

Frequently Asked Questions About Accessing FORZINITY™ (elamipretide)

The Barth Syndrome Foundation is learning about this process alongside you, and we're committed to communicating with our families as information becomes available. Please sign up for our email newsletter for regular updates about FORZINITY and other BSF updates [here](#).

Who can be prescribed FORZINITY?

The United States' Food and Drug Administration (FDA) approved FORZINITY for individuals living in the United States who are genetically confirmed to have Barth syndrome and weigh 30 kg (66 lbs) or more.

Patients and caregivers should speak with their healthcare provider to determine if FORZINITY is appropriate for them.

Who will distribute FORZINITY and when will it be available?

FORZINITY is manufactured by Stealth BioTherapeutics (Stealth). Stealth has selected [AnovoRx Specialty Pharmacy](#) (AnovoRx) as the only commercial distribution partner for FORZINITY in the United States.

The commercial product is currently available only through AnovoRx.

How can I or my child gain access to FORZINITY?

The patient or patient representative and their healthcare provider must complete the [Patient Enrollment Form](#) available on the AnovoRx website.

This form is the official prescription needed to start the process toward accessing FORZINITY.

The Patient Enrollment Form must be printed out and completed, then faxed by your healthcare provider to AnovoRx at their fax number, 1-855-813-2039. Due to privacy laws, the form may only be received via fax from your healthcare provider.

Who should prescribe FORZINITY?

We anticipate it may be easier to navigate access if you receive a prescription from a healthcare specialist, like a cardiologist or a metabolic specialist, rather than your primary care provider.

What is MitoAssist™? How will I get support for the treatment?

Stealth has launched the MitoAssist Patient Support Program (MitoAssist).

Mito Assist will offer personalized patient support services to help affected individuals and caregivers understand coverage options, manage insurance submissions, and access financial assistance resources. This includes:

- Co-pay assistance for eligible commercially insured patients.
- Patient assistance programs for uninsured or underinsured individuals.
- Support for at-home subcutaneous injection training.
- Dedicated case management through AnovoRx to provide ongoing communication with patients, caregivers, and healthcare providers.

While involvement in MitoAssist is voluntary and is not necessary to receive a prescription for FORZINITY from your healthcare provider, the zero-cost program will play a critical role in helping patients and their caregivers navigate insurance coverage, among other areas of support.

How do I sign up for MitoAssist?

While you are completing the Patient Enrollment Form for FORZINITY, Section 9 contains the Consent and Authorization Form for MitoAssist. Both the Patient Enrollment Form and the Consent and Authorization Form must be completed in their entirety to enroll in MitoAssist.

If you did not complete the Consent and Authorization Form when you completed the Patient Enrollment Form, you may submit it [online through this link](#) at a later date.

Questions about the process should be addressed to AnovoRx at 1-833-458-9099.

What is the cost of the drug?

Stealth established the wholesale cost for patients in the United States who meet the FDA's requirements at approximately \$61,000 for a 28-day supply.

Stealth has stated that the goal is to keep the out-of-pocket costs for insured, on-label individuals to a minimum through insurance coverage and the MitoAssist program.

Will insurance cover FORZINITY?

The FDA approval of FORZINITY is a big step toward insurance coverage of the drug, but challenges in securing coverage for any new approved drug are common, particularly for therapies granted accelerated approval by the FDA.

The degree of coverage will vary depending on your specific insurance plan. MitoAssist will conduct a benefits investigation to help you understand your specific insurance coverage and will support with insurance challenges and appeals. Questions about the process should be addressed to AnovoRx at 833-458-9099.

Will FORZINITY be covered through pharmacy or medical insurance coverage?

We anticipate that the medication will be covered through your pharmacy benefits coverage rather than your medical benefits coverage.

Is the Expanded Access Program still an option for patients who are too young or don't weigh enough to meet the drug's label requirements?

Yes. Healthcare providers who are treating Barth syndrome patients who do not yet meet on-label requirements (the requirements set out by the FDA) may submit a request directly to Stealth to request enrollment of the patient in their [Expanded Access Program](#) (EAP). Applications are reviewed by Stealth on a case-by-case basis.

If I am currently receiving the drug through the Expanded Access Program (EAP), what do I need to do to continue receiving the therapy?

Patients who are currently receiving elamipretide through [Stealth's EAP](#) and weigh at least 30 kg (66 lbs) may be contacted directly by their healthcare provider to facilitate the transition to commercial therapy. If you or the person you are caring for intend to stay on therapy, it is important to initiate the Patient Enrollment paperwork as soon as possible. The EAP program for people who meet the on-label criteria will be discontinued early next year. The EAP will only remain in effect for emergent cases with patients who do not meet the current labeling criteria and for the preservative-free formulation for babies weighing less than 10 kg.

Disclaimer of Endorsement: The Barth Syndrome Foundation (BSF) is an independent nonprofit organization and does not endorse or recommend the use of any particular product, medication, remedy, procedure or therapy. Information is provided for educational purposes only. Always seek the advice of your physician or other qualified health provider.