

Medical Drug Clinical Criteria

Subject: Forzinity (elamipretide)

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Overview

This document addresses the use of Forzinity (elamipretide), approved by the Food and Drug Administration (FDA) to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kg. This indication is approved under accelerated approval based on an improvement in knee extensor muscle strength, an intermediate clinical endpoint. Continued approval may be contingent upon verification of clinical benefit in a confirmatory trial.

The efficacy of Forzinity was evaluated in a randomized, double-blind, placebo-controlled 12-week trial and a 192-week, open-label extension period. The randomized portion of the trial included 12 participants age 12 or older and weighing at least 30 kg with genetically confirmed Barth syndrome. All trial participants were required to be ambulatory. In the randomized trial, the primary endpoints included distance walked during a 6-minute walk test and fatigue score on the Barth Syndrome Symptom Assessment. Forzinity did not demonstrate superiority to placebo on the primary endpoints. During the open-label extension, increases in knee extensor muscle strength were observed.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Initial requests for Forzinity (elamipretide) may be approved if the following criteria are met:

- I. Individual is 12 years of age or older; **AND**
- II. Individual weighs 30 kg or greater; **AND**
- III. Individual has a diagnosis of Barth syndrome; **AND**
- IV. Documentation is provided that diagnosis has been verified by a pathogenic genetic variant in *TAZ*; **AND**
- V. Documentation is provided that individual is ambulatory (able to complete a 6-minute walk test) (Thompson 2021); **AND**
- VI. Individual has been objectively assessed for functional impairment related to muscle strength.

Continuation requests for Forzinity (elamipretide) may be approved if the following criteria are met:

- I. Individual has a diagnosis of Barth syndrome; **AND**
- II. Documentation is provided that diagnosis has been verified by a pathogenic genetic variant in *TAZ*; **AND**
- III. There is clinically significant improvement in muscle strength.

Requests for Forzinity (elamipretide) may not be approved for the following:

- I. Individual is age 18 years or older with renal failure (eGFR less than 30 mL/minute) and on dialysis; **OR**
- II. Individual is less than 18 years of age with any renal impairment.

Approval Duration

Initial: 6 months

Continuation: 12 months

Quantity Limits

Forzinity (elamipretide) Quantity Limit

Drug	Limit
Forzinity (elamipretide) 280 mg/3.5 mL vial	4 vials per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Forzinity (elamipretide)]
J3490	Unclassified drugs [when specified as Forzinity (elamipretide)]

ICD-10 Diagnosis

E78.71	Barth syndrome
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Document History

New: 11/14/2025

Document History:

- 11/14/2025 – Annual Review: New clinical criteria and quantity limit for Forzinity. Administrative update to add documentation. Coding Reviewed: Added HCPCS NOC C9399, J3490 and ICD-10-CM E78.71 for Forzinity.

References

- DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: October 3, 2025.
- DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
- Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.
- Thompson WR, Hornby B, Manuel R, et al. A phase 2/3 randomized clinical trial followed by an open-label extension to evaluate the effectiveness of elamipretide in Barth syndrome, a genetic disorder of mitochondrial cardiolipin metabolism. *Genet Med*. 2021;23(3):471-478.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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