

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: Forzinity™ (elamipretide)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code, if applicable: _____

Weight (if applicable): _____ Date weight obtained: _____

Recommended Dosage: SUBQ: 40 mg once daily

Quantity Limits: 4 vials (14 mL) per 28 days

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 6 months

- Member is 12 years of age or older
- Member weighs 30 kg or greater
- Prescriber is a geneticist, cardiologist, metabolic specialist, hematologist, pediatrician, or a physician who specializes in the treatment of mitochondrial disorder

(Continued on next page)

- Member meets **ONE** of the following:
 - Member is an adult and meets **ONE** of the following (**submit documentation**):
 - Member has estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min
 - Member has an eGFR less than 30 mL/min and is **NOT** on dialysis
 - Member is a pediatric patient and is **NOT** renally impaired
- Member's diagnosis of Barth syndrome was confirmed by at least **ONE** of the following (**submit documentation**):
 - Genetic testing documenting a pathogenic variant in the TFAZZIN gene [**NOTE: Gene testing must demonstrate a hemizygous pathogenic variant in the TFAZZIN (TAZ) gene**]
 - Increased monolysocardiolipin: cardiolipin (MLCL/CL) ratio
- Provider must submit documentation to confirm member is ambulatory (i.e., able to complete a 6-minute walk test)
- Provider must submit documentation to confirm the member has functional impairment related to muscle strength (e.g., knee extensor muscle strength measured by handheld dynamometry)
- Member has **NOT** previously undergone and is **NOT** planned to undergo heart transplantation

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- Member continues to meet all initial authorization criteria
- Member is responding positively to therapy as evidenced by improvement in muscle strength (e.g. knee extensor muscle strength measured by handheld dynamometry) (**submit documentation**)

Medication being provided by Specialty Pharmacy – Proprium Rx

*****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.*****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****