Commercial/Healthcare Exchange PA Criteria

Effective: April 27, 2020

Prior Authorization: Strensiq (asfotase alfa)

Products Affected: Strensiq subcutaneous solution

Medication Description:

Asfotase alfa is a human recombinant tissue-nonspecific alkaline phosphatase (TNSALP) fusion protein with enzymatic activity that promotes bone mineralization in patients with perinatal/infantile and juvenile-onset hypophosphatasia (HPP). In HPP, abnormalities in the gene that makes TNSALP lead to low TNSALP enzyme activity and the elevation of several TNSALP substrates, including inorganic pyrophosphate. The extracellular accumulation of inorganic pyrophosphate, an inhibitor of mineralization, causes defective calcification of bones seen in infants and children as rickets and in adults as osteomalacia. Replacement of the TNSALP enzyme upon STRENSIQ treatment reduces the enzyme substrate levels, including inorganic pyrophosphatase, which in turn promotes bone mineralization.

Covered Uses:

- Treatment of perinatal/infantile-and juvenile-onset hypophosphatasia (HPP)

Exclusion Criteria: N/A

Required Medical Information:

- Confirmed diagnosis of perinatal/infantile or juvenile- onset hypophosphatasia (HPP)
- Patient weight

Age Restrictions: N/A

Prescriber Restrictions: prescribed by or in consultation with a specialist experienced in the treatment of inborn error of metabolism

Coverage Duration:

- Initial: 6 months
- Continuation: 12 months

Other Criteria:

Initial Coverage:

Approve Strensiq if the patient meets ALL of the following criteria (A **and** B):

A. Patient was ≤ 18 years of age at onset
B. 80mg/0.8ml strength: patient's weight is ≥ 40kg (if applicable)

Continuation:

Approve Strensiq if the patient meets ALL of the following criteria (A **and** B):

A. Patient meets all of the above criteria for initial treatment
B. Patient has an adequate response to therapy with Strensiq (improvement in respiratory status, improved growth or improved radiographic findings)

References:

1. Strensiq [package insert]. Cheshire, CT; Alexion; October 2015.
2. Whyte MP, Greenday CR, Salman NJ, et al. Enzyme replacement therapy in life-threatening hypophosphatasia. N Engl J Med. 2012; 366(10): 904-913. DOI: 10.1056/NEJMoa1106173.
3. Whyte MP, Rockman-Greenberg C, Ozono K, et al. Asfotase alfa treatment improves survival for perinatal and infantile hypophosphatasia. J Clin Endocrinol Metab. 2015. jc20153462. [Epub ahead of print]
4. FDA okays asfotase alfa (*Strensiq*) for rare bone disorder. Available at: http://www.medscape.com/viewarticle/853196. Accessed December 9, 2015.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	03/17/2016
2	Policy Update	CCI adoption of EH Policy Removal from CCI PA to indication policy	Reviewed covered uses and exclusion criteria to FDA label	4/27/2020