive or growth failure/short stature;
      iii. Nephrocalcinosis with hypercalcemia/hypercalciuria;
      iv. Skeletal abnormalities and associated impairments (a, b, c, d, e, or f):
         a) Craniosynostosis (premature fusion of one or more cranial sutures) with increased intracranial pressure;
         b) Rachitic chest deformity (costochondral junction enlargement seen in advanced rickets) with associated respiratory compromise;
         c) Limb deformity with delayed walking or gait abnormality;
         d) Compromised exercise capacity due to rickets and muscle weakness;
         e) Low bone mineral density for age with unexplained fractures;
         f) Alveolar bone loss with premature loss of deciduous (primary) teeth.

Approval Duration

All Lines of Business (except Medicare): 6 months

II. Continued Therapy Approval

A. Perinatal/Infantile- and Juvenile-Onset Hypophosphatasia (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 120 days, excluding manufacturer samples;
2. Member is responding positively to therapy as evidenced by improvement in any of the following (a, b, c, or d):
   a. Heigh velocity;
   b. Respiratory function;

c. Skeletal manifestations (e.g., bone mineralization, bone formation and remodeling, fractures, deformities);
d. Motor function, mobility, or gait.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. Scott LJ. Asfotase alfa in perinatal/infantile-onset and juvenile-onset hypophosphatasia: A guide to its use in the USA. Bio Drugs. 2016; 30:41-48. DOI 10.1007/s40259-016-0161-x. Available at: https://pubmed.ncbi.nlm.nih.gov/26832358/. Accessed on August 08, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 4. References were updated.	08/28/2020	12/07/2020
Policy was reviewed: 1. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 2. References were reviewed and updated.	09/16/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria and Continued Therapy Criteria: Updated to add note that patients requesting the 80 mg/0.8 mL vial only: Patient's weight is ≥ 40 kg. 2. References were reviewed and updated.	08/02/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with the new verbiage containing 120 days lookback period. 5. Updated approval duration verbiage. 6. References were reviewed and updated.	08/28/2024	09/13/2024