BlueCross BlueShield Federal Employee Program

STRENSIQ
(asfotase alfa)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Strensiq is used to treat hypophosphatasia (HPP) a rare genetic disorder characterized by the abnormal development of bones and teeth. These abnormalities occur due to defective mineralization, the process by which bones and teeth take up minerals such as calcium and phosphorus. These minerals are required for proper hardness and strength. Hypophosphatasia is caused by mutations in the tissue nonspecific alkaline phosphatase gene. Such mutations lead to low levels of the tissue nonspecific alkaline phosphatase (TNSALP) enzyme. This enzyme is needed for the proper development and health of bones and teeth (1). Strensiq is administered via injection three or six times per week (2).

Regulatory Status

FDA-approved indication: Strensiq is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia (2).

Strensiq contains a boxed warning for hypersensitivity reactions, including anaphylaxis. If a severe hypersensitivity reaction occurs, discontinue Strensiq and immediately initiate appropriate medical treatment, including use of epinephrine (2).

Patients with HPP are at increased risk for developing ectopic calcifications of the eye and kidneys. Ophthalmology (eye) examinations and renal ultrasounds are recommended at baseline and periodically during treatment to monitor for signs and symptoms of ophthalmic and renal ectopic calcifications and for changes in vision or renal function (2).

During clinical trials, anti-drug antibodies have been detected in patients receiving treatment with Strensiq using an electrochemiluminescent (ECL) immunoassay. Antibody positive samples were tested to determine the presence of neutralizing antibodies based on in vitro inhibition of the catalytic activity of Strensiq. Formation of anti-drug antibody resulted in a reduced systemic exposure Strensiq (2).

The safety and effectiveness of Strensiq have been established in pediatric patients. The majority of patients in the clinical trials were pediatric patients 1 day to 16 years of age (2).

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Summary

Strensiq is a tissue nonspecific alkaline phosphatase indicated for the treatment of patients with perinatal/infantile- and juvenile-onset hypophosphatasia. Strensiq has a boxed warning for hypersensitivity reactions. Ophthalmology (eye) examinations and renal ultrasounds are recommended at baseline and periodically during treatment to monitor for signs and symptoms of ophthalmic and renal ectopic calcifications and for changes in vision or renal function. The safety and effectiveness of Strensiq have been established in pediatric patients (2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Strensiq while maintaining optimal therapeutic outcomes.

References

1. Hypophosphatasia. Rare disease information. National Organization for Rare Disorders (NORD) website.
2. Strensiq [package insert]. New Haven, CT: Alexion Pharmaceuticals, Inc.; July 2024