

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2026 P 2388-1
Program	Prior Authorization/Medical Necessity
Medication	Forzinity™ (elamipretide)
P&T Approval Date	1/2026
Effective Date	4/1/2026

**1. Background:**

Forzinity™ (elamipretide) is a mitochondrial cardiolipin binder indicated 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 for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

**2. Coverage Criteria<sup>a</sup>:**

**A. Initial Authorization**

1. **Forzinity** will be approved based on **all** of the following criteria:

a. Diagnosis of Barth syndrome

-AND-

b. Diagnosis has been confirmed by the presence of a pathogenic variant in the *TAFAZZIN* gene identified by molecular genetic testing

-AND-

c. Patient weight is greater than or equal to 30 kg

-AND-

d. Prescribed by or in consultation with one of the following:

- (1) Cardiologist
- (2) Geneticist
- (3) Metabolic specialist
- (4) Neurologist

**Authorization will be issued for 12 months.**

**B. Reauthorization**

1. **Forzinity** will be approved based on **both** of the following criteria:

<p>a. Documentation of positive clinical response to <b>Forzinity</b> therapy (e.g., improvement or stabilization in 6-minute walk test, improvement or stabilization in knee extensor muscle strength)</p> <p style="text-align: center;"><b>-AND-</b></p> <p>b. Prescribed by or in consultation with one of the following:</p> <ul style="list-style-type: none"> <li>(1) Cardiologist</li> <li>(2) Geneticist</li> <li>(3) Metabolic specialist</li> <li>(4) Neurologist</li> </ul> <p><b>Authorization will be issued for 12 months.</b></p> <p><sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>
--

**3. Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits and/or Medical Necessity may be in place.

**4. References:**

1. Forzinity™ [package insert]. Needham, MA: Stealth BioTherapeutics Inc.; September 2025.

Program	Prior Authorization/Medical Necessity - Forzinity™ (elamipretide)
<b>Change Control</b>	
Date	Change
1/2026	New program.