

# UnitedHealthcare Pharmacy Clinical Pharmacy Programs

| Program Number    | 2025 P 1176-11  |
|-------------------|---|
| Program           | Prior Authorization/Notification                              |
| Medication        | Strensiq <sup>™</sup> (asfotase alfa)                         |
| P&T Approval Date | 2/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, |
|                   | 11/2022, 11/2023, 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<sup>a</sup>:

## A. Initial Authorization

- 1. **Strensiq** will be approved based on <u>one</u> of the following criteria:
  - a. Diagnosis of perinatal/infantile-onset hypophosphatasia

#### -OR-

b. Diagnosis of juvenile-onset hypophosphatasia

Authorization will be issued for 12 months.

### **B.** Reauthorization

- 1. **Strensiq** will be approved based on the following criterion:
  - a. Documentation of positive clinical response to Strensiq therapy

#### Authorization will be issued for 12 months.

<sup>a</sup> 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 reauthorization 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.

| Program        | Prior Authorization/Notification - Strensiq (asfotase alfa)          |
|----------------|--|
| Change Control |  |
| 2/2016         | New program.   |
| 12/2016        | Annual Review. Revised background. Extended initial authorization to |
|                | 12 months.   |
| 11/2017        | Annual Review. Updated references.                                   |
| 11/2018        | Annual Review. Updated references.                                   |
| 11/2019        | Annual Review. No changes.   |
| 11/2020        | Annual review. Updated reference.                                    |
| 11/2021        | Annual review with no changes to clinical coverage criteria.         |
| 11/2022        | Annual review with no changes to clinical coverage criteria. Added   |
|                | state mandate footnote.  |
| 11/2023        | Annual review with no changes to clinical coverage criteria.         |
| 10/2024        | Annual review with no changes to clinical coverage criteria. Updated |
|                | reference.   |
| 10/2025        | Annual review with no changes.                                       |