

TRYNGOLZA[®] (olezarsen) for the treatment
of familial chylomicronemia syndrome (FCS)

Access Guide

Ionis Pharmaceuticals, Inc., 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 Important Safety Information on the first page and full Prescribing Information for TRYNGOLZA, also available at 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:



*For qualified or eligible patients.

There are 3 simple ways to enroll your patient in the Ionis Every Step program:

Sign up online at
TRYNGOLZA.com/Enroll

OR

Call Ionis Every Step
at 1-844-789-8744
Monday to Friday
8 AM to 8 PM ET

OR

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 TRYNGOLZAhcp.com

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[†] (front and back)
- Any/all relevant correspondences from health insurer
- Supporting clinical documentation (see prior authorization checklist)

[†]If patient has health insurance.

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 Field Access Managers and Ionis Every Step 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

- Age
- Diet
- Family History of FCS

FCS Diagnosis

- ICD-10-CM Code
- Indication
- Genetic Test
- Moulin et al Clinical Criteria
- North American FCS (NAFCS) Score

Supporting Clinical Documentation

- Triglyceride (TG) Levels
- Medical history of any of the following (especially if an indeterminate genetic test occurred)¹:
 - Pancreatitis (includes hospitalization history due to acute pancreatitis)
 - Lipemia retinalis
 - Eruptive xanthomas
 - Recurrent abdominal pain
- Previous therapy including failure of maximum tolerated doses, contraindication, intolerance, or if the patient is not a candidate for the following^{2,3}:
 - Fibrates
 - Statins
 - Omega-3 fatty acids
 - Other lipid-lowering medications

ICD-10-CM, International Classification of Diseases, Tenth Revision, Clinical Modification.

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

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Navigating Access

Genetic Testing

Utilizing genetic testing may confirm the clinical diagnosis of 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/coinsurance 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
Positive	FCS has been detected in your patient. Send documentation of appropriate genetic test, along with laboratory results for triglyceride (TG) levels, to your patient's health insurance company and the Ionis Every Step Program to optimize support of your patient.
Indeterminate	<p>One or more variants of uncertain significance of FCS were found—neither confirmed nor denies FCS in your patients. Send additional documentation to your patient's health insurance company and the Ionis Every Step Program to optimize support for your patient. These documents include</p> <ul style="list-style-type: none"> • Laboratory results for TG levels (highest fasting levels measured, preferably within the last year) • Medical history of pancreatic events and/or related hospitalizations due to severe abdominal pain • FCS clinical scoring tool results: <ul style="list-style-type: none"> – North American FCS (NAFCS) Score,⁴ or – Moulin et al Clinical Criteria⁵ • TG-lowering medication history including trial and failure of fibrates, omega-3s, statins, or other TG-lowering medications
Negative	<p>FCS has not been detected in your patients. Even with a negative result, patients may still be diagnosed with FCS.^{5,6} Diagnosis must now be confirmed by your patient's health insurance plan using alternative documentation of the disease. Consider providing them with the following:</p> <ul style="list-style-type: none"> • A Letter of Medical Necessity outlining the rationale for the diagnosis and the need for the treatment • Medical history of pancreatic events and/or related hospitalizations due to severe abdominal pain • FCS Clinical Scoring Tool Results: NAFCS Score or Moulin et al Clinical Criteria • Additional supporting documentation, including TG lab results, TG-lowering medication history, etc <p>In certain instances, health insurance providers may offer, or sometimes request, a one-on-one conference between the healthcare provider and the health plan's clinical reviewer to discuss the diagnosis and requested treatments.</p>

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 Field Access Manager (FAM)

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

References: **1.** Witztum JL, Gaudet D, Freedman SD, et al. Volanesorsen and triglyceride levels in familial chylomicronemia syndrome. *N Engl J Med.* 2019;381(6):531-542. **2.** Bashir B, Ho JH, Downie P, et al. Severe hypertriglyceridaemia and chylomicronaemia syndrome—causes, clinical presentation, and therapeutic options. *Metabolites.* 2023;13(5):621. **3.** Jellinger PS, Handelsman Y, Rosenblit PD, et al. AACE Guidelines. *Endocr Pract.* 2017;23(suppl 2):1-87. **4.** Hegele RA, Ahmad Z, Ashraf A, et al. Development and validation of clinical criteria to identify familial chylomicronemia syndrome (FCS) in North America. *J Clin Lipidol.* 2025;19(1):83-94. doi:10.1016/j.jacl.2024.09.008. **5.** Moulin P, Dufour R, Aversa M, et al. Identification and diagnosis of patients with familial chylomicronaemia syndrome (FCS): expert panel recommendations and proposal of an "FCS score". *Atherosclerosis.* 2018;275:265-272. doi:10.1016/j.atherosclerosis.2018.06.814. **6.** Aguilar-Salinas CA, Alonso R, Berg G, et al. A multi-society Delphi consensus statement on the diagnosis of familial chylomicronemia syndrome. *Arch Endocrinol Metab.* 2025;69(5):e250071. doi:10.20945/2359-4292-2025-0071.