HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Tryngolza (olezarsen)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Tryngolza, approved by the FDA in 2024, is an apoC-III-directed antisense oligonucleotide (ASO) indicated as an adjunct to diet to reduce triglycerides (TG) in adults with familial chylomicronemia syndrome (FCS). Reduction of apoC-III protein leads to increased clearance of plasma TG and very low-density lipoproteins (VLDL).
FCS is a rare, monogenic form of severe hypertriglyceridemia (HTG). Chylomicronemia is the accumulation in the bloodstream of chylomicrons (large TG-rich lipoprotein particles). FCS is caused by biallelic defects in lipoprotein lipase (LPL) or other genes related to LPL function. LPL is an enzyme that catabolizes triglyceride-rich lipoproteins, in particular chylomicrons and VLDL. Triglycerides can accumulate to a degree that impairs blood flow to the pancreas, leading to severe acute pancreatitis. Other symptoms include xanthomas, lipemia retinalis, and hepatosplenomegaly. Standard lipid-lowering drugs are only minimally effective in FCS due to the compromised activity of LPL.
Approval of Tryngolza was based on results of the phase 3 placebo-controlled BALANCE study, making it the first drug indicated for FCS and the first in its class.

Tryngolza (olezarsen) will be considered for coverage when the following criteria are met:

Familial Chylomicronemia Syndrome (FCS)

For **initial** authorization:
1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with an endocrinologist, cardiologist, or lipid specialist; AND
3. Member has a diagnosis of FCS confirmed by genetic test results (i.e., pathogenic gene mutations in *LPL, APOC2, APOA5, GPIHBP1, LMF1,* or *G3PDH1*); AND
4. Pretreatment labs show a fasting triglyceride (TG) level of at least 880 mg/dL (10 mmol/L); AND
5. Documentation to show the member will maintain a low-fat diet (i.e., 20 g fat or less per day).
6. **Dosage allowed/Quantity limit:** 80 mg administered subcutaneously once monthly.
   QL: 1 autoinjector per 28 days

If all the above requirements are met, the medication will be approved for 6 months.

For **reauthorization**:
1. Chart notes must show a clinically significant reduction of triglyceride levels in response to Tryngolza; AND
2. Attestation that the member is continuing a diet with less than 20 g of fat per day.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Tryngolza (olezarsen) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
12/30/2024	New policy for Tryngolza created.

References:

1. Tryngolza [prescribing information]. Ionis Pharmaceuticals Inc.; 2024.
2. Stroes E, Moulin P, Parhofer KG, Rebours V, Löhr JM, Averna M. Diagnostic algorithm for familial chylomicronemia syndrome. *Atheroscler Suppl*. 2017;23:1-7. doi:10.1016/j.atherosclerosissup.2016.10.002
3. 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. doi:10.1016/j.atherosclerosis.2018.06.814
4. Mach F, Baigent C, Catapano AL, et al. 2019 ESC/EAS Guidelines for the management of dyslipidaemias: lipid modification to reduce cardiovascular risk [published correction appears in Eur Heart J. 2020 Nov 21;41(44):4255. doi: 10.1093/eurheartj/ehz826]. *Eur Heart J*. 2020;41(1):111-188. doi:10.1093/eurheartj/ehz455

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Revised date: 12/30/2024