MEDICAL MUTUAL®

Drug Policy

Policy:	Strensiq (asfotase alfa)	Annual Review Date: 01/18/2024 Last Revised Date: 01/18/2024

OVERVIEW

Strensiq is indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (HPP). Strensiq is an enzyme replacement therapy which replaces human tissue non-specific alkaline phosphatase (TNSALP). Strensiq is produced via recombinant DNA technology in Chinese hamster ovary cells. It is a soluble glycoprotein composed of two identical polypeptide chains, each containing TNSALP, bound to the Fc domain of human immunoglobulin G_1 and a deca-aspartate peptide for targeting the bone.

POLICY STATEMENT

This policy involves the use of Strensiq. Prior authorization is recommended for pharmacy benefit coverage of Strensiq. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Strensiq as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Strensiq be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Strensiq is recommended in those who meet the following criteria:

1. <u>Perinatal/Infantile- and Juvenile-Onset Hypophosphatasia (HPP)</u>
Criteria. *Patient must meet the following criteria*

- **A.** Patient was 18 years of age or younger at onset; AND
- **B.** Patient has symptoms of hypophosphatasia (if diagnosed in infancy, examples may include – short limbs, abnormal shaped chest, soft skull bones, rickets, failure to thrive, respiratory problems, hypercalcemia; if diagnosed in childhood, examples may include – early loss of primary teeth, short stature, enlarged waist and ankle joints, abnormal skull shape, osteomalacia, recurrent fractures, joint pain, rickets) [documentation required]; AND
- **C.** Patient had low baseline alkaline phosphatase (ALP) activity (age adjusted) [documentation required]; AND

D. Diagnosis of HPP was confirmed by presence of elevated ALP substrate levels (increased serum pyridoxal 5'-phosphate or urinary phosphoethanolamine) [documentation required]; AND
E. Patient has at least one pathogenic variant in ALPL gene [documentation required]; AND
F. Strensiq is prescribed by or in consultation with a geneticist, an endocrinologist, a metabolic disorder sub-specialist, or a physician who specializes in the treatment of hypophosphatasia or related disorders.

2. <u>Perinatal/Infantile- and Juvenile-Onset Hypophosphatasia (HPP) – Continuation of Therapy</u>
Criteria. *Patient must meet the following criteria*

A. Patient meets all criteria noted above; AND
B. Patient has responded to therapy with Strensiq with an improvement or stabilization in the clinical signs or symptoms of hypophosphatasia (e.g. improvement in respiratory status, growth, or radiographic findings) [documentation required]

Initial Approval/ Extended Approval.
A) *Initial Approval:* 6 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Strensiq has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

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