

Commercial PA Criteria Effective: February 6, 2025

Prior Authorization: Tryngolza (olezarsen)

Products Affected: Tryngolza (olezarsen) subcutaneous injection

Medication Description: Olezarsen is an ASO-GalNAc3 conjugate that binds to apoC-III mRNA leading to mRNA degradation and resulting in a reduction of serum apoC-III protein. Reduction of apoC-III protein leads to increased clearance of plasma TG and VLDL.

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

Exclusion Criteria:

1. Tryngolza is contraindicated in patients with a history of serious hypersensitivity to olezarsen or any of the excipients in Tryngolza

Required Medical Information:

1. Diagnosis
2. Medical History
3. Lab Values; including genetic testing results.

Prescriber Restriction: Medication is prescribed by a cardiologist, an endocrinologist, or a physician who focuses in the treatment of disorders related to severe hypertriglyceridemia

Age Restriction: Patient is ≥ 18 years of age.

Coverage Duration: Coverage will be provided 12 months and can be renewed.

Other Criteria:

Initial Approval Criteria

1. **Familial Chylomicronemia Syndrome.** Approve if the patient meets ALL of the following (A, B, C, D, and E):
 - A. Patient is ≥ 18 years of age; **AND**
 - B. Patient has a fasting triglyceride level ≥ 880 mg/dL **[documentation required]**; **AND**
 - C. The patient has undergone genetic testing and meets **ONE** of the following (i or ii):
 - i. Molecular genetic test results demonstrate biallelic pathogenic variants in at least one gene causing familial chylomicronemia syndrome **[documentation required]**; **OR**
Note: Examples of genes causing Familial Chylomicronemia Syndrome include lipoprotein lipase (LPL), glycosylphosphatidylinositol-anchored high-density lipoprotein-binding protein 1 (GPIHBP1), apolipoprotein A-V (APOA5), apolipoprotein C-II (APOC2), or lipase maturation factor 1 (LMF1).
 - ii. Molecular genetic test results are inconclusive and the patient has **ONE** of the following (a, b, c, d, or e) **[documentation required]**:
 - a. Patient has a familial chylomicronemia syndrome score ≥ 10 ; **OR**
 - b. Patient has a North American familial chylomicronemia syndrome score ≥ 45 ; **OR**

February 2025



- c. Patient has a history of pancreatitis; **OR**
- d. Patient has a history of eruptive xanthomas; **OR**
- e. Patient has a history of lipemia retinalis; **AND**
- D. The medication will be used concomitantly with a low-fat diet; **AND**
- E. Medication is prescribed by a cardiologist, an endocrinologist, or a physician who focuses in the treatment of disorders related to severe hypertriglyceridemia.

Renewal Criteria

- 1. Member has responded positively to therapy according to the prescriber; **AND**
- 2. Member has not experienced unacceptable toxicity from the medication

References:

- 1. Tryngolza™ subcutaneous injection [prescribing information]. Carlsbad, CA: Ionis; December 2024.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	02/06/2025

