

DRUG POLICY

Tryngolza® (olezarsen)

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Tryngolza is indicated as an adjunct to diet

- To reduce triglycerides in adults with familial chylomicronemia syndrome (FCS).
- To reduce triglycerides and the risk of acute pancreatitis in adults with severe hypertriglyceridemia (sHTG).

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. Initial Requests
 - a. Genetic test(s) confirming diagnosis of FCS (if applicable)
 - b. Chart notes, medical records or laboratory values documenting fasting triglycerides (TG) level
2. Continuation requests
 - a. Chart notes, medical records, or laboratory values documenting positive clinical response

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Endocrinologist
2. Cardiologist

3. Lipid specialist
4. Gastroenterologist
5. Geneticist

Criteria for Initial Approval

Familial Chylomicronemia Syndrome (FCS)

Authorization of 6 months may be granted for treatment of FCS (type 1 hyperlipoproteinemia) in members when all of the following criteria are met:

1. Member is 18 years of age or older
2. Member has genetic confirmation of pathogenic variants in FCS-causing genes (e.g., LPL, GPIIIBP1, APOA5, APOC2, LMF1)
3. Member has an untreated fasting triglycerides (TG) level of ≥ 880 mg/dL (≥ 10 mmol/L)
4. Member is adhering to a very low fat diet (e.g., ≤ 20 g of total fat per day)
5. Traditional lipid lowering medications (e.g., statins, ezetimibe, niacin, fibrates, omega-3 fatty acids, PCSK9 inhibitors) have been ineffective in lowering fasting triglyceride level
6. Member will not use the requested medication in combination with Redempho

Severe Hypertriglyceridemia (sHTG)

Authorization of 6 months may be granted for treatment of severe hypertriglyceridemia in members when all of the following criteria are met:

1. Member is 18 years of age or older
2. Member is stable on one or more lipid lowering medications (e.g., statins, ezetimibe, niacin, fibrates, omega-3 fatty acids, PCSK9 inhibitors) or lipid lowering medications have been ineffective in lowering fasting triglyceride level
3. Member has persistently elevated fasting triglycerides (TG) level of ≥ 500 mg/dL (≥ 5.65 mmol/L) prior to initiating therapy with the requested medication
4. Modifiable secondary causes of hypertriglyceridemia have been addressed (i.e. medications, alcohol intake)
5. The requested medication will be used concomitantly with dietary modifications (i.e. low-fat diet)
6. Member will not use the requested medication in combination with Redempho

Continuation of Therapy

Familial chylomicronemia syndrome

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for FCS when both of the following criteria are met:

1. Member has demonstrated a positive clinical response with the requested medication (e.g., reduction in TG level from baseline, reduction in episodes of acute pancreatitis)
2. Member is adhering to a very low-fat diet (e.g., ≤ 20 g of total fat per day)

Severe Hypertriglyceridemia

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for sHTG when both of the following criteria are met:

1. Member has demonstrated a positive clinical response with the requested medication (e.g., reduction in TG level from baseline, reduction in episodes of acute pancreatitis)
2. The requested medication will be used concomitantly with dietary modifications (i.e. low-fat diet)

Other

Tryngolza (olezarsen) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits Apply

Medication	Standard Limit	FDA Recommended Dosing
Tryngolza (olezarsen) 80 mg injection	One 80 mg/0.8 mL autoinjector pen per 28 days	Adults with FCS: 80 mg injected subcutaneously once monthly
Tryngolza (olezarsen) 50 mg injection	One 50 mg/0.8 mL autoinjector pen per 28 days	Adults with sHTG: 50 mg injected subcutaneously once monthly If 50 mg is tolerated, dosage may be increased to 80 mg injected subcutaneously once monthly

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

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3. Javed F, et al. Familial chylomicronemia syndrome: an expert clinical review from the National Lipid Association. *J Clin Lipidol*. 2025;19(3):382-403.
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7. Hegele RA, Boren J, Ginsberg HN, et al. Rare dyslipidaemias, from phenotype to genotype to management: a European Atherosclerosis Society task force consensus statement. *Lancet Diabetes Endocrinol*. 2020;8(1):50-67.
8. Spagnuolo CM, Hegele RA. Etiology and emerging treatments for familial chylomicronemia syndrome. *Expert Rev Endocrinol Metab*. 2024;19(4):299-306.
9. Marston NA, Bergmark BA, Alexander VJ, et al. Olezarsen for managing severe hypertriglyceridemia and pancreatitis risk. *N Engl J Med*. 2026;394(5):429-441.

10. Blumenthal et al. 2026 ACC/AHA/AACVPR/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the management of Dyslipidemia: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. JACC. Published Online March 13, 2026. Doi:10.1016/j.jacc.2025.11.016

POLICY HISTORY

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