PRIOR AUTHORIZATION CRITERIA

BRAND NAME	**STRENSIQ**
(generic)	**(asfotase alfa)**
Status: CVS Caremark Criteria	***MDC***
Type: Initial Prior Authorization	***Ref # 1300-A***

FDA-APPROVED INDICATIONS

Strensiq is indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP).

CRITERIA FOR APPROVAL

1	Does the patient have a diagnosis of hypophosphatasia? [If no, no further questions.]	Yes	No
2	Was the onset of the disease perinatal/infantile or juvenile? [If no, no further questions.]	Yes	No
3	Does the patient have clinical signs and/or symptoms of hypophosphatasia? (eg, generalized hypomineralization with rachitic features, chest deformities and rib fractures, respiratory problems, hypercalcemia, failure to thrive, bone/joint pain, seizures) [If no, no further questions.]	Yes	No
4	Has alkaline phosphatase liver type (ALPL) molecular genetic testing been performed? [If no, skip to question 6.]	Yes	No
5	Is the patient positive for mutation(s) in the alkaline phosphatase liver type (ALPL) gene? [No further questions.]	Yes	No
6	Does radiographic imaging show skeletal abnormalities that support the diagnosis of hypophosphatasia? (eg, infantile rickets, alveolar bone loss, focal bony defects of the metaphyses, metatarsal stress fractures) Please select 'no' if radiographic imaging not performed. [If no, no further questions.]	Yes	No
7	Is the serum alkaline phosphatase (ALP) level below the laboratory's reference normal range based on age and gender? Please select 'no' if laboratory testing not performed. [If no, no further questions.]	Yes	No
8	Does the patient have an elevated level of a tissue non-specific alkaline phosphatase (TNALP) substrate (eg, serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])? Please select 'no' if laboratory testing not performed.	Yes	No

Guidelines for Approval			
Duration of Approval		**12 months**	
Set 1: HPP, genetic testing		**Set 2: HPP, radiographic imaging and laboratory testing**	
Yes to question(s)	**No to question(s)**	**Yes to question(s)**	**No to question(s)**
1	None	1	4

2		2	
3		3	
4		6	
5		7	
		8	

Mapping Instructions		
	Yes	**No**
1	Go to 2	Deny
2	Go to 3	Deny
3	Go to 4	Deny
4	Go to 5	Go to 6
5	Approve, 12 months	Deny
6	Go to 7	Deny
7	Go to 8	Deny
8	Approve, 12 months	Deny

RATIONALE

These criteria meet the Medicare Part D definition of a medically accepted indication. This definition includes uses which are approved by the FDA or supported by a citation included, or approved for inclusion, in one of the Medicare approved compendia.

The intent of the criteria is to ensure that patients follow selection elements noted in labeling and/or practice guidelines in order to decrease the potential for inappropriate utilization.

REFERENCES

1. Strensiq [package insert]. Cheshire, CT: Alexion Pharmaceuticals, Inc.; October 2016.
2. Bianchi ML. Hypophosphatasia: an overview of the disease and its treatment. Osteoporos Int. 2015;26(12):2743-57.
3. Mornet E, Nunes ME. Hypophosphatasia. GeneReviews [Internet]. http://www.ncbi.nlm.nih.gov/books/NBK1150/. Updated Nov 10, 2011. Accessed October 26, 2015.

DOCUMENT HISTORY

Created:	Specialty Clinical Development (ST) 10/2015
Revised:	ST 06/2016 (CMS); HY 05/2016 (annual review), 07/2017 (CMS)
Reviewed:	CDPR / DNC 11/2015, MC 05/2016
External Review:	11/2015, 09/2016