# EVH Clinical Guideline 5110.CC for Tryngolza (Olezarsen)

| **Guideline Number:**<br>EVH_CG_5110.CC | **Applicable Codes** | |
|---|---|---|
| ***"Evolent" refers to Evolent Health LLC and Evolent Specialty Services, Inc.***<br> | | |
| **Original Date:**<br>December 2025 | **Last Revised Date:**<br>October 2025 | **Implementation Date:**<br>December 2025 |

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# STATEMENT

## General Information

- *It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Medical Policy Committee.*
- *If the established criteria are not met, the request is referred to a Medical Director for review, if required for the plan and level of request.*

## Purpose

The purpose of this guideline is to define the prior authorization process for Tryngolza (olezarsen).

## Scope

This guideline applies to all practitioners who are involved in providing the requested drug. This guideline is specific to the Health Plan's medical benefit.

# INITIAL REVIEW CRITERIA

The request must meet all of the criteria listed below.

- Must be prescribed by a cardiologist, an endocrinologist, or a physician who focuses in the treatment of disorders related to severe hypertriglyceridemia
- Must have a diagnosis of genetically confirmed Familial Chylomicronemia Syndrome (type 1 Hyperlipoproteinemia)
- Must be 18 years of age or older
- Must have a fasting triglyceride of ≥ 880 mg/dL
- Must have a history of pancreatitis
- Must be on stable dose of statins, omega-3 fatty acids, fibrates, or other lipid-lowering medications
- Must maintain a low-fat diet (≤ 20g fat per day) in conjunction with Tryngolza
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA approved labeling

# REAUTHORIZATION CRITERIA

All prior authorization renewals are reviewed on an annual basis to determine the Medical Necessity for continuation of therapy. The request must meet all of the criteria listed below.

- Must have updated chart documentation from the prescriber that the member's condition has improved based upon the prescriber's assessment while on therapy
- Must be prescribed at a dose within the manufacturer's dosing guidelines (based on diagnosis, weight, etc.) listed in the FDA-approved labeling

# APPROVAL DURATIONS

| | |
|---|---|
| **Initial Authorization** | 1 year |
| **Reauthorization** | Same as initial |

# CODING AND STANDARDS

## Codes

| Code | Brand | Description |
|---|---|---|
| J3490 | Tryngolza | Olezarsen |

## Applicable Lines of Business

| | |
|---|---|
| ☐ | CHIP (Children's Health Insurance Program) |
| ☐ | Commercial |
| ☐ | Exchange/Marketplace |
| ☒ | Medicaid |
| ☐ | Medicare Advantage |

# BACKGROUND

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

# POLICY HISTORY

| Date | Summary |
|---|---|
| October 2025 | • New Guideline |

# LEGAL AND COMPLIANCE

## Guideline Approval

### *Committee*

**Reviewed / Approved by Evolent Administrative Services Medical Policy Committee**

## Disclaimer

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# REFERENCES


1. Tryngolza [package insert]. Carlsbad, CA: Ionis Pharmaceuticals Inc., 2024
2. Stroes ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al. Olezarsen, Acute Pancreatitis, and Familial Chylomicronemia Syndrome. N Engl J Med. 2024;390(19):1781-1792. doi:10.1056/NEJMoa2400201studies