MEDICATION POLICY:

Familial Chylomicronemia Syndrome (FCS)

Generic Name: N/A

Therapeutic Class or Brand Name: N/A

Applicable Drugs: Tryngolza (olezarsen), Redemplo (plozasiran)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 6/1/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

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

I. Documented diagnosis of Familial Chylomicronemia Syndrome (FCS) confirmed with genetic testing (i.e., variants in LPL, APOC2, APOA5, GPIHBP1, GPD1, 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 fibrate therapy at maximally tolerated, optimized dosing.

V. Minimum age requirement: 18 years old.

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

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

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

EXCLUSION CRITERIA

- Concomitant use of Tryngolza with Redemplo.
- 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

- Redemplo (plozasiran) 25 mg/0.5 mL single-dose pre-filled syringe
    - 1 syringe every 3 months

Approval Length

- **Authorization:** 6 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

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   https://arrowheadpharma.com/en-us/redemplo/prescribing-information.pdf

2. Tryngolza [Prescribing Information], Carlsbad, CA; Ionis Pharmaceuticals, Inc.; 2025. Accessed June 1, 2026.

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

3. 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.

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

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   https://pubmed.ncbi.nlm.nih.gov/39537503/

9. Berglund L, Brunzell JD, Goldberg AC, et al. Evaluation and treatment of hypertriglyceridemia: an Endocrine Society clinical practice guideline. *J Clin Endocrinol Metab*. 2012;97(9):2969-2989. doi:10.1210/jc.2011-3213

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

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    https://pubmed.ncbi.nlm.nih.gov/32083235/

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    https://pubmed.ncbi.nlm.nih.gov/41378317/