Generic Name: Olezarsen

Therapeutic Class or Brand Name: Tryngolza

Applicable Drugs: N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/2/2025

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through IX are met)

I. Documented diagnosis of Familial Chylomicronemia Syndrome (FCS) confirmed with genetic testing (i.e., variants in LPL, APO2, GPIHBP1, APOA5, GPD1, CREB3L3, or LMF1).

II. Documented concomitant lifestyle interventions, including a low-fat diet (≤20 g fat per day) and avoidance of alcohol.

III. Documented baseline fasting triglyceride (TG) levels ≥880 mg/dL (10 mmol/L).

IV. Documented trial and failure of at least three of the following TG-lowering drug classes at maximally tolerated, optimized dosing:

   A. High-intensity statins (i.e., atorvastatin 40 mg to 80 mg daily or rosuvastatin 20 mg to 40 mg daily)

   B. Fibrates

   C. Omega-3 fatty acids

   D. Niacin

V. Documented baseline platelet count >100,000/mm^3 prior to initiation.

VI. Minimum age requirement: 18 years old.

VII. Treatment must be prescribed by or in consultation with an endocrinologist or physician who specializes in the treatment of FCS.

VIII. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IX. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- History of severe renal impairment (eGFR < 30 mL/min) or end-stage renal disease.
- History of moderate or severe hepatic impairment.

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Tryngolza (olezarsen) 80 mg/0.8 mL single-dose autoinjector: 1 autoinjector per 28 days

Approval Length

- **Authorization:** 12 months
- **Re-Authorization:** 1 year. An updated letter of medical necessity or progress notes showing positive clinical response, as confirmed with a reduction triglycerides or episodes of acute pancreatitis.

Appendix

N/A

References

1. Tryngolza [Prescribing Information], Carlsbad, CA; Ionis Pharmaceuticals, Inc.; 2024. Accessed April 21, 2025.

   https://ionis.com/sites/default/files/2025-03/TRYNGOLZA-olezarsen-FPI.pdf

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. Accessed April 21, 2025.

   https://pubmed.ncbi.nlm.nih.gov/38587247/

3. Falko JM. Familial Chylomicronemia Syndrome: A Clinical Guide for Endocrinologists. Endocr Pract. 2018;24(8):756-763. doi:10.4158/EP-2018-0157. Accessed April 21, 2025.

   https://pubmed.ncbi.nlm.nih.gov/30183397/

4. Berglund L, Brunzell JD, Goldberg AC, et al. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society clinical practice guideline [published correction appears in J Clin Endocrinol Metab. 2015 Dec;100(12):4685. doi: 10.1210/jc.2015-3649.]. J Clin Endocrinol Metab. 2012;97(9):2969-2989. doi:10.1210/jc.2011-3213

   https://pubmed.ncbi.nlm.nih.gov/22962670/