Louisiana Medicaid
Elamipretide (Forzinity™)

The *Louisiana Uniform Prescription Drug Prior Authorization Form* should be utilized to request clinical authorization for elamipretide (Forzinity™).

Additional Point-of-Sale edits may apply.

By submitting the authorization request, the prescriber attests to the conditions available HERE.

This medication is approved under accelerated approval based on an improvement in knee extensor muscle strength, an intermediate clinical endpoint. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

Approval Criteria for Initiation of Therapy

- The recipient weighs ≥ 30 kg; **AND**
- The recipient has a diagnosis of Barth syndrome confirmed by a genetic test demonstrating the presence of a mutation in the tafazzin (TAZ) gene; **AND**
- This medication is prescribed by, or the request states that the medication is being prescribed in consultation with, a geneticist, metabolic disease specialist, cardiologist, hematologist, or a physician who specializes in the treatment of mitochondrial disorders.

Duration of approval for initiation of therapy: 6 months

Approval Criteria for Continuation of Therapy

- The prescriber **states on the request** that the recipient is established on the medication with evidence of a positive response to therapy as evidenced by improvement in muscle strength.

Duration of approval for continuation of therapy: 12 months

References

Forzinity (elamipretide) [package insert]. Needham, MA: Stealth BioTherapeutics Inc; September 2025. https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf

Reid Thompson W, Hornby B, Manuel R, Bradley E, Laux J, Carr J, Vernon HJ. 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 Mar;23(3):471-478. doi: 10.1038/s41436-020-01006-8. Epub 2020 Oct 20. PMID: 33077895; PMCID: PMC7935714.

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