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Fish Oil Triglycerides

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Related Coverage Resources

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Overview

This policy supports medical necessity review for Fish Oil Triglycerides (Omegaven®).

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Fish Oil Triglycerides (Omegaven) are considered medically necessary for the treatment of Parenteral nutrition-associated cholestasis (PNAC) when the individual is less than 18 years of age.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

## Continuation of Therapy

Fish Oil Triglycerides (Omegaven) are considered medically necessary for continued use when initial criteria are met.

## Authorization Duration

Initial approval duration: up to 12 months.

Reauthorization approval duration: up to 12 months.

## Conditions Not Covered

Any other use is considered experimental, investigational or unproven, including the following (this list may not be all inclusive):

**Prevention of Parenteral nutrition-associated cholestasis (PNAC).** Omegaven is not indicated for the prevention of PNAC. It has not been demonstrated that Omegaven prevents PNAC in parenteral nutrition (PN)-dependent patients.

## Coding

**Note:** 1) This list of codes may not be all-inclusive.

2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

**Considered Medically Necessary when criteria in the applicable policy statements listed above are met:**

HCPCS Codes	Description
B4187	Omegaven, 10 grams lipids

## Background

### FDA Approved Indication

Omegaven is indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associated cholestasis (PNAC).

Limitations of Use:

- Omegaven is not indicated for the prevention of PNAC. It has not been demonstrated that Omegaven prevents PNAC in parenteral nutrition (PN)-dependent patients
- It has not been demonstrated that the clinical outcomes observed in patients treated with Omegaven are a result of the omega-6:omega-3 fatty acid ratio of the product

### FDA Recommended Dosing

Recommended Pediatric Dosing

- The recommended Omegaven dosage for pediatric patients is 1 g/kg/day; this is also the maximum daily dose.
- The initial rate of infusion should not exceed 0.05 mL/minute for the first 15 to 30 minutes of infusion. If tolerated, gradually increase until reaching the required rate after 30 minutes. The maximum infusion rate should not exceed 1.5 mL/kg/hour, corresponding to 0.15 g/kg/hour.
- If hypertriglyceridemia (triglycerides greater than 250 mg/dL in neonates and infants or greater than 400 mg/dL in older children) develops once Omegaven has been initiated at the recommended dosage,

consider stopping the administration of Omegaven for 4 hours and obtain a repeat serum triglyceride level. Resume Omegaven based on new result as indicated.

- In patients with elevated triglyceride levels, consider other reasons for hypertriglyceridemia (e.g., renal disease, other drugs). If triglycerides remain at elevated levels, consider a reduced dose of 0.5 g to 0.75 g/kg/day with an incremental increase to 1 g/kg/day.
- Monitor triglyceride levels during treatment
- The recommended duration for infusion of Omegaven is between 8 and 24 hours, depending on the clinical situation.
- Administer Omegaven until DBil levels are less than 2 mg/dL or until the patient no longer requires PN.

### **Drug Availability**

Injectable Emulsion: 5 g/50 mL and 10 g/100 mL (0.1 g/mL) sterile, white, homogenous emulsion in a 50-mL and 100-mL single-dose bottle.

### **American Society for Parenteral and Enteral Nutrition (ASPEN)**

Current ASPEN guidelines do not recommend any specific lipid source over another for nutritional support of adults or children. For patients with existing PNAC who require parenteral nutrition, ASPEN recommends reducing the dose of soybean oil-based lipid until symptoms resolve, although use of fish oil-based lipid or mixed fish/soybean lipid may also be considered. (Vanek, 2012, Vanek, 2014)

## **References**

1. Omegaven [package insert]. Graz, Australia: Fresenius Kabi; 2020.
2. Vanek VW, Seidner DL, Allen P, et al. A.S.P.E.N. position paper: clinical role for alternative intravenous fat emulsions. *Nutr Clin Pract.* 2012;27(2):150-192.
3. Vanek VW, Seidner DL, Allen P, et al. Update to A.S.P.E.N. position paper: clinical role for alternative intravenous fat emulsions. *Nutr Clin Pract.* 2014;29(6):841

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