

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

| Program Number | 2023 P 1176-9 |
|-------------------|---|
| Program | Prior Authorization/Notification |
| Medication | Strensiq [™] (asfotase alfa) |
| P&T Approval Date | 2/2016, 12/2016, 11/2017, 11/2018, 11/2019, 11/2020, 11/2021, |
| | 11/2022, 11/2023 |
| Effective Date | 2/1/2024 |

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 Authorization

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

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.; June 2020.

| Program | Prior Authorization/Notification - Strensiq (asfotase alfa) |
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| 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. |