

Market Applicability/Effective Date														
Market	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	N/A	N/A	X	N/A	X	X	X	X	X	X	N/A	N/A	X

*FHK- Florida Healthy Kids

Strensiq (asfotase alfa)

DRUG.00087

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Strensiq (asfotase alfa)

APPROVAL CRITERIA

Strensiq (asfotase alfa) may be approved for the treatment of hypophosphatasia when the following criteria are met:

- I. Onset of symptoms occurred prior to 6 months of age; **AND**
- II. Total serum alkaline phosphatase is below the lower limit of normal for the individual's age and gender at diagnosis; **AND**
- III. Plasma pyridoxal 5'-phosphate levels are greater than; the upper limit of normal at the time of diagnosis; **AND**
- IV. One or more of the following:
 - A. Radiographic evidence of poor bone mineralization such as flared and frayed metaphyses, severe/generalized osteopenia or widened growth plates; **OR**
 - B. Genetic test results that confirm infantile HPP; **OR**
 - C. One or more of the following:
 1. History or presence of nontraumatic postnatal fracture healing; **OR**
 2. History of elevated serum calcium; **OR**
 3. Functional craniosynostosis with decreased head circumference growth; **OR**
 4. Nephrocalcinosis; **OR**
 5. Rachitic chest deformity; **OR**
 6. Respiratory compromise; **OR**
 7. Vitamin B6-responsive seizures; **OR**
 8. Failure to thrive.

Continuation of treatment with Strensiq (asfotase alfa) may be approved when the following criteria have been met:

- I. The above criteria are met at the time of initiation; **and**
- II. The individual has demonstrated clinical improvement in symptoms following asfotase alfa therapy.

Asfotase alfa **may not** be approved when criteria above are not met.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

1. Agency for Healthcare Research and Quality. AHRQ Healthcare Horizon Scanning System – Potential High-Impact Interventions Report. Priority Area 08: Functional Limitations and Disability. Asfotase Alfa (Strensiq™) for Treatment of Hypophosphatasia in Infants and Children. 2015 December. Available at: <https://www.effectivehealthcare.ahrq.gov/ehc/assets/File/Functional-Limitations-Horizon-Scan-High-Impact-1512.pdf>. Accessed on June 21, 2017.
2. National Institutes of Health. Hypophosphatasia. April 2016. Available at: <https://ghr.nlm.nih.gov/condition/hypophosphatasia>. Accessed on June 21, 2017.
3. U.S. Food and Drug Administration (FDA). Asfotase alfa (Strensiq™) Original BLA 125513. October 2015. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125513Orig1s000Approv.pdf. Accessed on June 21, 2017.
4. U.S. National Institutes of Health. ClinicalTrials.gov. Hypophosphatasia. Available at: <https://clinicaltrials.gov/ct2/results?term=Hypophosphatasia&Search=Search>. Accessed on June 21, 2017.

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