UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Strensiq

Program	Prior Authorization
Medication	Strensiq (asfotase alfa)
Markets in Scope	Arizona, California, Florida-CHIP, Hawaii, Maryland, Nevada, New York, New York EPP, Ohio, Rhode Island, Pennsylvania, New Jersey
Issue Date	8/2016
Pharmacy and Therapeutics Approval Date	5/2019
Effective Date	7/2019

1. Background:

Strensiq® (asfotase alfa) is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile and juvenile-onset hypophosphatasia (HPP).[1]

2. Coverage Criteria:

A. Initial Therapy

1. **Strensiq** will be approved based on **all** of the following criteria:

   a. Diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia based on **all** of the following:

      (1) **One** of the following:

         a. Onset of clinical signs and symptoms of hypophosphatasia prior to age 18 (e.g., respiratory insufficiency, vitamin B6 responsive seizures, hypotonia, failure to thrive, delayed walking, waddling gait, dental abnormalities, low trauma fractures)
         b. Radiographic evidence supporting the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., craniosynostosis, infantile rickets, non-traumatic fractures)

      -AND-

      (2) **One** of the following:

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a. **Both** of the following:

i. Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age-adjusted normal range
ii. Patient has 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-

b. Confirmation of tissue-nonspecific alkaline phosphatase (TNSALP) gene mutation by ALPL genomic DNA testing*

-AND-

b. Prescribed by **one** of the following:

(1) Endocrinologist

(2) A specialist experienced in the treatment of metabolic bone disorders

-AND-

c. **One** of the following:

(1) **Both** of the following:

a. Diagnosis of perinatal/infantile-onset hypophosphatasia

b. Coverage will be provided up to a maximum supply limit of 9 mg/kg/week

-OR-

(2) **Both** of the following:

a. Diagnosis of juvenile-onset hypophosphatasia

b. Coverage will be provided up to a maximum supply limit of 6 mg/kg/week

-AND-

d. **One** of the following:

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(1) Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

-OR-

(2) **Both** of the following:

a. Patient is prescribed Strensiq 80 mg/0.8 mL vial

b. Patient's weight is greater than or equal to 40 kg

-AND-

e. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

*Results of prior genetic testing can be submitted as confirmation of diagnosis of HPP, however please note that the provider should confirm coverage status of any new genetic testing under the patient's UnitedHealthcare plan prior to ordering

Authorization will be issued for 6 months.

B. Reauthorization

1. **Strensiq** will be approved based on **all** of the following criteria:

a. Clinically relevant 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])

-AND-

b. Prescribed by **one** of the following:

(1) Endocrinologist

(2) A specialist experienced in the treatment of metabolic bone diseases

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-AND-

c. **One** of the following:

(1) **Both** of the following:

a. Diagnosis of perinatal/infantile-onset hypophosphatasia

b. Coverage will be provided up to a maximum supply limit of 9 mg/kg/week

-OR-

(2) **Both** of the following:

a. Diagnosis of juvenile-onset hypophosphatasia

b. Coverage will be provided up to a maximum supply limit of 6 mg/kg/week

-AND-

d. **One** of the following:

(1) Patient is prescribed Strensiq 18 mg/0.45 mL, Strensiq 28 mg/0.7 mL, or Strensiq 40 mg/mL vials

-OR-

(2) **Both** of the following:

a. Patient is prescribed Strensiq 80 mg/0.8 mL vials

b. Patient's weight is greater than or equal to 40 kg

-AND-

e. Prescriber attests to the following: the information provided is true and accurate to the best of their knowledge and they understand that UnitedHealthcare may perform a routine audit and request the medical information necessary to verify the accuracy of the information provided

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UnitedHealthcare Community Plan

Authorization will be issued for 12 months.

3. References:

1. Strensiq prescribing information, Alexion Pharmaceuticals. New Haven, CT. January 2018.
2. Strensiq (asfotase alfa) CEDR Medical Review. FDA/CEDR resources page. Food and Drug Administration Web site. https://www.accessdata.fda.gov/drugsatfda_docs/nda/2015/125513Orig1s000MedR.pdf Accessed October 11, 2017.

Program	Prior Authorization –Strensiq (asfotase alfa)
Change Control	
Date	Change
8/2016	New program
2/2017	Annual review. Updated policy template.
11/2017	Updated criteria to align with Employer and Individual's medical necessity program. Added more stringent criteria around the diagnosis, revised prescriber check, added maximum supply limit, and added provider attestation. Updated references.
11/2018	Annual review. Updated references.
5/2019	Annual review. No changes to criteria.

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