UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2136-5
Program	Prior Authorization/Medical Necessity
Medication	Strensiq® (asfotase alfa)
P&T Approval Date	11/2017, 5/2019, 5/2020, 5/2021, 6/2021
Effective Date	9/1/2021; Oxford only: 9/1/2021

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]:

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 years (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:

         a. **Both** of the following:

            i. Patient has low level activity of serum alkaline phosphatase (ALP) evidenced by an ALP level below the age and gender-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. Request does not exceed a maximum supply limit of 9 mg/kg/week

-OR-

(2) **Both** of the following:
a. Diagnosis of juvenile-onset hypophosphatasia
b. Request does not exceed 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 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

Authorization will be issued for 6 months

*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.

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

   -AND-

   c. **One** of the following:
      (1) **Both** of the following:
         a. Diagnosis of perinatal/infantile-onset hypophosphatasia
         b. Request does not exceed a maximum supply limit of 9 mg/kg/week

      -OR-

      (2) **Both** of the following:
         a. Diagnosis of juvenile-onset hypophosphatasia
         b. Request does not exceed 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

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Strensiq prescribing information. Alexion Pharmaceuticals, Inc. Cheshire, CT. June 2020.
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 March 26, 2021.

Program	Prior Authorization/Medical Necessity – Strensiq (asfotase alfa)
Change Control	
11/2017	New program.
5/2019	Annual review. Updated references.
5/2020	Annual review with no changes to coverage criteria. Updated reference.
5/2021	Annual review. No changes to coverage criteria. Updated references.
6/2021	Updated language to coverage of maximum supply limit.