
5.40.039

Section:	Prescription Drugs	Effective Date:	July 1, 2025
Subsection:	Cardiovascular Agents	Original Policy Date:	January 24, 2025
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Last Review Date: June 12, 2025

Tryngolza

Description

Tryngolza (olezarsen)

Background

Tryngolza (olezarsen) is an antisense oligonucleotide (ASO) directed inhibitor of apolipoprotein C-III (apoC-III) mRNA, conjugated to a ligand containing three N-acetyl-galactosamine (Ga1Nac) residues to enable delivery of the ASO to hepatocytes. This leads to mRNA degradation and results in a reduction of serum apoC-III protein. Reduction of apoC-III protein leads to increased clearance of plasma triglycerides (TG) and very low-density lipoprotein (VLDL) (1).

Regulatory status

FDA-approved indication: Tryngolza is an apoC-III-directed antisense oligonucleotide (ASO) indicated as an adjunct to diet to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS) (1).

Tryngolza may be associated with hypersensitivity reactions. Advise patient on the signs and symptoms of hypersensitivity reactions, and to promptly seek medical attention and discontinue Tryngolza if hypersensitivity reactions occur (1).

The safety and effectiveness of Tryngolza in pediatric patients less than 18 years of age have not been established (1).

Related policies

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Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Tryngolza may be considered **medically necessary** if the conditions indicated below are met.

Tryngolza may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Familial chylomicronemia syndrome (FCS)

AND ALL of the following:

1. Diagnosis confirmed by genetic testing documenting biallelic pathogenic variants in FCS-causing genes (e.g., LPL, GPIHBP1, APOA5, APO2, LMF1, GPD1, CREB3L3)
2. Fasting triglyceride (TG) levels ≥ 880 mg/dL
3. Used in combination with a low-fat diet (≤ 20 g of fat per day)

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Familial chylomicronemia syndrome (FCS)

AND ALL of the following:

1. Reduction in fasting triglycerides from baseline

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2. Used in combination with a low-fat diet (≤ 20 g of fat per day)

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 3 autoinjectors per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Tryngolza is an apoC-III-directed antisense oligonucleotide (ASO) indicated to reduce triglycerides in adults with familial chylomicronemia syndrome (FCS). Tryngolza has been associated with hypersensitivity reactions. The safety and effectiveness of Tryngolza in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Tryngolza while maintaining optimal therapeutic outcomes.

References

1. Tryngolza [package insert]. Carlsbad, CA: Ionis Pharmaceuticals US Inc.; January 2025.

Policy History

Date	Action
January 2025	Addition to PA
June 2025	Annual review and reference update

Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 12, 2025 and is effective on July 1, 2025.