UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2025 P 2136-10 |
| Program | Prior Authorization/Medical Necessity |
| Medication | Strensiq® (asfotase alfa) |
| P&T Approval Date | 11/2017, 5/2019, 5/2020, 5/2021, 6/2021, 6/2022, 6/2023, 10/2023, 10/2024, 10/2025 |
| Effective Date | 12/1/2025 |

**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).

**2. Coverage Criteria[a]:**

A. **Initial Therapy**

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

a. Submission of medical records documenting diagnosis of perinatal/infantile or juvenile-onset hypophosphatasia

**-AND-**

b. Submission of medical records documenting confirmation of diagnosis by **all** of the following:

(1) Presence of clinical signs and symptoms of hypophosphatasia (e.g., skeletal abnormalities, respiratory insufficiency, failure to thrive, hypotonia, dental abnormalities, short stature, rickets, fractures, delayed walking, waddling gate)

**-AND-**

(2) Onset of disease < 18 years of age [If member is ≥ 18 years of age at time of request, documentation of disease onset before age of 18 must be provided (e.g., member began experiencing symptoms at age 8)]

**-AND-**

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

(a) **All** of the following:

i. Persistent serum alkaline phosphatase (ALP) levels below the gender- and age-specific reference range (i.e., present in at least two measurements)
ii. Elevated tissue non-specific alkaline phosphatase (TNSALP)

substrate level (e.g., serum pyridoxal 5'-phosphate [PLP] level, serum or urine phosphoethanolamine [PEA] level, urinary inorganic pyrophosphate [PPi level])

iii. Radiographic imaging demonstrating skeletal abnormalities (e.g., craniosynostosis, rickets, non-traumatic fractures)

**-OR-**

(b) Presence of a known pathological mutation in the ALPL gene as detected by ALPL molecular genetic testing*

**-AND-**

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

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

**-AND-**

d. **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-**

e. **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

**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. Documentation of positive clinical response to Strensiq therapy (e.g., improvement in clinical symptoms, improvement in Radiographic Global Impression of Change)

**-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

**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 [package insert]. Boston, MA: Alexion Pharmaceuticals, Inc.; July 2024.
2. Khan AA, Brandi ML, Rush ET, et al. Hypophosphatasia diagnosis: current state of the art and proposed diagnostic criteria for children and adults. *Osteoporos Int*. 2024;35(3):431-438.
3. Cárdenas-Aguilera JG, González-López V, Zarante-Bahamón AM, et al. Diagnosis, treatment, and follow-up of patients with hypophosphatasia. *Endocrine*. 2025;87(2):400-419.


| 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. |
| 6/2022 | Annual review. Added criterion for clinical response to reauthorization coverage criteria per prescribing information. Updated references. |
| 6/2023 | Annual review with no changes to criteria. Updated references. |
| 10/2023 | Annual review with no changes to criteria except removal of "routine audit" language. |
| 10/2024 | Annual review with no changes to clinical coverage criteria. Updated references. |
| 10/2025 | Annual review. Updated initial and reauthorization criteria. Updated references. |