Omega-3 Acid Ethyl Esters & Ethyl eicosapentaenoic acid for hypertriglyceridemia

Adjudication Guideline

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Pharmaceutical	2024-PH-42	Version No. V3.0	1/06/2025	15/05/2026

Approved by:	Responsible:	Related Adjudication Guidelines:
Daman	Pharmaceutical Standards& Governance	N/A

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1. Abstract

1.1 For Members

Omega-3-Acid Ethyl Esters and Ethyl eicosapentaenoic acid is prescribed to help lower elevated triglyceride levels in adults with hypertriglyceridemia as part of a comprehensive treatment plan that includes diet and exercise. This medication must be taken under medical supervision.

1.2 For Medical Professionals

Omega-3 fatty acid ester and and Ethyl eicosapentaenoic acid is a prescription medication indicated for the management of hypertriglyceridemia in adults. To assess its effectiveness, lipid panel evaluations are necessary. Long-term use should only be considered if there is a significant reduction in triglyceride levels.

2. Scope

This Adjudication Rule outlines the coverage and payment requirements by Daman for Omega3-Acid Ethyl Esters and Icosapent Ethyl. It outlines the medical criteria for initial approval, continued therapy, and outlines the step therapy protocol applicable for coverage

2.1 Indications

Omega-3-Acid Ethyl Esters and Icosapent Ethyl are lipid-regulating agents indicated as adjuncts to dietary measures for the reduction of elevated triglyceride levels in adult patients with severe hypertriglyceridemia: Type IV, Type IIb, or Type III hypertriglyceridemia

Dose of Omega-3-Acid Ethyl Esters & Icosapent Ethyl:

- **Omega-3-Acid Ethyl Esters**: The recommended initial dose is 1-2 gram. If the reduction in triglyceride levels is insufficient after 6 months, the dosage may be increased to 4 grams per day (i.e., 4 soft capsules daily).

- **Icosapent Ethyl: The** recommended daily dose is 4 grams, which can be administered as:
  - Four 0.5-gram capsules taken twice daily with food, or
  - Two 1-gram capsules taken twice daily with food

Generic Name	Dose strength
Icosapent Ethyl	1000 mg
Omega-3 acid ethyl esters	1000 mg

2.2 Mechanism of Action

Inhibiting Triglyceride synthesis:

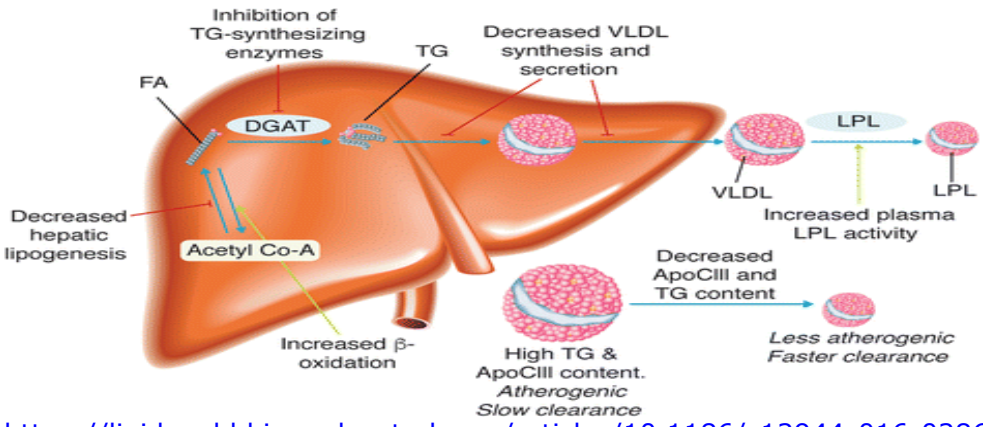
- It interferes with the production of VLDL in the liver, VLDL are the main carrier of triglycerides in the blood.

Decreased Fatty Acids esterification:

- EPA and DHA compete with other fatty acids for incorporation into triglycerides within the liver, leading to reduced triglyceride production.

Triglyceride breakdown:

- It promotes triglyceride breakdown within the liver and other tissues by oxidation.



https://lipidworld.biomedcentral.com/articles/10.1186/s12944-016-0286-4

3. Adjudication Policy

3.1 Medical coverage criteria (Initiation)

A. Hypertriglyceridemia (TG 200–499 mg/dL)

Omega-3 fatty acids will be covered when **ALL** of the following criteria are met:

A.1 Triglyceride Level
- Documented triglyceride level of 200–499 mg/dL

A.2 Elevated ASCVD Risk
- Patient meets the definition of elevated ASCVD risk as specified in **Section C**

A.3 Prior Therapy Requirement

- Documented failure, contraindication, or intolerance to at least one lipid-lowering therapy, including:
    - Statin or Fibrate

B. Severe Hypertriglyceridemia (TG ≥500 mg/dL)

Omega-3 fatty acids will be covered when **ALL** of the following criteria are met:

B.1 Triglyceride Level
- Documented fasting triglyceride level of ≥500 mg/dL

B.2 Prior Therapy Requirement
- Documented failure, contraindication, or intolerance to at least one lipid-lowering therapy, including:
    - Statin or Fibrate

C. Definition of Elevated ASCVD Risk

The following definitions apply solely for determining elevated ASCVD risk where referenced in the eligibility criteria above.

Elevated ASCVD risk is defined as either of the following:

C.1 Established ASCVD (Secondary Prevention)

Documented history of **any** of the following:
- Acute coronary syndrome (e.g., myocardial infarction or unstable angina requiring hospitalization)
- Coronary or other arterial revascularization procedures
- Coronary heart disease
- Ischemic stroke
- Peripheral arterial disease

OR

C.2 Diabetes Mellitus Plus ≥2 Additional ASCVD Risk Factors
Documented diagnosis of diabetes mellitus and **at least two (2)** of the following risk factors:

- Age ≥50 years
- Cigarette smoking
- Hypertension
- HDL-C ≤40 mg/dL (males) or ≤50 mg/dL (females)
- High-sensitivity C-reactive protein (hs-CRP) >3 mg/L (0.3 mg/dL)
- Creatinine clearance <60 mL/min
- Diabetic retinopathy
- Micro- or macroalbuminuria
- Ankle-brachial index (ABI) <0.9

3.2 Medical coverage criteria (Refill/Continuation)

- A follow-up lipid panel should be obtained approximately one year after initiating therapy for severe hypertriglyceridemia.

- Continuation of therapy requires evidence of clinical benefit, such as a reduction in triglyceride levels, improved lipid parameters, or decreased cardiovascular risk markers.

Target Reduction:

- Achieving a decrease of 20% in triglyceride levels from baseline in patients with severe Hypertriglyceridemia

- Effectiveness of the treatment should be evaluated with reassessments conducted every year.

3.3 Stop Criteria:

- **Failure to Achieve Target Levels:** If triglyceride levels remain significantly elevated and there is less than a 20% reduction from baseline after one year of treatment with Omega-3-Acid Ethyl Esters or Icosapent ethyl—despite confirmed adherence to dietary, lifestyle, and pharmacologic interventions—discontinuation of therapy may be considered.

- **Adverse Effects:** If the patient experiences significant side effects or adverse reactions (such as gastrointestinal issues, allergic reactions, or unusual bleeding), the medication should be stopped.

3.4 Red Flags:

- This medication is not considered a first-line therapy for the treatment of hypertriglyceridemia.

- Not covered for conditions outside of hypertriglyceridemia.

- Prescribing Omega-3 Acid Ethyl Esters is restricted to healthcare professionals with the requisite medical expertise in managing hypertriglyceridemia, excluding those in ophthalmology and other unrelated specialties.

3.5 Non-Coverage

- Not covered for visitor plan
- Age less than 18 years

3.6 Payment and Coding Rules

- Kindly apply DOH payment rules and regulations and relevant coding manuals for ICD, Drugs.

4. Denial Codes

Code	Code Description
MNEC-004	Service is not clinically indicated based on good clinical practice, without additional supporting diagnoses/activities
MNEC-005	Service(s) is(are) done/approved previously, request is too frequent
MNEC-006	Alternative service should have been utilized
CODE-010	Activity/diagnosis inconsistent with clinician specialty
CODE-014	Activity/diagnosis is inconsistent with the patient's age/gender

5. Appendices

5.1 References

- https://www.accessdata.fda.gov/drugsatfda
- Hypertriglyceridemia Management According to the 2026 AHA/ACC Guideline - American College of Cardiology
- Hypertriglyceridaemia - Treatment algorithm | BMJ Best Practice
- Hypertriglyceridemia : LearnYourLipids
- ESC/EAS Guidelines for the management of dyslipidemias (escardio.org)
- Association Between Omega-3 Fatty Acid Intake and Dyslipidemia: A Continuous Dose–
- Response Meta-Analysis of Randomized Controlled Trials - PMC (nih.gov)
- 2021 ACC Expert Consensus Decision Pathway on the Management of ASCVD Risk Reduction in Patients With Persistent Hypertriglyceridemia: A Report of the American College of Cardiology Solution Set Oversight Committee - ScienceDirect
- Hypertriglyceridaemia - Treatment algorithm | BMJ Best Practice
- Hypertriglyceridemia in adults: Management - UpToDate

5.2 Revision History

Date	Change(s)
01.06.2025	Creation of Adjudication Guideline-External Instruction Template.
30.03.2026	Revised
15.5.2026	Coverage Eligibility criteria