UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2364-1
Program	Prior Authorization/Medical Necessity
Medication	Tryngolza™ (olezarsen)
P&T Approval Date	2/2025
Effective Date	5/1/2025

1. Background:

Tryngolza™ (olezarsen) is an *APOC-III*-directed antisense oligonucleotide (ASO) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).

2. Coverage Criteria[a]:

A. Initial Authorization

1. Tryngolza will be approved based on **both** of the following criteria:

   a. **Both** of the following:

      (1) Diagnosis of familial chylomicronemia syndrome (FCS) (i.e., monogenic chylomicronemia, type 1 hyperlipoproteinemia)

      -AND-

      (2) Diagnosis has been confirmed by **both** of the following:

         (a) **One** of the following:

            i. Genetic confirmation of biallelic pathogenic variants (i.e., homozygosity, compound heterozygosity or double heterozygosity) in FCS-causing genes (i.e., *LPL*, *GPIHBP1*, *APOA5*, *APOC2*, or *LMF1*)

            -OR-

            ii. North American FCS (NAFCS) Score ≥ 45

         -AND-

         (b) Untreated fasting triglyceride levels greater than or equal to 880 mg/dL

   -AND-

   b. Prescribed by **one** of the following:

      (1) Cardiologist
      (2) Endocrinologist

(3) Gastroenterologist
(4) Lipid specialist (lipidologist)

Authorization will be issued for 12 months

B. Reauthorization

1. **Tryngolza** will be approved based on **both** of the following criteria:

   a. Documentation of positive clinical response to Tryngolza therapy (e.g., reduction in triglycerides, reduction in episodes of acute pancreatitis)

   -AND-

   b. Prescribed by **one** of the following:
   (1) Cardiologist
   (2) Endocrinologist
   (3) Gastroenterologist
   (4) Lipid specialist (lipidologist)

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Tryngolza [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; December 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/NEJMoa2400201
3. Davidson M, Stevenson M, Hsieh A, et al. The burden of familial chylomicronemia syndrome: Results from the global IN-FOCUS study. *J Clin Lipidol*. 2018;12(4):898-907.e2. doi:10.1016/j.jacl.2018.04.009
4. Baass A, Paquette M, Bernard S, Hegele RA. Familial chylomicronemia syndrome: an under-recognized cause of severe hypertriglyceridaemia. *J Intern Med*. 2020;287(4):340-348. doi:10.1111/joim.13016
5. 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*. Published online November 12, 2024. doi:10.1016/j.jacl.2024.09.008

Program	Prior Authorization/Medical Necessity - Tryngolza™ (olezarsen)
Change Control	
Date	Change
2/2025	New program.