Tryngolza®
(olezarsen) injection

Navigating the Coverage Process for TRYNGOLZA® (olezarsen)

Guide to managing prior authorizations and appeals

TRYNGOLZA is covered under the pharmacy benefit, and patients may need to meet coverage criteria to receive approval from their insurance plan. This resource will help you understand potential coverage criteria for prior authorization (PA) requests, what to do if coverage is denied, and how Ionis Every Step™ and our pharmacy partners can help your office navigate these processes.

INDICATION

TRYNGOLZA (olezarsen) is indicated as an adjunct to diet to reduce triglycerides (TG) and the risk of acute pancreatitis in adults with severe hypertriglyceridemia (sHTG: TG ≥500 mg/dL).

SELECT 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.

Please see Important Safety Information throughout and full Prescribing Information for TRYNGOLZA.

Indication and Important Safety Information for TRYNGOLZA

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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.

Liver Enzyme Abnormalities

TRYNGOLZA can cause increases in liver enzymes and hepatic fat in adults. Increases in liver enzymes were more frequently reported with the 80 mg dose as compared with the 50 mg dose. Consider liver enzyme testing before TRYNGOLZA initiation or an increase in dosage and when clinically indicated thereafter. If persistent elevations in liver enzymes occur, consider dose interruption and/or dose reduction. If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue TRYNGOLZA.

ADVERSE REACTIONS

Most common adverse reactions in patients with sHTG (incidence ≥2% higher than placebo) were injection site reactions and liver enzyme increases.

Please see full Prescribing Information for TRYNGOLZA, also available at TRYNGOLZAhcp.com.

You've Prescribed TRYNGOLZA—What's Next?

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Help your patients access TRYNGOLZA

After sending the TRYNGOLZA prescription using your preferred prescribing method (electronically through your EHR system or by faxing the TRYNGOLZA Start Form), your patient's pharmacy will:

- **Send your office a PA request electronically through CoverMyMeds® or via fax**; it is important to complete this submission in a timely manner to help minimize treatment delays for your patients
- Reach out directly to your patient for an **introductory call** and to answer any questions they might have

The pharmacy will provide plan-specific forms and can direct you to materials supporting the PA process. You can also visit TRYNGOLZAhcp.com to download helpful resources

EHR, electronic health record; PA, prior authorization.

Information That May Be Required by the Insurance Plan

Generally, insurance plans require several key pieces of clinical information to approve coverage. Consider including the following information and documentation with a PA request for TRYNGOLZA.

Patient information

- ☐ **Age**[1]
  - Patient is at least 18 years of age
- ☐ **Diet**[1]
  - Patient is following a low-fat diet

Diagnosis

- ☐ **Diagnosis code (ICD-10-CM) and date of diagnosis**

  Potential ICD-10-CM diagnosis codes include[2]
  - E78.1 (pure hyperglyceridemia)
  - E78.2 (mixed hyperlipidemia)
  - E78.3 (hyperchylomicronemia)
  - E78.4 (other hyperlipidemia)

Supporting clinical documentation

- ☐ **Triglyceride levels**[3]
  - All fasting levels measured in medical records ≥500 mg/dL
- ☐ **Medical history (as applicable)**[4]
  - Pancreatitis events and/or related hospitalizations due to severe abdominal pain
  - Lipemia retinalis
  - Eruptive xanthomas
  - Recurrent, unexplained abdominal pain
- ☐ **Previous or current lipid-lowering therapy**

  Documentation of failure of maximum tolerated doses, contraindication, intolerance, or if patient is not a candidate for the following[5,6]:
  - Fibrates
  - Statins
  - Omega-3 fatty acids
  - Other lipid-lowering medications
- ☐ **Prescribed by, or in consultation with, a specialist**

Optional supporting documentation

- ☐ **FDA approval letter***
- ☐ **TRYNGOLZA Prescribing Information***
- ☐ **Letter of Medical Necessity***
- ☐ **sHTG treatment guidelines, such as AHA/ACC Multi-Society (2026)***

*These materials are especially important to include with your request during the pre-policy period.

AHA/ACC, American Heart Association/American College of Cardiology; FDA, Food & Drug Administration; ICD-10-CM, International Classification of Disease, Tenth Revision, Clinical Modification.

Considerations for Completing a Letter of Medical Necessity

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After the pharmacy sends your office a PA request through CoverMyMeds or fax, you may consider including a Letter of Medical Necessity with the submission. The insurance plan will review this document while making the coverage decision, as it presents the prescriber's rationale for treatment with TRYNGOLZA.

Keep these considerations in mind when drafting your letter.

- Include details to help **identify your patient**, such as their insurance plan policy and group numbers
- State that you are writing on behalf of your patient to **document medical necessity** for TRYNGOLZA
- Describe your **patient's medical history**, including diagnosis, relevant lab results (fasting triglycerides), history of acute pancreatitis events, hospitalization history, whether TRYNGOLZA was prescribed by (or in consultation with) a specialist, and triglyceride-lowering medication history, including trial and failure of
  - Fibrates
  - Statins
  - Omega-3 fatty acids
  - Other lipid-lowering medications
- List additional documents that will be included with the letter such as US Prescribing Information (USPI) for TRYNGOLZA, FDA approval letter, relevant medical records (eg, lab results), or relevant scientific literature (eg, pivotal clinical trial results from the USPI)

A Sample Letter of Medical Necessity is available for TRYNGOLZA.
Visit TRYNGOLZAhcp.com to download this resource

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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.

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Next Steps if Coverage Is Denied

If you receive a denial, you can appeal and ask the insurance plan to reconsider their decision. Get started with the steps below.

Review the communication from the insurance plan to understand the reason(s) for denial, then send the denial letter to the pharmacy so they can help you navigate next steps

Draft a Letter of Appeal to provide additional rationale for your treatment decision and include relevant documentation

- A Sample Letter of Appeal is available for TRYNGOLZA. Visit **TRYNGOLZAhcp.com** to download this resource

Scheduling a peer-to-peer review may be especially helpful before a coverage decision has been made

- Use this conversation to discuss your clinical rationale for why the denial should be overturned
- If this does not result in the denial being overturned, the next step is sending a formal Letter of Appeal

The pharmacy can assist your office after a coverage rejection or denial. Reach out to them for support, or if you have additional questions, call the TRYNGOLZA Support Center at 1-844-798-8744, Monday to Friday, 8 AM to 8 PM

SELECT IMPORTANT SAFETY INFORMATION

WARNINGS AND PRECAUTIONS

Liver Enzyme Abnormalities

TRYNGOLZA can cause increases in liver enzymes and hepatic fat in adults. Increases in liver enzymes were more frequently reported with the 80 mg dose as compared with the 50 mg dose. Consider liver enzyme testing before TRYNGOLZA initiation or an increase in dosage and when clinically indicated thereafter. If persistent elevations in liver enzymes occur, consider dose interruption and/or dose reduction. If serious hepatic injury with clinical symptoms and/or hyperbilirubinemia or jaundice occurs, promptly discontinue TRYNGOLZA.

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Potential Reasons for Coverage Denials

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The insurance plan may deny coverage of TRYNGOLZA for several reasons. The recommendations below may help overcome a denied PA request.

Reason for denial	Recommendation
TRYNGOLZA is not on the patient's formulary	Submit an appeal and include the TRYNGOLZA Prescribing Information and FDA approval letter
Lack of documentation or lab results not supporting diagnosis	Confirm correct diagnosis code and appropriate number of lab tests demonstrating ≥500 mg/dL are provided
Patient did not previously fail other lipid-lowering therapies	Explain (eg, via Letter of Appeal) all previous and/or concurrent therapies and corresponding reason(s) for failure, if applicable
Plan requires genetic testing or other criteria not applicable to sHTG	Submit an appeal and include the TRYNGOLZA Prescribing Information and FDA approval letter

The pharmacy can help initiate an appeal on behalf of your patient, if needed

sHTG, severe hypertriglyceridemia.

Considerations for Requesting a Peer-to-Peer Medical Review

You may have the option to request a peer-to-peer review to discuss your clinical rationale for why the denial should be overturned. This can be requested before drafting a Letter of Appeal.

Before the review

- **Confirm** the date and time of the meeting
- **Gather** appropriate clinical documentation
- **Review** the insurance plan's policy to understand the coverage requirements
- **Ensure** you have the following:
  - NDC for TRYNGOLZA[1]
    - 50 mg: 71860-102-01
    - 80 mg: 71860-101-01
  - TRYNGOLZA US Prescribing Information
  - PA request
  - Letter of Medical Necessity
  - Insurance plan denial letter

During the review

- **State** that you want to discuss the approval of TRYNGOLZA for your patient
- **Be prepared** to discuss your treatment rationale
- **Reference** your patient's condition and medical history
- **Confirm** timing on a decision and any follow-up steps

After the review

- **Contact** your patient to
  - Inform them of the meeting
  - Request any additional information (if needed)
  - Update them on important dates and deadlines related to the appeal
- **Provide any additional documentation** requested by the insurance plan

Our pharmacy partners can help you navigate next steps after a coverage denial. Reach out to them for support by calling the TRYNGOLZA Support Center at 1-844-798-8744, Monday to Friday, 8 AM to 8 PM

NDC, national drug code.

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ADVERSE REACTIONS

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Considerations for Completing a Letter of Appeal

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Your office can submit a Letter of Appeal to the insurance plan to request a reconsideration of the coverage denial.

Keep these considerations in mind when drafting your letter.

- Review the communication from the insurance plan to **understand the reason(s)** for denial, and send the denial letter to the pharmacy for their records
- Use the same language from the insurance plan's letter to explain the reason(s) for denial
- State that you are writing on behalf of your patient to **appeal the denial** of coverage for TRYNGOLZA
- Describe your **patient's medical history**, including diagnosis, previous and current triglyceride levels, history of acute pancreatitis, ED visits, hospitalizations, documentation of current and previous lipid-lowering treatments (including response/failure), additional symptoms related to their condition, and whether TRYNGOLZA was prescribed by (or in consultation with) a specialist
- Consider including details from the TRYNGOLZA USPI on the Phase 3 clinical trials for patients with sHTG
- Reiterate that, based on your clinical judgment, TRYNGOLZA is appropriate and medically necessary for your patient
- List **additional documents** that will be included with the letter
  - Original denial letter and Letter of Medical Necessity
  - USPI for TRYNGOLZA and FDA approval letter
  - Patient's clinical records
  - Patient authorization and notice of release information

A Sample Letter of Appeal is available for TRYNGOLZA.
Visit TRYNGOLZAhcp.com to download this resource

ED, emergency department.

What's Next After Coverage Is Approved?

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A coverage approval means that the insurance plan has decided to cover TRYNGOLZA for your patient. After receiving a coverage approval, consider these next steps.

Document the length of approval from the insurance plan (eg, 6 or 12 months) and when/if reauthorization is necessary

- This is important to prevent potential lapses in treatment

Follow up with your patient's pharmacy to ensure the prescription was received

Let your patient know that their **pharmacy will contact them** to discuss potential out-of-pocket costs, arrange delivery, and coordinate refills

- Encourage your patient to save their pharmacy's number in their phone

Plan for reauthorization— keep track of your patient's

- Recent triglyceride levels while on treatment to support clinical response
- Lack of hospitalization since starting treatment
- Commitment to maintaining a low-fat diet

Ionis Every Step and our pharmacy partners can help set expectations for your patients when starting TRYNGOLZA. Encourage patients to reach out to their pharmacy or call the TRYNGOLZA Support Center at 1-844-789-8744 (select option 2), Monday to Friday, 8 AM to 8 PM ET, for more support

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Support to Help Your Patients Take Control

IONIS EVERY STEP SUPPORT SERVICES

Access support from our pharmacy partners

Our select network of pharmacies can support your patients and your office while managing PA requests and appeal submissions.

If you have questions about the support available to your office, please reach out to your patient's pharmacy. If you are not sure which pharmacy to call, or if you need additional support, call the TRYNGOLZA Support Center at 1-844-789-8744, Monday to Friday, 8 AM to 8 PM ET.

Support designed to help your patients navigate treatment with TRYNGOLZA

Ionis Every Step offers a broad range of support to help your patients at every step of their TRYNGOLZA treatment journey.

Programs to support access and affordability for TRYNGOLZA, regardless of insurance type*

Support for starting and staying on TRYNGOLZA

Education to keep patients informed and engaged throughout their treatment journey

Encourage patients to sign up for Ionis Every Step today by visiting TRYNGOLZA.com/Enroll, or for additional support, they can call 1-844-789-8744 (select option 2), Monday to Friday, 8 AM to 8 PM ET

*Subject to program terms, conditions, and limits. Ionis Every Step consent is required for participation in all Ionis Every Step coverage and affordability programs.

IONIS EVERY STEP™ SUPPORT SERVICES

For additional support helping your patients access TRYNGOLZA

- Reach out to your patient's pharmacy
- Call the TRYNGOLZA Support Center at 1-844-789-8744, Monday to Friday, 8 AM to 8 PM ET
- Visit **TRYNGOLZAhcp.com**

References: 1. TRYNGOLZA. Prescribing information. Ionis Pharmaceuticals. **2.** Centers for Medicare & Medicaid Services. ICD-10-CM tabular list of diseases and injuries. https://www.cms.gov/files/zip/2025-code-tables-tabular-and-indexapril.zip. Updated January 15, 2025. Accessed April 27, 2026. **3.** Saadatagah S, Larouche M, Naderian M, et al. Recognition and management of persistent chylomicronemia: A joint expert clinical consensus by the National Lipid Association and the American Society for Preventive Cardiology. *J Clin Lipidol*. 2025;19(4):723-736. doi:10.1016/j.jacl.2025.03.012. **4.** 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. doi:10.1056/NEJMoa1715944. **5.** Bashir B, Ho JH, Downie P, et al. Severe hypertriglyceridaemia and chylomicronaemia syndrome—causes, clinical presentation, and therapeutic options. *Metabolites*. 2023;13(5):621. **6.** Jellinger PS, Handelsman Y, Rosenblit PD, et al. AACE Guidelines. *Endocr Pract*. 2017;23(suppl 2):1-87.

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