Effective Date: 08/1/2025
Reviewed: 05/2025 Scope: Medicaid

Tryngolza (olezarsen)

POLICY

I. INDICATION

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

II. INITAL CRITERIA FOR APPROVAL

Familial Chylomicronemia Syndrome (FCS)
An authorization of 6 months may be granted when the requested drug is being prescribed to lower triglyceride levels when all of the following criteria are met:

1. Member is 18 years of age or older
2. Documentation that member has a confirmed diagnosis of FCS by one of the following:
    a. Genetic testing (i.e., biallelic pathogenic variants in FCS-causing genes [e.g., 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), glycerol-3-phosphate dehydrogenase 1 (GPD1)])
    b. National Acute Familial Chylomicronemia Syndrome (NAFCS) Score ≥ 60
    c. Member has recurrent acute pancreatitis
3. Documentation that member has a fasting triglyceride level ≥ 880 mg/dL (10 mmol/L)
4. Documentation that member is refractory to standard triglyceride-lowering therapies (e.g., statins, fibrates, or other lipid-lowering medications)
5. Secondary factors have been excluded (e.g., high alcohol intake, uncontrolled diabetes, medications, and medical conditions known to increase TG)
6. Member is adherent to and will continue with a low-fat diet (e.g., ≤ 20 to 30 grams of total fat per day, 10% to 15% of calories per day of fat)
7. The medication is prescribed by or in consultation with a lipidologist, endocrinologist, or cardiologist
8. Platelet count > 100,000/mm^3 prior to treatment initiation
9. Coverage will not be provided for a diagnosis of multifactorial chylomicronemia (MCS)

III. CONTINUATION OF TERAPY

Familial Chylomicronemia Syndrome (FCS)
An authorization of 6 months may be granted for continued treatment in members requesting reauthorization for FCS when all of the following criteria are met:

1. Documentation supporting a positive clinical response with the requested medication (e.g., reduction in fasting triglyceride level from baseline, reduction in episodes of acute pancreatitis)
2. The member continues to be adherent to a low-fat diet (e.g., ≤ 20 to 30 grams of total fat per day, 10% to 15% of calories per day of fat)

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3. The member continues to be managed by or in consultation with a lipidologist, endocrinologist, or cardiologist

IV. DOSAGE AND ADMINISTRATION

The recommended dosage of Tryngolza is 80 mg administered subcutaneously once monthly.

V. QUANTITY LIMIT

Tryngolza 80 mg/0.8 mL single-dose autoinjector pen: 1 autoinjector pen per month (0.03 mL/day)

VI. REFERENCES

1. Tryngolza [package insert]. Carlsbad, CA: Ionis Pharmaceuticals, Inc.; 2024.
2. Stroes ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al, for the Balance investigators. Olezarsen, acute pancreatitis, and familial chylomicronemia syndrome. N Engl J Med. 2024;390(19):1781-1792.
3. Falko JM. Familial Chylomicronemia Syndrome: A Clinical Guide For Endocrinologists. Endocr Pract. 2018 Aug;24(8):756-763.
4. Moulin P, Dufour R, Averna M, et al. Identification and diagnosis of patients with familial chylomicronaemia syndrome (FCS): expert panel recommendations and proposal of an "FCS score". Atherosclerosis. 2018;275:265-272.
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. 2024 Nov 12.
6. Ellerton C, et al. Current dietary practice in the management of adults with familial chylomicronaemia syndrome: a UK expert panel opinion piece. Complete Nutrition website. September 2021.
7. Williams L, Rhodes KS, Karmally W, et al. Familial chylomicronemia syndrome: Bringing to life dietary recommendations throughout the life span. J Clin Lipidol. 2018;12(4):908-919.
8. Deshotels MR, Hadley TD, Roth M, et al. Genetic Testing for Hypertriglyceridemia in Academic Lipid Clinics: Implications for Precision Medicine – Brief Report. Arteriosclerosis, Thrombosis, and Vascular Biology. 2022;42(12): 1461-1467.