CVS Caremark®

| 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 Indications1

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.