BlueCross BlueShield
Federal Employee Program
Blue Cross Blue Shield Association
750 9th St NW, Suite 900
Washington, D.C. 20001
1-800-624-5060
Fax 1-877-378-4727

5.30.101

Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Endocrine and Metabolic Drugs	**Original Policy Date:**	October 24, 2025
Subject:	Forzinity	**Page:**	1 of 4

Last Review Date: March 6, 2026

Forzinity

Description

Forzinity (elamipretide)

Background
Forzinity (elamipretide) is a mitochondrial cardiolipin binder that localizes to the inner mitochondrial membrane and improves mitochondrial morphology and function. Barth Syndrome is an X-linked genetic disorder, primarily affecting males, resulting in an inborn error of lipid metabolism. It is caused by a mutation in the TAFAZZIN gene and can affect many systems. Cardinal characteristics of the disorder may include cardiomyopathy, neutropenia, low muscle mass and muscle weakness, growth delay, exercise intolerance, feeding problems, cardiolipin abnormalities, and 3-methylglutaconic aciduria (1-2).

Regulatory Status
FDA-approved indication: Forzinity is a mitochondrial cardiolipin binder indicated to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg (1).

Forzinity contains warnings regarding the risk of benzyl alcohol toxicity in neonates and hypersensitivity reactions (1).

The safety and effectiveness of Forzinity in pediatric patients weighing less than 30 kg have not been established (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Forzinity may be considered **medically necessary** if the conditions indicated below are met.

Forzinity may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnosis

Patient must have the following:

1. Barth syndrome

AND ALL of the following:

a. TAFAZZIN gene mutation
b. Patient weight ≥ 30 kg
c. Baseline Barth Syndrome Symptom Assessment (BTHS-SA) score (*https://pmc.ncbi.nlm.nih.gov/articles/instance/7935714/bin/41436_2020_1006_MOESM1_ESM.pdf*)
d. Forzinity is being used to improve muscle strength
e. Prescriber agrees to monitor for signs and symptoms of hypersensitivity reactions

Prior – Approval *Renewal* Requirements

Diagnosis

Patient must have the following:

1. Barth syndrome

AND ALL of the following:

a. Patient weight ≥ 30 kg
b. Patient has demonstrated a positive clinical response to therapy (e.g., an improvement in rate of disease progression)
c. Forzinity is being used to improve muscle strength

d. Prescriber agrees to monitor for signs and symptoms of hypersensitivity reactions

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 12 vials per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Forzinity is a mitochondrial cardiolipin binder indicated to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg. The safety and effectiveness of Forzinity in pediatric patients weighing less than 30 kg have not been established (1).

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

References

1. Forzinity [package insert]. Needham, MA: Stealth BioTherapeutics Inc.; September 2025.
2. “What is Barth Syndrome?”. Barth Syndrome Foundation 2025. Accessed at barthsyndrome.org.

Policy History

Date	Action
October 2025	Addition to PA
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.