Reference number(s)
6786-A

Specialty Guideline Management
Tryngolza

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Tryngolza	olezarsen

Indications

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

FDA-approved Indications[1]

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

Documentation

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

Initial requests:

- Genetic test(s) confirming diagnosis of FCS.

- Laboratory tests or medical record documentation of fasting triglycerides (TG) level.

Continuation requests:

- Chart notes or medical record documentation supporting positive clinical response.

Coverage Criteria

Familial chylomicronemia syndrome (FCS)[1-5]

Authorization of 12 months may be granted for treatment of familial chylomicronemia syndrome (FCS) (type 1 hyperlipoproteinemia) in members when all of the following criteria are met:

- Member has a confirmed FCS diagnosis by genetic testing (i.e., biallelic pathogenic variants in FCS-causing genes [e.g., LPL, GPIHBP1, APOA5, APO2, LMF1, GPD1, CREB3L3]).
- Member has a fasting triglycerides (TG) level of ≥ 880 mg/dL.
- Member is currently receiving a very-low fat diet (e.g., less than 20 to 30 g of total fat per day, 10% to 15% of calories per day of fat).

Continuation of Therapy

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

- 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).
- Member is currently receiving a very-low fat diet (e.g., less than 20 to 30 g of total fat per day, 10% to 15% of calories of fat).

References

1. Tryngolza [package insert]. Carlsbad, CA: Ionis Pharmaceuticals Inc.; December 2024.
2. Stroes, ESG, Alexander VJ, Karwatowska-Prokopczuk E, et al. Olezarsen, acute pancreatitis, and familial chylomicronemia syndrome. N Engl J Med. 2024;390(19):1781-192.
3. Falko JM. Familial chylomicronemia syndrome: a clinical guide for endocrinologists. Endocr Pract. 2018;24(8):756-763.
4. 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.

5. Spagnuolo CM, Hegele RA. Etiology and emerging treatments for familial chylomicronemia syndrome. Expert Rev Endocrinol Metab. 2024;19(4):299-306.