mito ASSIST

Forzinity™ (elamipretide) injection

Patient Enrollment Form **Fax completed forms to: 1 (855) 813-2039**

FORZINITY™ (elamipretide) injection Patient Enrollment Form

Mito Assist™ is a patient and family support program available at no cost for eligible patients prescribed FORZINITY™ (elamipretide) injection for subcutaneous administration. Sponsored by Stealth BioTherapeutics Inc., the maker of FORZINITY, Mito Assist offers support services for qualified patients related to insurance coverage and access for FORZINITY, patient support programs, support for at-home subcutaneous injection training, and education and resources.

Accessing Mito Assist starts with a Patient Enrollment Form completed by the prescribing healthcare provider (HCP) and eligible patient/patient representative. **This form allows eligible patients to register for Mito Assist and also serves as a prescription for FORZINITY.**

Getting started with Mito Assist:

1. **Complete the Patient Enrollment Form in its entirety – fill out all 5 pages**
   a. Sections 1-3 can be completed by the patient/patient representative or the HCP
   b. Sections 4-8 should be filled out and signed by the HCP
      i. Section 5 is the prescription (Rx) and should be filled out according to the label instructions on the FORZINITY package insert
      ii. Section 6 includes medical criteria/clinical information that should be filled out by the HCP to confirm the patient's diagnosis
      iii. Section 7 contains the prescriber authorization
      iv. Section 8 is an optional order for nurse support
      v. Section 9 is the Healthcare Provider Attestation of Mito Assist Patient Assistance and Bridge Programs
   c. Section 10 should be read and signed by the patient/patient representative
2. **The HCP must sign and date the Healthcare Provider Attestation of the Patient Enrollment Form (Section 9) for their patient's eligibility for Mito Assist to be assessed**
   a. The HCP signature is required for patient eligibility screening for Mito Assist patient support programs
3. **The patient/patient representative must sign and date the Patient Consent and Authorization of the Patient Enrollment Form (Section 10) to be enrolled in Mito Assist**
   a. The patient/patient representative (or caregiver) signature is required to access Mito Assist support services (for example, patient and copay assistance), and other financial assistance programs
   b. HCPs are strongly encouraged to have the patient/patient representative sign the consent form during the in-person visit when FORZINITY is prescribed to facilitate relevant support
4. **Fax the completed Patient Enrollment Form to 1 (855) 813-2039, along with the following documents:**
   a. Copy of patient's primary and secondary (if applicable) insurance cards (front and back)
   b. Supporting medical information to aid the prior authorization process
5. **Let your patient know that you are submitting the Patient Enrollment Form and that they should expect a call from our exclusive specialty pharmacy partner, AnovoRx Group, LLC ("Anovo")**

Stealth BIOTHERAPEUTICS

Patient Enrollment Form

This form will also act as a prescription and statement of medical necessity for FORZINITY.

Forzinity™ (elamipretide) injection

Please select one: ☐ Newly prescribed patient ☐ Patient currently on elamipretide

Patient Information *please print

Section 1: To be completed by healthcare provider or patient/patient representative

Patient Last Name: **Patient First Name:**		**SSN:**	**Sex** ☐ **M** ☐ **F**
Address:	**City:**	**State:**	**ZIP:**
Phone: Day #	**Evening #:**	**Cell #:**	**Preferred method of contact:** **Day** ☐ **Evening** ☐ **Cell** ☐
DOB: **Age:**	**Weight lb:** **kg:**	**Height ft:** **in:**	
If Patient Is a Minor, Parent/Legal Guard Name:		**Relation to Patient:**	
Emergency Contact/Relation:	**Phone #:**	**Email:**	

Insurance Information

Section 2: To be completed by healthcare provider or patient/patient representative (Please circle the respondent to indicate who is completing this section.)

Does the patient have insurance?

Yes ☐ (Please fill out the information below and/or provide copies of insurance card[s], front and back, for primary and secondary insurance)

No ☐ (Skip this section)

Primary Insurance Company Name:		Phone #:
Policy Holder Name:	Policy #:	Group #:
Prescription Card Name:		Phone #:
Policy #:		Group #:
Secondary Insurance Company Name:		Phone #:
Policy Holder Name:	Policy #:	Group #:

Patient's Relationship to Policy Holder: ☐ Self ☐ Child ☐ Spouse ☐ Other

Additional Team Information (Optional)

Section 3: To be completed by healthcare provider or patient/patient representative

Are there any other members of the patient's healthcare team that the patient would like Stealth BioTherapeutics (including its representatives and agents) to discuss care and treatment on FORZINITY with? If so, please include their information below.

By electing to provide this information, I certify that I have permission from the following healthcare team members to disclose their personally identifiable information to, and be contacted by, Stealth BioTherapeutics (including its representatives and agents) for the purpose of supporting the patient's care and treatment on FORZINITY.

Care Team Role/Specialty	Name	Email	Phone

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Stealth BIOTHERAPEUTICS

Patient's Full Name _____ DOB (MM/DD/YYYY)_____

Prescriber Information

Section 4: To be completed by healthcare provider

Prescriber Name:		Institution Name:
NPI:	Medicaid UPIN:	State License #:
Address:	City:	State: ZIP:
Name & Title of Office Contact Person:		Office Contact Person Email:
Office Contact Person Phone:		Office Contact Person Fax:
PA Office Contact Name:		PA Office Contact Number:

Prescription

Section 5: To be completed by healthcare provider

Prescription for FORZINITY™ (elamipretide) injection

The recommended dosage for patients weighing at least 30 kg is 40 mg (0.5 mL) once daily by subcutaneous injection. For patients with eGFR <30 mL per minute and NOT on dialysis the recommended dosage is 20 mg (0.25 mL) subcutaneously once daily.

Carton contains four 280 mg/3.5 mL (80 mg/mL) single-patient-use vial

Rx

SIG: ☐ **Inject subcutaneously 40 mg (0.5 mL) once daily** ☐ **Inject subcutaneously 20 mg (0.25 mL) once daily**

Dispense: 28-Day Supply Refills: _____

Additional Prescribing Instructions: _____

Medical Necessity

Section 6: To be completed by healthcare provider

Primary Diagnosis:	Date of Diagnosis:	Patient Age at Diagnosis:

ICD-10 code: ☐ E78.71 ☐ Other _____ Therapy Start Date: _____

Confirmed Barth syndrome diagnosis based on:
- ☐ Genetic Testing
- ☐ Cardiolipin (MLCL:CL) Analysis of Muscle, Platelets, or Cultured Cells
- ☐ Other _____

Patient's Allergies: ○ NKDA

Current Medications:

Prescriber Authorization

Section 7: To be completed by healthcare provider

I certify I am prescribing FORZINITY™ for this patient for a medically necessary purpose and in the best interest of the named patient.

I attest that I have obtained written permission, in the event it is required under applicable federal and/or state law, of my patient (or the patient's legal representative) for the release of my patient's Protected Health Information ("PHI"), as defined by the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), to Stealth BioTherapeutics Inc. or its service providers (collectively "Stealth") as may be necessary for the patient's participation in various assistance programs. I authorize Stealth to convey this prescription on my behalf to the appropriate specialty pharmacy.

I understand that I must comply with the state-specific prescription requirements such as e-prescribing, state-specific prescription form, fax language, etc. I agree that I may be contacted for additional information as needed related to my patient's FORZINITY treatment and/or coordination of care.

I understand that I am under no obligation to prescribe FORZINITY or any other Stealth products. **The prescriber's signature is required to initiate enrollment in Mito Assist and to fill he prescription for FORZINITY.**

Signature (Dispense as Written): _____ Date: _____
No Stamp Signature

OR

Signature (Substitution Allowed): _____ Date: _____
No Stamp Signature

This Patient Enrollment Form is only valid if FAXED to Anovo at 1 (855) 813-2039

Before prescribing Forzinity™, please read the accompanying full Prescribing Information
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf

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Patient's Full Name _____ DOB (MM/DD/YYYY)_____

Optional Nursing Order

Section 8: To be completed by healthcare provider

Skilled nursing visit as needed to provide patient/patient representative education related to administration (or self-administration) of medication as prescribed.

☐ Yes, I would like the specialty pharmacy to coordinate in-home subcutaneous injection training.

Signature: _____ Date: _____

Healthcare Provider Attestation for Mito Assist Patient Assistance and Bridge Programs

Section 9: To be completed by healthcare provider

The Mito Assist Patient Support Programs (PSP)* may provide no-cost supply of FORZINITY to eligible patients who enroll in the program and meet the eligibility criteria. Terms, conditions, eligibility criteria, and restrictions may apply.

By signing this form below I certify that, to the best of my knowledge, the information provided in this form is complete and accurate and that FORZINITY is medically necessary for my patient. I agree to notify Mito Assist if I become aware at any time of changes in my patient's circumstances that would affect his or her eligibility for any Mito Assist PSP, including but not limited to changes in health insurance status or coverage, financial status, residency status in the United States, or the indication for which FORZINITY has been prescribed for my patient.

I attest that I will not bill, charge, seek credit for, or otherwise submit any claim for reimbursement to any insurer, including federal healthcare programs such as Medicare and Medicaid for free products distributed through the Mito Assist PSPs.

I understand that any free product distributed through the Mito Assist PSPs is not contingent on any past or future purchase or prescribing of FORZINITY or other products manufactured or marketed by Stealth. I understand that I am under no obligation to prescribe FORZINITY or any other Stealth products and no free product may be sold, traded, or distributed for sale.

I agree to supervise the patient's treatment and comply with all terms and conditions of the PSPs. I understand that the PSPs are administered in accordance with applicable federal and state laws and may be changed, suspended, or canceled at any time without notice.

PAP Program*
The Mito Assist Patient Assistance Program (PAP) provides no-cost supply of FORZINITY to eligible patients who are uninsured or underinsured and meet the financial need criteria.

I understand that eligibility under the PAP is subject to approval by Mito Assist and my patient must meet certain financial criteria to be eligible for the program. I understand that signing this form does not guarantee that assistance will be provided to my patient. As part of my patient's eligibility, I agree to periodically verify continued use of FORZINITY.

Bridge Program*
The Mito Assist Bridge Program provides limited, no cost supply of FORZINITY for a temporary period to eligible patients who experience a gap in insurance coverage.

I understand that eligibility under the Bridge Program is subject to approval by Mito Assist. I understand that for my patient to be eligible for the Bridge Program, I must actively continue efforts to secure insurance coverage. I further agree that once my patient is approved for the Bridge Program, I will continue efforts to obtain coverage and provide prior authorization denial and appeal documentation as requested by Mito Assist. I understand that Bridge is not health insurance, and is not a guarantee of ongoing access, and is a limited time supply as defined by the program.

Signature: _____ Date: _____

This Patient Enrollment Form is only valid if FAXED to Anovo at 1 (855) 813-2039

** Terms, conditions, eligibility criteria and restrictions apply. Mito Assist is available only in the United States. Submission of an application or enrollment form does not guarantee participation, coverage, medication, or savings. Eligibility and assistance determinations are made on an individual, case-by-case basis and are subject to verification. Mito Assist does not provide medical or treatment advice and is not insurance and does not replace insurance coverage. No purchase is required for enrollment in Mito Assist; treatment decisions are made solely by patients and their healthcare providers. Programs are administered in accordance with applicable federal and state laws and may be changed, suspended, or canceled at any time without notice.*

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Patient's Full Name _____ DOB (MM/DD/YYYY)_____

Patient/Patient Representative Authorization (Optional)

Section 10: To be completed by patient/patient representative

☐ I opt **not** to enroll in Mito Assist at this time. I understand that I do not have to sign this authorization to obtain healthcare treatment or insurance benefits.

Patient Consent and Authorization to Share Personal Information: By signing this Authorization, I hereby authorize my healthcare provider, including physicians and their staff, my health plan(s) providing medical care and prescription coverage, and any pharmacies providing FORZINITY™, to disclose my personally identifiable health and insurance information to Mito Assist™ operated by Stealth BioTherapeutics Inc. and their respective partners, affiliates, agents, and Mito Assist service providers (collectively, "Stealth"). This information includes but is not limited to my medical records, prescriptions, insurance coverage information, name, address, telephone number, and any additional information provided in this consent form and any prescription (my "Information"). I authorize Stealth to use my Information and to share it with my healthcare provider, including physicians and their staff, my health plan(s) providing medical care and prescription coverage, and my pharmacies providing FORZINITY.

I authorize Stealth to use and disclose my Information to (i) determine my eligibility for, facilitate my enrollment into, and administer the Mito Assist programs, (ii) ensure quality and safety and improve Stealth's products and services, (iii) analyze the effectiveness of the patient support programs, including data analysis and compliance reviews, (iv) fulfill legal and regulatory requirements, and (v) conduct data analytics and other internal business activities.

Patient Support Services: I authorize Stealth to contact me by mail, email, fax, telephone call, text message (including calls and text messages made with an automatic telephone dialing system or a prerecorded voicemail).* I authorize Stealth to use my Information to provide support related to FORZINITY, including but not limited to verifying and navigating insurance coverage, providing financial assistance services, providing prescription fulfillment and delivery, administering and evaluating the effectiveness of the patient support program, and offering other support services and disease-related information. I understand that any personnel providing patient support services as part of Mito Assist are not employed by my healthcare provider(s) and may receive compensation from Stealth.

I understand that signing this Authorization is not required to receive medical treatment, health insurance benefits, or other healthcare services, but I will not be able to participate in Mito Assist patient support services without it. I may revoke this Authorization at any time by calling (833) 458-9099. Cancellation will end my consent to further disclosure of my health information to Stealth by my healthcare entities after they are notified of my cancellation but will not affect previous disclosures by them pursuant to this Authorization. Canceling this Authorization will not affect my ability to receive treatment, or my eligibility for health insurance. I have a right to receive a copy of this Authorization. This Authorization expires five (5) years from the date signed unless a shorter period is required by state law. I understand that the specialty pharmacy may receive payment from Stealth for providing patient support services and disclosing associated health information to Stealth pursuant to this Form. I understand that although Stealth has implemented privacy and security controls designed to help protect my Information, once my Information has been disclosed to Stealth, state and federal privacy laws, including the Health Insurance Portability and Affordability Act ("HIPAA"), may no longer apply and my Information may be subject to redisclosure. Stealth will not sell or trade my personal data to any unrelated third party. More information on Stealth's privacy practices, including specific rights I may have as a resident of certain states, can be found in Stealth's privacy policy at: https://stealthbt.com/privacy-policy/

***Data rates may apply.**

By signing below, I confirm that I have read and understand the above Authorization and agree to the terms.

_____

Printed Patient/Legal Representative Name

_____

Signature of Patient/Patient's Legal Representative Date

_____

If Legal Representative, Relationship to Patient_____

Stealth services and support are subject to change.

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Patient's Full Name _____ DOB (MM/DD/YYYY)_____

Optional

Opt-in for Other Resources: (optional)

☐ Yes, please, I would like Stealth to contact me regarding other potential topics of interest to me, customer surveys, opportunities to participate in marketing or disease awareness campaigns, or occasionally for market research purposes. I authorize such contact by mail, email, fax, text messaging, telephone (including calls and text messages made with an automatic telephone dialing system or a prerecorded voicemail).* I understand that I am not required to provide this consent as a condition for receiving any Stealth medicine or Mito Assist patient support services.

☐ No, thank you, I would like to opt out of receiving other resources

*Data rates may apply.

By signing this Authorization, I (the patient or legal representative) hereby authorize the following individuals, in addition to my healthcare provider (physicians and their staff), my health plan(s) providing medical care and prescription coverage, and any pharmacies providing FORZINITY, to disclose my personally identifiable health and insurance information to Mito Assist operated by Stealth BioTherapeutics Inc. and their respective partners, affiliates, agents, and Mito Assist service providers (collectively, "Stealth").

Name	Relationship to Patient

Signature of Patient/Patient's Legal Representative _____ Date _____

Stealth services and support are subject to change.

Before prescribing Forzinity™, please read the accompanying full Prescribing Information
https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/215244s000lbl.pdf

About FORZINITY™ (elamipretide) injection

INDICATION

FORZINITY™ 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).

CONTRAINDICATIONS

Serious hypersensitivity to elamipretide or any of the ingredients.

WARNINGS AND PRECAUTIONS

FORZINITY is not approved in neonates. FORZINITY contains benzyl alcohol and serious adverse reactions including fatal reactions have been reported in low-birth weight neonates and preterm neonates who received benzyl alcohol–containing drugs intravenously. FORZINITY is not approved for intravenous use.
Hypersensitivity reactions, including serious allergic reactions requiring emergency medical intervention, have been reported in patients receiving FORZINITY. Monitor patients for signs and symptoms of hypersensitivity reactions during treatment.

ADVERSE REACTIONS

Most common adverse reactions are injection site reactions.

To report SUSPECTED ADVERSE REACTIONS, contact Stealth BioTherapeutics Inc. at 1-844-444-6486 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

For more information about FORZINITY, please see the full US Prescribing Information.

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