MEDICATION POLICY:
Forzinity (elamipretide)

Applicable Drugs: Forzinity (elamipretide)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 4/23/2026

Date Last Reviewed / Revised: 10/28/2026

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met)

I. Barth Syndrome (BTHS)
   1. Documented diagnosis of BTHS and must meet criteria A or B
      A. Confirmed by genetic testing that detects mutation in the *TAFAZZIN (TAZ)* gene
      B. Elevated monolysocardiolipin to tetralinoleoyl-cardiolipin (MLCL:CL) ratio
   2. Documentation of impaired baseline assessment (e.g., 6-minute walk test (6MWT), knee extensor strength, etc.) within the past 3 months.
   3. Documentation that the patient has been optimized on the following supportive therapies, A through C:
      A. Medications for the management of heart failure.
      B. Medications for the prevention and treatment of infections.
      C. Physical Therapy.

II. Minimum age requirement: 12 years old.

III. Treatment must be prescribed by or in consultation with a cardiologist, endocrinologist, hematologist, geneticist, or neurologist.

IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- Weight <30kg.
- Uncontrolled hypertension.
- Currently on dialysis.
- Pediatric patients >30kg with renal impairment.
- History of heart transplantation.

- Plan to undergo implantation of an ICD or known occurrence of ICD discharge in the past 3 months.

OTHER CRITERIA

Recommended dosage in Adults with Renal Impairment

- eGFR > 30mL/minute = 40mg subcutaneous dose
- eGFR <30m/minute and NOT on dialysis = 20mg subcutaneous dose

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Four 280mg/3.5mL (80mg/mL) single-patient use vials per 28-day supply

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** 6 months. An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and that the medication is effective.

APPENDIX

N/A

REFERENCES

1. Forzinity. Prescribing information. Stealth BioTherapeutics Inc.; September 2025. Accessed October 28, 2026. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf
2. Bowron A, Honeychurch J, Williams M, et al. Barth syndrome without tetralinoleoyl cardiolipin deficiency: a possible ameliorated phenotype. *J Inherit Metab Dis*. 2015;38(2):279-286. doi:10.1007/s10545-014-9747-y
3. Finsterer J. Barth syndrome: mechanisms and management. *Appl Clin Genet*. 2019;12:95-106. Published 2019 Jun 5. doi:10.2147/TACG.S171481
4. Houtkooper RH, Rodenburg RJ, Thiels C, et al. Cardiolipin and monolysocardiolipin analysis in fibroblasts, lymphocytes, and tissues using high-performance liquid chromatography-mass spectrometry as a diagnostic test for Barth syndrome. *Anal Biochem*. 2009;387(2):230-237. doi:10.1016/j.ab.2009.01.032

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.