Omega-3-Acid Ethyl Esters & Icosapent Ethyl for Management of Hypertriglyceridemia in Adults

Adjudication Guideline

Rule Category:	Ref: No:	Version Control:	Effective Date:	Revision Date:
Pharmaceutical	2024-PH-42	Version No.V2.0	30/09/2025	22/08/2026

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

Table of Contents

1. Abstract

1.1 For Members

Omega-3-Acid Ethyl Esters and Icosapent Ethyl are 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-Acid Ethyl Esters and Icosapent Ethyl are prescription medication indicated for the management of hypertriglyceridemia in adults and as add on to prevent the risk of secondary myocardial infarction.
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. They are derived from marine sources and primarily contain eicosapentaenoic acid (EPA), with or without docosahexaenoic acid (DHA)

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.

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

Mechanism Of Action:

Inhibiting Triglyceride synthesis:

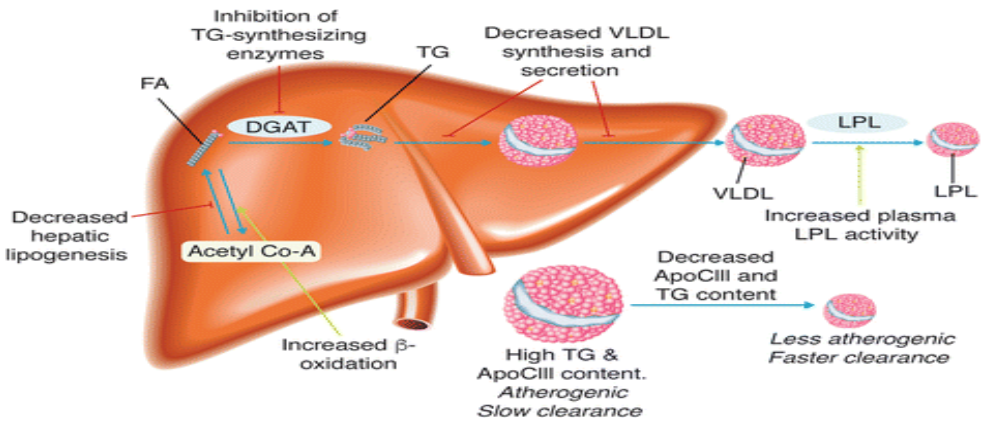
- It interferes with the production of VLDL in the liver, VLDL are the main carrier of triglycerides in the blood.

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 Eligibility / Coverage Criteria

Initial Approval Criteria:

Dietary and lifestyle interventions—including reduced intake of refined carbohydrates and added sugars, increased physical activity, weight management, and limited alcohol consumption—are considered first-line therapy in the management of hypertriglyceridemia. Pharmacologic treatment should only be initiated when these measures have been implemented, and triglyceride levels remain significantly elevated

- The patient has a confirmed diagnosis of hypertriglyceridemia corresponding to one of the following:
    - Type IV: Triglycerides ≥500 mg/dL despite dietary modifications
    - Type IIb or Type III: Triglycerides ≥400 mg/dL and not adequately controlled with statin therapy
- The patient has documented failure or intolerance to at least one of the following lipid-lowering therapies:
    1. Statins (e.g., atorvastatin, rosuvastatin)
    2. Fibrates (e.g., fenofibrate, gemfibrozil)

Type	Lipoprotein Abnormality	Typical Triglyceride Level	Cholesterol Profile (mg/dL)
Type IV (Familial Hypertriglyceridemia)	↑ VLDL	500–1000+	Total: 200–300, LDL: 100–130, HDL: <40
Type IIb (Familial Combined Hyperlipidemia)	↑ VLDL and LDL	>400, often >1000	Total: 250–350+, LDL: 130–190+, HDL: <40
Type III (Dysbetalipoproteinemia)	↑ IDL and chylomicron remnants	>400, often >1000	Total: 300–600+, LDL: normal or mildly ↑, HDL: <40

American Board of Family Medicine (ABFM). The article titled *"Hypertriglyceridemia"*https://www.jabfm.org/content/jabfp/19/3/310.full.pdf

Continued Therapy:

- 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.

Stop therapy 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.

3.2 Requirements for Coverage

Kindly code the ICD-10 and the CPT codes to the highest level of specificity

Red flags:

- These agents are not considered first-line therapy for hypertriglyceridemia management.
- Omega-3-Acid Ethyl Esters and Icosapent Ethyl are considered adjunct and preventive therapies for patients at high risk of myocardial infarction, considering as a supplementary treatment
- Non-prescription omega-3 supplements are not approved for the treatment of severe hypertriglyceridemia

3.3 Non-Coverage

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

3.4 Payment and Coding Rules

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

Eligible clinician Specialties
Cardiology
Internal Medicine
Endocrinology
Family Medicine

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_docs/label/2004/21654lbl.pdf
- Hypertriglyceridemia Management According to the 2018 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)

5.2 Revision History

Date	Change(s)
02.07.2025	Release of V1.0
22.08.2025	Add Triglyceride level per type