

Strensiq Prior Authorization Program Summary

POLICY REVIEW CYCLE

Effective Date
12-15-2025

Date of Origin

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Strensiq	asfotase alfa subcutaneous inj	18 MG/0.45ML ; 28 MG/0.7ML ; 40 MG/ML ; 80 MG/0.8ML	M ; N ; O ; Y	N		

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Strensiq	asfotase alfa subcutaneous inj	18 MG/0.45ML ; 28 MG/0.7ML ; 40 MG/ML ; 80 MG/0.8ML	Balanced ; Balanced Biosimilar ; Basic ; Basic Annual ; Enhanced ; Enhanced Annual ; HIM Annual 2024 ; HIM Quarterly 2024 ; HIM Quarterly 2025 ; HIM Quarterly 2026 ; IL HIM Annual 2025 ; IL HIM Annual 2026 ; IL HMO Performance Quarterly ; IL non-HMO Performance Full ; Jade ; MT Performance Full ; OK Performance Full ; Performance ; Performance Annual ; Performance Biosimilar ; Performance Select ; Performance Select Biosimilar ; TX HIM Annual 2025 ; TX HIM Annual 2026 ; Topaz ; Whole Foods

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	<p>Initial Evaluation</p> <p>Target Agent(s) will be approved when ALL of the following are met:</p> <ol style="list-style-type: none"> 1. The patient has a diagnosis of either perinatal/infantile- OR juvenile-onset hypophosphatasia (HPP) AND ALL of the following: <ol style="list-style-type: none"> A. The patient was less than 18 years of age at onset [chart notes required] AND B. The patient is experiencing active disease (e.g., bone pain, fractures, gait problems) AND C. The patient has/had clinical manifestations consistent with hypophosphatasia at the age of onset prior to age 18 (e.g., vitamin B6-dependent seizures, fractures, lost teeth with roots, skeletal abnormalities: such as rachitic chest

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	<p>deformity leading to respiratory problems or bowed arms/legs, “failure to thrive”) [chart notes required] AND</p> <p>D. ONE of the following [chart notes required]:</p> <ol style="list-style-type: none"> 1. Molecular genetic testing has been completed confirming mutations in the <i>ALPL</i> gene that encodes the tissue nonspecific isoenzyme of ALP (TNSALP) OR 2. ALL of the following <ol style="list-style-type: none"> A. The patient has/had radiographic imaging confirming the diagnosis of hypophosphatasia at the age of onset prior to age 18 (e.g., infantile rickets, alveolar bone loss, craniosynostosis) AND B. The patient has reduced activity of unfractionated serum alkaline phosphatase (ALP) in the absence of bisphosphonate therapy (i.e., below the normal lab reference range for age and sex) AND C. ONE of the following: <ol style="list-style-type: none"> 1. Elevated serum concentration of pyridoxal 5'-phosphate (PLP) in the absence of vitamin supplements within one week prior to the test OR 2. Elevated urine concentration of phosphoethanolamine (PEA) OR 3. Elevated urinary inorganic pyrophosphate (PPi) AND 2. The prescriber is a specialist in the area of the patient’s diagnosis (e.g., endocrinologist, geneticist) or the prescriber has consulted with a specialist in the area of the patient’s diagnosis AND 3. The patient has had an ophthalmology examination and renal ultrasound at baseline (prior to starting therapy with the requested agent) AND 4. The patient does NOT have any FDA labeled contraindications to the requested agent AND 5. ONE of the following: <ol style="list-style-type: none"> A. The requested quantity (dose) is within FDA labeled dosing for the requested indication based on the patient’s weight OR B. There is support for therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months BCBSIL and BCBSMT: 12 months ALL other plans: 6 months</p> <p>The requested agent will also be approved when the following are met:</p> <ol style="list-style-type: none"> 1. The request is for a BCBS MT Fully Insured or MT HIM member AND <ol style="list-style-type: none"> A. The patient is under the age of 18 years old AND B. The patient does NOT have any FDA labeled contraindications to the requested agent AND C. The patient has an indication that is supported in TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] AND D. There is support for an age in the patient’s given age bracket in TWO articles from major peer-reviewed professional medical journals as generally safe and effective. The age brackets are: 1. infancy (birth up to, but not including, 2 years of age), 2. childhood (2 years of age through 11 years of age), 3. adolescence (12 years of age through 17 years of age). Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled

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	<p>clinical trials. NOTE: Case studies are not acceptable [journal articles required] OR</p> <p>2. ALL of the following:</p> <ul style="list-style-type: none"> A. The member resides in Ohio AND B. The plan is Fully Insured or HIM Shop (SG) AND C. The patient does NOT have any FDA labeled contraindications to the requested agent AND D. ONE of the following: <ul style="list-style-type: none"> 1. The patient has another FDA labeled indication for the requested agent and route of administration OR 2. The patient has another indication that is supported in compendia for the requested agent and route of administration OR 3. The prescriber has submitted TWO articles from major peer-reviewed professional medical journals [e.g., Journal of American Medical Association (JAMA), New England Journal of Medicine (NEJM), Lancet] supporting the proposed use(s) as generally safe and effective. Accepted study designs may include, but are not limited to, randomized, double blind, placebo controlled clinical trials. NOTE: Case studies are not acceptable [journal articles required] <p>Non-oncology compendia allowed: DrugDex level 1, 2A or 2B, AHFS-DI (narrative text must be supportive)</p> <p>Oncology compendia allowed: NCCN 1 or 2A, AHFS-DI (narrative text must be supportive), DrugDex level 1, 2A, or 2B, or Clinical Pharmacology (narrative text must be supportive), Lexi-Drugs evidence level A, peer-reviewed medical literature</p> <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p> <p>NOTE: If Quantity Limit applies, please refer to Quantity Limit Criteria</p> <p>Renewal Evaluation</p> <p>Target Agent(s) will be approved when ALL the following are met:</p> <ul style="list-style-type: none"> 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process (Note: patients not previously approved for the requested agent will require initial evaluation review) AND 2. The patient has had clinical improvement from baseline (prior to starting therapy with the requested agent) in at least ONE of the following [chart notes required]: <ul style="list-style-type: none"> A. Respiratory status (e.g., level of respiratory support is required) OR B. Growth (e.g., an improvement in length/height, weight, or head circumference as measured by z-scores) OR C. Radiographic findings (e.g., improvement in skeletal manifestations as measured by RSS or RGI-C or a decrease in fractures) OR D. Level of activity (e.g., improvement in motor function or activities in daily living) AND 3. The prescriber is a specialist in the area of the patient's diagnosis (e.g., endocrinologist, geneticist), or the prescriber has consulted with a specialist in the area of the patient's diagnosis AND 4. The patient has been monitored for signs and symptoms of ophthalmic and renal calcifications and for changes in vision or renal function AND

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	<p>5. The patient does NOT have any FDA labeled contraindications to the requested agent AND</p> <p>6. ONE of the following:</p> <ul style="list-style-type: none"> A. The requested quantity (dose) is within FDA labeled dosing for the requested indication based on the patient's weight OR B. There is support for therapy with a higher dose for the requested indication <p>Length of Approval:</p> <p>BCBSOK: 36 months ALL other plans: 12 months</p>