

TRYNGOLZA™ (olezarsen) for the treatment  
of Familial Chylomicronemia Syndrome (FCS)

# Access Guide

Ionis Pharmaceuticals®, the manufacturer of TRYNGOLZA™, is committed to supporting patients seeking medically appropriate treatment of FCS and healthcare providers (HCPs) utilizing it in treatment adjunct to dietary restrictions. As a part of that commitment, this guide was developed to provide information to help you, the healthcare provider, to better understand some of the administrative aspects of TRYNGOLZA access and the Ionis Every Step™ program.



Please note the information provided in this guide is for informational purposes only. Accurate completion of coverage-related documentation is the sole responsibility of the provider and patient. Coverage policies change periodically and vary by payer, plan, and patient. All services must be medically appropriate and properly supported in the patient's medical record.

## INDICATION

TRYNGOLZA (olezarsen) is indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

## IMPORTANT SAFETY INFORMATION

### Contraindications

TRYNGOLZA is contraindicated in patients with a history of serious hypersensitivity to TRYNGOLZA or any of the excipients in TRYNGOLZA. Hypersensitivity reactions requiring medical treatment have occurred.

### Warnings and Precautions

#### Hypersensitivity Reactions

Hypersensitivity reactions (including symptoms of bronchospasm, diffuse erythema, facial swelling, urticaria, chills, and myalgias) have been reported in patients treated with TRYNGOLZA. Advise patients on the signs and symptoms of hypersensitivity reactions and instruct patients to promptly seek medical attention and discontinue use of TRYNGOLZA if hypersensitivity reactions occur.

#### Adverse Reactions

Most common adverse reactions (incidence >5% of TRYNGOLZA-treated patients and >3% higher frequency than placebo) were injection site reactions, decreased platelet count, and arthralgia.

**Please see full Prescribing Information for TRYNGOLZA, also available at [TRYNGOLZAhcp.com](http://TRYNGOLZAhcp.com)**

## Ionis Every Step supports patients and their care teams throughout the TRYNGOLZA treatment journey

We understand the challenges your patients face and are committed to simplifying the TRYNGOLZA approval process. Ionis Every Step services include the following:



**Insurance assistance**



**Patient Education Managers**



**Coordinated TRYNGOLZA delivery**



**Financial assistance\***



**Nutrition support**

\*For qualified or eligible patients

### There are three simple ways to enroll your patient in the Ionis Every Step program:

Your patient can sign up online at  
**TRYNGOLZA.com/Enroll**

OR

Your patient can  
**call Ionis Every Step at 1-844-789-8744**  
Monday to Friday  
8 AM to 8 PM ET

OR

Have your patient sign the second page of the TRYNGOLZA Patient Enrollment and Prescription Form then **fax it** to Ionis Every Step at 1-877-914-0660

### Prescribing is easy

To prescribe TRYNGOLZA for your patient, download the TRYNGOLZA Patient Enrollment and Prescription Form. Once you have completed the form, fax it to 1-877-914-0660. You can also e-prescribe TRYNGOLZA through your electronic medical records system by submitting an eRx straight to PANTHERx Specialty Pharmacy, our single-source, exclusive specialty pharmacy.



Download and print the TRYNGOLZA Patient Enrollment and Prescription Form by scanning the QR code or visit [TRYNGOLZA.com/Enroll](https://www.ionisbiotech.com/TRYNGOLZA.com/Enroll)

### Financial Assistance

Commercially insured patients may pay as little as \$0 out of pocket per fill.

Ionis Every Step will assess each patient's eligibility for our financial support programs and provide them with information on the appropriate programs if their insurance is not covering TRYNGOLZA.

### Checklist of items to send to Ionis Every Step

To ensure Ionis Every Step has all the documentation needed to support you and your patient, below is a list of items to send to Ionis Every Step:

- Completed enrollment form
- All insurance cards<sup>†</sup> (front and back)
- Any/all relevant correspondences from health insurer
- Supporting clinical documentation (see prior authorization checklist)

<sup>†</sup>If patient has health insurance.

**See full Indication and Important Safety Information for TRYNGOLZA on the first page. Please see full Prescribing Information for TRYNGOLZA, also available at [TRYNGOLZAhcp.com](https://www.ionisbiotech.com/TRYNGOLZAhcp.com)**

## Prior authorization and appeals support

TRYNGOLZA may require a Prior Authorization (PA) from some health insurance providers.

Ionis Every Step provides information and resources if coverage for TRYNGOLZA requires prior authorization by your patient's health plan. Ionis Every Step Case Managers are available to assist your office with the prior authorization process, including preparing a package of supporting documentation to submit to the patient's health plan for consideration.

### Prior authorization checklist

The submission of a completed PA form may expedite the approval of treatment for TRYNGOLZA. Note PA requirements vary among insurers; the following information may need to be included in the submission:

#### Patient Information

- Name
- Address
- Date of birth
- Health insurance information

#### Healthcare Provider Information

- Prescribing physician name
- Tax ID
- Address
- Phone and fax numbers
- NPI and provider number

#### Clinical Diagnosis

- Diagnosis, including ICD-10-MC code
- Indication

#### Supporting clinical documentation

- Genetic testing results
- Supporting clinical documentation, including:
  - Patient test results for triglycerides (TG) levels (highest fasting levels measured within the last year, preferably)
  - Hospitalization history due to acute pancreatitis and/or severe abdominal pain
  - TG-lowering medication history, including trial and failure of fibrates, omega-3s, statins, or other TG-lowering medication
- FCS Clinical Scoring—  
Use scoring tool provided by the Rare Disease Account Specialist

Ionis Every Step is committed to providing educational and supporting materials along the way.

See full Indication and Important Safety Information for TRYNGOLZA on the first page. Please see full Prescribing Information for TRYNGOLZA, also available at [TRYNGOLZAhcp.com](http://TRYNGOLZAhcp.com)

# Navigating Access

## Genetic Testing

Utilizing genetic testing may confirm clinical diagnosis FCS in your patients, and can have multiple benefits:

- Allows for earlier disease identification, intervention, and treatment
- Aids to support rare disease status for many health insurance providers
- Potentially accelerates the prior authorization documentation process(es) should they be required by your patient's health insurance provider
- May allow patients to save out-of-pocket costs by avoiding travel and associated copay/co-insurance to visit a specialist for diagnostic purposes

Genetic testing of FCS may result in multiple outcomes such as the following:

Testing Result	Potential Next Steps
<b>Positive</b>	FCS has been confirmed in your patient. Forward the appropriate genetic test documentation along with laboratory results for TG levels to your patient's health insurance company AND the Ionis Every Step program to optimize support of your patient.
<b>Indeterminant</b>	<p>An indeterminant genetic testing result indicates that one or more variants of uncertain significance were found, which neither confirms nor denies FCS in your patient. As a result, the following documentation should be forwarded to your patient's health insurance company AND the Ionis Every Step program to optimize support of your patient:</p> <ul style="list-style-type: none"><li>• Laboratory results for TG levels (highest fasting levels measured within the last year, preferably)</li><li>• Medical history of pancreatic events and/or related hospitalizations due to severe abdominal pain</li><li>• FCS Clinical Scoring Tool: Please use the scoring tool provided by the Rare Disease Account Specialist</li><li>• Triglyceride-lowering medication history including trial and failure of fibrates, omega-3s, statins, or other TG-lowering medications</li></ul>

You may fax supporting clinical documentation to Ionis Every Step at 1-877-914-0660.

**For help navigating access for genetic testing,  
please contact your Ionis Every Step Case Manager.**

**See full Indication and Important Safety Information on the first page.  
Please see full Prescribing Information for TRYNGOLZA, also available at [TRYNGOLZAhcp.com](https://www.ionispharm.com/TRYNGOLZAhcp.com)**