

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

Adjudication Guideline

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Standards& Governance



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1. Abstract

1.1 For Members

Omega-3-Acid Ethyl Esters and Ethyl eicosapentaenoic acid 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 esters and Ethyl eicosapentaenoic acid are 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 Ethyl eicosapentaenoic acid. It outlines the medical criteria for initial approval, continued therapy, and outlines the step therapy protocol applicable for coverage

Indications:

Omega-3 acid esters and Ethyl eicosapentaenoic acid are lipid-regulating agent indicated as an adjunct to diet for the reduction of triglyceride levels in adults with severe hypertriglyceridemia (≥ 500 mg/dL). It is prescribed when dietary modifications alone are insufficient to achieve optimal lipid control.

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:

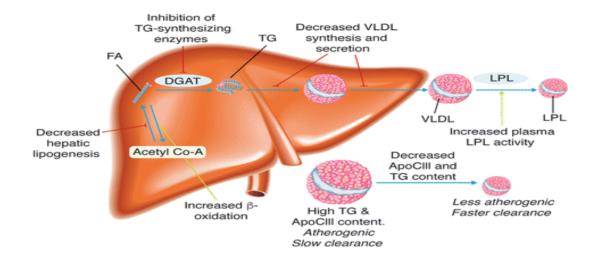
• EPA and DHA compete with other fatty acids for incorporation into triglycerides within the liver, leading to reduced triglyceride production.

Triglyceride breakdown:

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

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

3. Adjudication Policy

3.1 Eligibility / Coverage Criteria

- Omega-3-Acid Ethyl Esters and Ethyl eicosapentaenoic acid are intended for patients diagnosed with hypertriglyceridemia who meet established criteria.
- Patients must have a documented history of triglyceride levels exceeding 500 mg/dL

Initial Approval Criteria:

- Triglyceride levels ≥ 500 mg/dL.
- Patient must have failed or be intolerant to at least one of the following:
 - 1. Statins (e.g., Atorvastatin, Rosuvastatin)
 - 2. Fibrates (e.g., Fenofibrate, Gemfibrozil)
- The typical recommended dose of omega-3-acid ethyl esters and eicosapentaenoic acid is as follows:
 - One gram once daily, or
 - Two grams, taken as two 1-gram doses, twice daily.

The maximum daily dose of 4 grams is reserved for patients with very high triglyceride levels who have not achieved adequate results with lower doses

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Continued Therapy:

• There should be a documented reduction in triglyceride levels or an enhancement in the lipid profile following the start of Omega-3-Acid Ethyl Esters or Ethyl eicosapentaenoic acid therapy within six months.

Target Reduction:

- Achieving a decrease of 20-30% in triglyceride levels
- Effectiveness of the treatment should be evaluated with reassessments conducted every year.

Stop therapy criteria:

- Failure to Achieve Target Levels: If there is no significant reduction in triglyceride levels after one year duration of treatment, the medication may be discontinued.
- 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:

- Omega-3-Acid Ethyl Esters and Ethyl eicosapentaenoic acid are not covered for patients whose triglyceride levels are below 500 mg/dL.
- 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 and Ethyl eicosapentaenoic acid is restricted to healthcare professionals with the requisite medical expertise in managing hypertriglyceridemia, excluding those in ophthalmology and other unrelated specialties.

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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.

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
- <u>Hypertriglyceridaemia Treatment algorithm | BMJ Best</u> 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)

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5.2 Revision History

Date	Change(s)
13/05/2025	Release of V1.0

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