

Forzinity (elamipretide)
 Effective 05/01/2026

Plan	<input type="checkbox"/> MassHealth UPPL <input checked="" type="checkbox"/> Commercial/Exchange	Program Type	<input checked="" type="checkbox"/> Prior Authorization <input type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
Benefit	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit		
Specialty Limitations	These medications have been designated specialty and must be filled through a contracted specialty pharmacy.		
Contact Information	Medical Benefit	Phone: 833-895-2611	Fax: 888-656-6671
	Pharmacy Benefit	Phone: 800-711-4555	Fax: 844-403-1029
Exceptions	N/A		

Overview

Forzinity (elamipretide) subcutaneous injection is a mitochondrial cardiolipin binder indicated to improve muscle strength in adult and pediatric patients with Barth syndrome weighing at least 30 kilograms.

Coverage Guidelines

If member is new to the plan (as evidenced by coverage effective date of less than or equal to 90 days), submission of medical records documenting that the member is currently receiving treatment with requested drug, excluding when the product is obtained as samples or via manufacturer's patient assistance programs

OR

Authorization may be granted when all of the following criteria are met:

1. Diagnosis of Barth syndrome
2. Submission of medical records (e.g., chart notes) confirming presence of a mutation in the Tafazzin gene
3. Member's weight is greater than or equal to 30 kilograms
4. Requested medication is prescribed by or in consultation with one of the following specialists:
 - a. Geneticist
 - b. Cardiologist
 - c. Neurologist
 - d. Specialist focused on the treatment of metabolic disorders

Continuation of Therapy

Requests for reauthorization will be approved when the following criteria are met:

1. Submission of medical records (e.g., chart notes) demonstrating member has had a positive clinical response to therapy (e.g., improvement in knee extensor muscle strength or 6-minute walking test, quality of life)

Limitations

1. Initial approvals will be granted for 6 months.
2. Reauthorizations will be granted for 12 months.
3. The following quantity limits apply

Drug Name and Dosage	Quantity Limit
Forzinity SC vial	4 vials per 28 days

References

1. ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS statement: guidelines for the six-minute walk test. *Am J Respir Crit Care Med*. 2002;166(1):111-117.
2. Barth Syndrome Foundation. Methods for obtaining a Barth syndrome diagnosis. Updated 2025. Accessed November 11, 2025. <https://www.barthsyndrome.org/barthsyndrome/diagnose/methods-for-obtaining-a-barth-syndrome-diagnosis.html>.
3. Bohannon RW. Sit-to-stand test for measuring performance of lower extremity muscles. *Percept Mot Skills*. 1995;80(1):163-166.
4. Cella D, Riley W, Stone A, et al. The Patient-Reported Outcomes Measurement Information System (PROMIS) developed and tested its first wave of adult self-reported health outcome item banks: 2005-2008. *J Clin Epidemiol*. 2010;63(11):1179-1194.
5. Hornby B, Thompson WR, Almuqbil M, et al. Natural history comparison study to assess the efficacy of elamipretide in patients with Barth syndrome. *Orphanet J Rare Dis*. 2022;17(1):336.
6. Hsu P, Liu X, Zhang J, Wang HG, Ye JM, Shi Y. Cardiolipin remodeling by TAZ/tafazzin is selectively required for the initiation of mitophagy. *Autophagy*. 2015;11(4):643-652.
7. Finsterer J. Barth syndrome: mechanisms and management. *Appl Clin Genet*. June 2019;12:95-106.
8. Forzinity (elamipretide) [prescribing information]. Needham, MA: Stealth BioTherapeutics Inc.; September 2025.
9. Lotz C, Lin AJ, Black CM, et al. Characterization, design, and function of the mitochondrial proteome: from organs to organisms. *J Proteome Res*. 2014;13(2):433-446.
10. Paradies G, Paradies V, Ruggiero FM, Petrosillo G. Role of cardiolipin in mitochondrial function and dynamics in health and disease: molecular and pharmacological aspects. *Cells*. 2019;8(7):728.
11. Patterson JA, Amick RZ, Thummar T, Rogers ME. Validation of measures from the smartphone sway balance application: a pilot study. *Int J Sports Phys Ther*. 2014;9(2):135-139.
12. Schlame M, Xu Y. The function of tafazzin, a mitochondrial phospholipid-lysophospholipid acyltransferase. *J Mol Biol*. 2020;432(18):5043-5051.
13. Stark T, Walker B, Phillips JK, Fejer R, Beck R. Hand-held dynamometry correlation with the gold standard isokinetic dynamometry: a systematic review. *PM R*. 2011;3(5):472-479.
14. 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
15. Thompson WR, Manuel R, Abbruscato A, et al. Long-term efficacy and safety of elamipretide in patients with Barth syndrome: 168-week open-label extension results of TAZPOWER. *Genet Med*. 2024;26(7):101138.
16. Vreken P, Valianpour F, Nijtmans LG, et al. Defective remodeling of cardiolipin and phosphatidylglycerol in Barth syndrome. *Biochem Biophys Res Commun*. 2000;279(2):378-382.

Review History

02/11/2026 – Reviewed at February P&T. Effective 05/01/2026.

