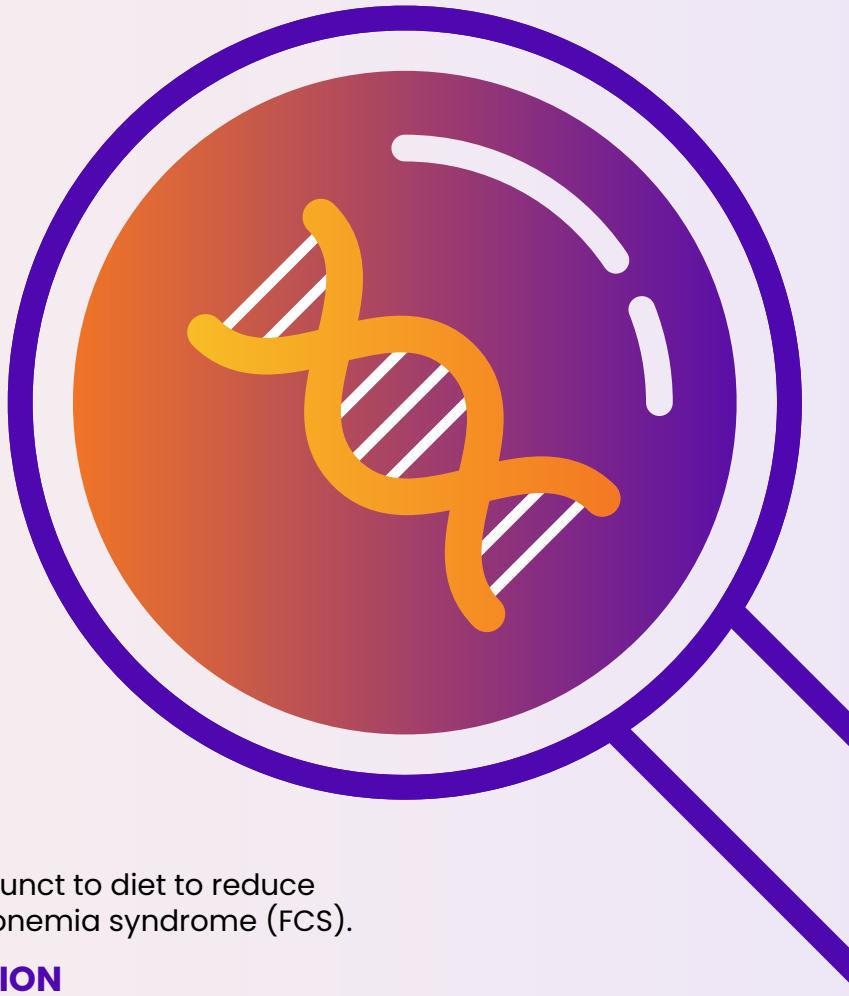
Tryngolza®
(olezarsen) 80 mg injection

Diagnosing FCS with clinical scoring tools and *no-cost* FCS genetic testing

PREVENTION GENETICS
part of EXACT SCIENCES

In partnership with Ionis Pharmaceuticals, PreventionGenetics is here to support genetic testing in the diagnosis of patients with familial chylomicronemia syndrome (FCS)



INDICATION

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

SELECT IMPORTANT SAFETY INFORMATION

CONTRAINDICATIONS

TRYNGOLZA is contraindicated in patients with a history of serious hypersensitivity to TRYNGOLZA or any of the excipients in TRYNGOLZA. Hypersensitivity reactions requiring medical treatment have occurred.

Please see Important Safety Information throughout and full Prescribing Information for TRYNGOLZA.

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FCS is an underdiagnosed, genetic form of severe hypertriglyceridemia (sHTG)[1,2]

A rare autosomal recessive disorder, FCS is characterized by[2-4]:

Fasting triglyceride levels of ≥880 mg/dL that are refractory to standard triglyceride-lowering therapies

Recurrent abdominal pain or history of acute pancreatitis (AP)

No known secondary causes for sHTG*

- The risk of AP significantly increases when triglyceride levels increase to ≥880 mg/dL[5]
- Patients with FCS also often suffer from other debilitating physical and psychosocial symptoms, social withdrawal, and difficulty maintaining employment[1]
- An accurate FCS diagnosis is crucial so that patients may receive appropriate treatment in a timely manner[6,7]

TRYNGOLZA is the first FDA-approved therapy proven to lower triglycerides in adults with FCS as an adjunct to diet.[7]

*Hypertriglyceridemia can be caused by medications such as glucocorticoids, ethinylestradiol, and neuroleptics, or conditions such as uncontrolled diabetes, hypothyroidism, and pregnancy.[3]

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WARNINGS AND PRECAUTIONS

Hypersensitivity Reactions

Hypersensitivity reactions (including symptoms of bronchospasm, diffuse erythema, facial swelling, urticaria, chills, and myalgias) have been reported in patients treated with TRYNGOLZA. Advise patients on the signs and symptoms of hypersensitivity reactions and instruct patients to promptly seek medical attention and discontinue use of TRYNGOLZA if hypersensitivity reactions occur.

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Supporting FCS diagnosis: genetic testing and clinical scoring

Both genetic testing and clinical scoring tools can support an FCS diagnosis.[2]

- Genetic testing results for FCS can show biallelic pathogenic variants in genes regulating lipolysis of triglyceride-rich lipoproteins[2]
- Patients with indeterminate genetic testing results may have FCS because not all genetic variants associated with FCS have been identified[3]
- Clinical scoring tools are available to support diagnosis of FCS in patients with indeterminate results or for patients without a genetic test:
  - North American FCS (NAFCS) Score[4]
  - Clinical criteria developed by Moulin et al[3]

Clinical scoring calculators are available at TRYNGOLZAHCP.com/FCScalculator

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ADVERSE REACTIONS

Most common adverse reactions (incidence >5% of TRYNGOLZA-treated patients and >3% higher frequency than placebo) were injection site reactions, decreased platelet count, and arthralgia.

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PreventionGenetics FCS testing program

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While clinical scoring tools are available, genetic testing continues to be an important option to support FCS diagnosis,[2] and some payers may require genetic test results. Because genetic testing can be expensive and may not be available for every patient, Ionis has partnered with **PreventionGenetics** to provide no-cost testing for eligible patients who*:

- Have severe refractory hypertriglyceridemia, defined by a minimum of 2 consecutive fasting triglyceride levels ≥880 mg/dL or 10 mmol/L
- Lack secondary causes or medical conditions known to cause sHTG
- Are residents of the United States

To learn more about *no-cost* FCS genetic testing, visit preventiongenetics.com/sponsoredTesting/Ionis_FCS

*Tests must be ordered by a qualified healthcare professional, and informed consent must be provided by the patient. Note that other companies also offer genetic testing services for FCS.

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References: 1. Davidson M, Stevenson M, Hsieh A, et al. The burden of familial chylomicronemia syndrome: results from the global IN-FOCUS study. *J Clin Lipidol*. 2018;12(4):898-907.e2. **2.** Javed F, Hegele RA, Garg A, et al. Familial chylomicronemia syndrome: an expert clinical review from the National Lipid Association. *J Clin Lipidol*. 2025;19(3):382-403. **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. **4.** Hegele RA, Ahmad Z, Ashraf A, et al. Development and validation of clinical criteria to identify familial chylomicronemia syndrome (FCS) in North America. *J Clin Lipidol*. 2025;19(1):83-94. **5.** Yuan G, Al-Shali KZ, Hegele RA. Hypertriglyceridemia: its etiology, effects and treatment. *CMAJ*. 2007;176(8):1113-1120. **6.** Chyzhyk V, Brown AS. Familial chylomicronemia syndrome: a rare but devastating autosomal recessive disorder characterized by refractory hypertriglyceridemia and recurrent pancreatitis. *Trends Cardiovasc Med*. 2020;30(2):80-85. **7.** TRYNGOLZA. Prescribing information. Ionis Pharmaceuticals.