FRESENIUS KABI

Omegaven®

(fish oil triglycerides) injectable emulsion, for intravenous use

Billing & Coding Guide for Healthcare Professionals



The information contained within this document is for educational purposes related to Omegaven® and does not provide a complete listing of all coding requirements for all insurance plans. Coverage and Coding requirements vary across insurance companies and the plans they offer. Coverage policies are constantly evolving with payers and are subject to change without notice. Coverage, coding, and billing requirements should be verified by the provider for each patient prior to treatment. Information provided herein is not a guarantee of coverage or payment of Omegaven®. It is the sole responsibility of the provider to select proper codes and to ensure the accuracy of all claims used in seeking reimbursement.

Product Information

Brand Name: **Omegaven®**

Generic Name: **(Fish oil triglycerides) injectable emulsion, for intravenous use**

Omegaven® Indication:

Omegaven is indicated as a source of calories and fatty acids in pediatric patients with parenteral nutrition-associatedcholestasis (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 this product.

Description:

Omegaven® (fish oil triglycerides) injectable emulsion, for intravenous use, 5 g/50 mL, and 10 g/100 mL, (0.1 g/mL) is a white homogenous sterile emulsion supplied as 50 mL single-dose glass bottle and 100 mL single-dose glass bottle.

IMPORTANT SAFETY INFORMATION

Protect the admixed PN solution from light. Prior to administration, correct severe fluid and electrolyte disorders and measure serum triglycerides to establish a baseline level. Initiate dosing in PN-dependent pediatric patients as soon as direct or conjugated bilirubin levels are 2 mg/dL or greater. The recommended nutritional requirements of fat and recommended dosages of Omegaven to meet those requirements for pediatric patients are provided in Table 1, along with recommendations for the initial and maximum infusion rates. Administer Omegaven until direct or conjugated bilirubin levels are less than 2 mg/dL or until the patient no longer requires PN.

Table 1: Recommended Pediatric Dosage and Infusion Rate

Nutritional Requirements	Direct Infusion Rate	
Recommended Initial Dosage and Maximum Dosage	Initial	Maximum
1 g/kg/day; this is also the maximum daily dose	0.2 mL/kg/hour for the first 15 to 30 minutes; gradually increase to the required rate after 30 minutes	1.5 mL/kg/hour

Omegaven is contraindicated in patients with known hypersensitivity to fish or egg protein or to any of the active ingredients or excipients, severe hemorrhagic disorders due to a potential effect on platelet aggregation, severe hyperlipidemia or severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride concentrations greater than 1,000 mg/dL). .

Clinical Decompensation with Rapid Infusion of Lipid Injectable Emulsions in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported. Hypertriglyceridemia was commonly reported. Strictly adhere to the recommended total daily dosage; the hourly infusion rate should not exceed 1.5 mL/kg/hour. Carefully monitor the infant's ability to eliminate the infused lipids from the circulation (e.g., measure serum triglycerides and/or plasma free fatty acid levels). If signs of poor clearance of lipids from the circulation occur, stop the infusion and initiate a medical evaluation.

Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reaction occurs.

Infections, Fat Overload Syndrome, Refeeding Syndrome, and Hypertriglyceridemia: Monitor for signs and symptoms; monitor laboratory parameters.

Aluminum Toxicity: Increased risk in patients with renal impairment, including preterm infants.

Monitoring and Laboratory Tests: Routine laboratory monitoring is recommended, including monitoring for essential fatty acid deficiency.

The most common adverse drug reactions (>15%) are vomiting, agitation, bradycardia, apnea and viral infection.

To report SUSPECTED ADVERSE REACTIONS, contact Fresenius Kabi USA, LLC at 1-800-551-7176, option 5, or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This Important Safety Information does not include all the information needed to use Omegaven safely and effectively. Please see full prescribing information for Omegaven (fish oil triglycerides) injectable emulsion for intravenous use at www.freseniuskabinutrition.com.

Prescribing Information:
To access **Omegaven®** Prescribing Information, please use the QR code or link below.

https://freseniuskabinutrition.com/OmegavenPI

Coding

Including:

NDC – National Drug Code, assigned by the FDA to identify specific drugs

ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification, assigned by World Health Organization (WHO), to classify diagnoses, used in all places of service

HCPCS – Healthcare Common Procedure Coding System assigned by CMS to identify products or procedures

NDC– National Drug Code

The NDC, or National Drug Code, is a unique 10-digit or 11–digit, 3 segment number, and a universal product identifier for human drugs in the United States. The 3 segments of the NDC identify:

- The labeler (Segment #1)
- The product (Segment #2)
- The commercial package sizes (Segment #3)

The NDC Codes below are assigned to Omegaven® (also known as: (fish oil triglycerides) injectable emulsion, for intravenous use) a human prescription drug labeled by Fresenius Kabi USA, LLC.

NDC	Description	Concentration	Unit of Use
63323-205-21	50 mL single-dose glass bottle	5 g/50 mL (0.1 grams per mL)	10 (1x10)
63323-205-31	100 mL single-dose glass bottle	10 g/100 mL (0.1 grams per mL)	10 (1x10)

For reimbursement purposes, some payers may require the Healthcare Provider (HCP) to include NDCs on the claim form. For claims-reporting purposes, some payers may also require HCPs to convert the 10-digit NDC to an 11-digit NDC by adding a "0" (zero) where appropriate to create a 5-4-2 configuration. The zero is added in front of the second segment of numbers when the 10-digit format is the 5-3-2 configuration. Below is an example of converting a 10-digit NDC to an 11-digit NDC for Omegaven®: NDC 63323-205-21 would become NDC 63323-0205-21.-00

ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification

Parenteral nutrition is the provision of nutritional requirements intravenously and the various insurance plans (Medicare, Medicaid, Commercial, etc.) may have specific policies pertaining to parenteral nutrition medical necessity requirements for patients.

Below is a table of applicable common diagnosis codes that may be covered by an insurance company. Patient specific diagnosis should be validated with the patient's insurance company. The list below provides examples of possible diagnosis codes and is not all inclusive:

Description	Diagnosis Code
Acquired absence of other specified parts of digestive tract	Z90.49
Acute Infarction of intestine, part and extent unspecified	K55.069
Complete intestinal obstruction, unspecified as to cause	K56.601
Crohn's disease of small intestine without complications	K50.00

Table continued on next page.

Coding (continued)

Description	Diagnosis Code
Fistula of Stomach and duodenum	K31.6
Gastroenteritis and colitis due to radiation	K52.0
Gastrointestinal transplantation	Z94.82
Malabsorption due to intolerance, not elsewhere classified	K90.48
Other malabsorption due to intolerance	K90.49
Other specfied diseases of liver	K76.89
Other specified diseases of galbladder	K82.8
Postsurgical malabsorption, not elsewhere classified	K91.2
Postsurgical malabsorption, not elsewhere classified	K91.2
Unspecfied protein-calorie malnutrition	E46

HCPCS – Healthcare Common Procedure Coding System

HCPCS codes (Healthcare Common Procedure Coding System) identify a specific product. Below is a table that lists the HCPCS code options for Omegaven®. Provision of these codes is not a guarantee that the codes will be accepted by every payer. It is important to verify coverage of these codes with each patient's insurance plan.

Omegaven® (fish oil triglycerides) injectable emulsion, for intravenous use

NDC	Fill Volume	Description	Concentration	HCPCS Code Options - Lipids
63323-205-21	50 mL	Single Dose Glass Bottle	5 grams per 50 mL (0.1 grams per mL)	**B4187** – Omegaven®, 10 grams lipids **B4185** – Parenteral Nutrition Solution, Not Otherwise Specified, 10 Grams Lipids
63323-205-31	100 mL	Single Dose Glass Bottle	10 grams per 100 mL (0.1 grams per mL)	**B4187** – Omegaven®, 10 grams lipids **B4185** – Parenteral Nutrition Solution, Not Otherwise Specified, 10 Grams Lipids

HCPCS Code B4185 should be billed with a billing unit of "1" for each 10 Grams. For the 50 mL the billing unit would be .5 units per day. In a 30-day month it would be 15 billing units administered at 5 grams per day.

Coding for Equipment and Supplies

The following HCPCS codes are associated with the listed equipment and supplies:

Equipment	HCPCS Code
IV Pole	E0776
Parenteral Nutrition Infusion Pump, Stationary	B9006
Parenteral Nutrition Supply Kit; ***Premix***, Per Day	B4220
Parenteral Nutrition Supply Kit; Home Mix, Per Day	B4222
Parenteral Nutrition Administration Kit, Per Day	B4224

Modifiers:

When an IV pole (E0776) is used in conjunction with parenteral nutrition, the BA modifier should be added to the code. Code E0776 is the only code with which the BA modifier may be used. Modifiers are to be placed in Box 24D of the CMS-1500. Up to 4 modifiers can be attached to each HCPCS code.

Billing Units: HCPCS Code B4187 should be billed with a billing unit of "1" for each 10 Grams. When administered for a 30-day period at 40g per day, the total billing units would be 120.

Coding (continued)

Parenteral nutrition supply allowances (HCPCS codes B4220, B4222 and B4224) describe a daily supply fee rather than a specifically defined "kit" and include all supplies required for the administration of parenteral nutrition to the beneficiary for one day. The use of individual items may differ from beneficiary to beneficiary, and from day to day. Daily allowances are considered all-inclusive and therefore refill requirements are not applicable to HCPCS codes B4220, B4222 and B4224. Only one unit of service may be billed for any one day. For example, June has 30 days, therefore the billing unit when billing for the month of June should be "30". This number should be in box 24G on the CMS 1500 claim form.

When parenteral nutrition is administered outside of the hospital, the pump used for its administration and IV pole will be denied as not separately payable. The pump and pole are not considered as rentals to a single beneficiary, but rather, as items of equipment used for multiple beneficiaries.

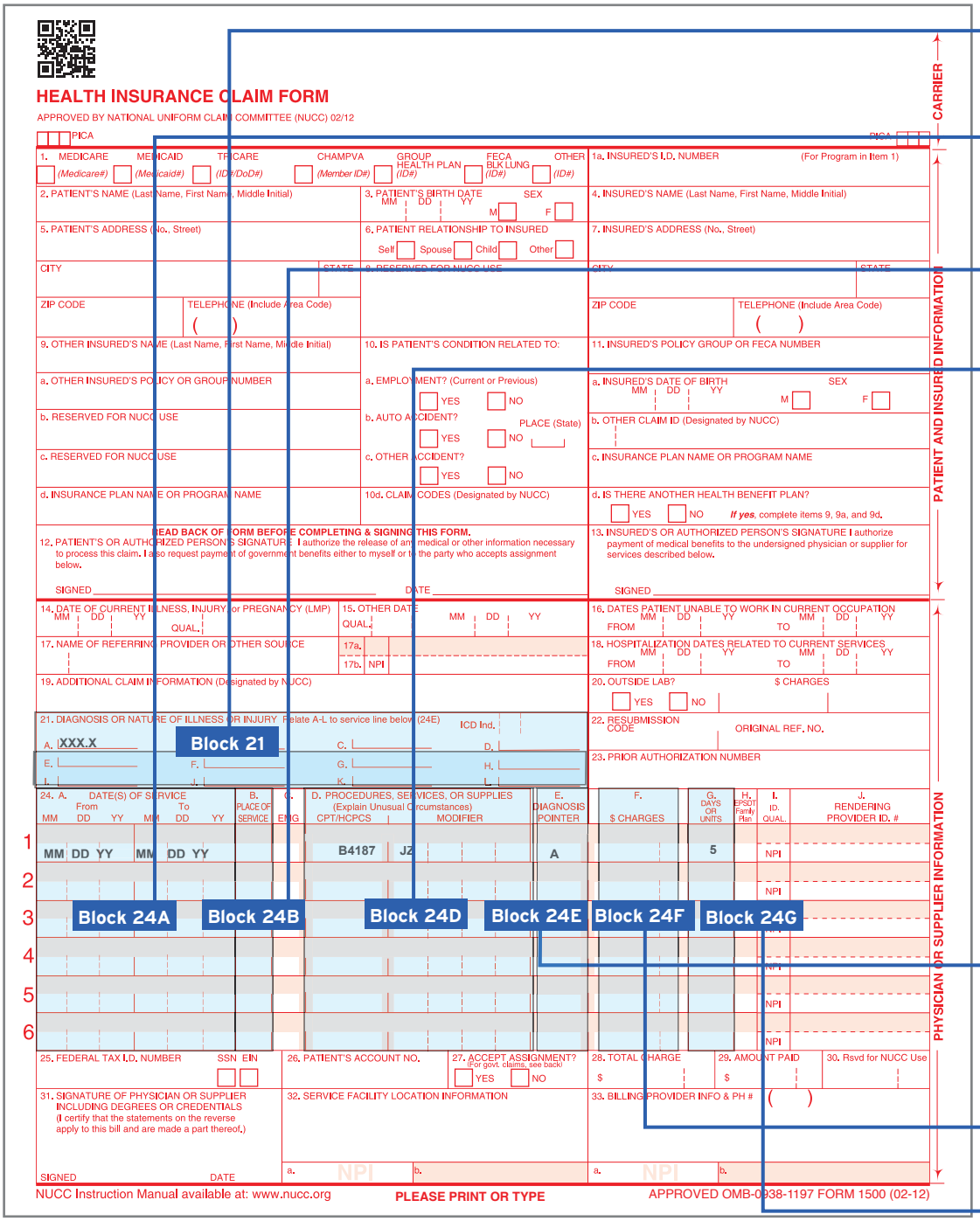
Place of Service Codes

Place of Service Codes tell the insurance company where Omegaven® is administered. The Place of Service code should be placed in Box 24B of the CMS-1500. Coverage of Parenteral Nutrition is based on the patient's place of service. Products are either paid for using HCPCS codes and payment amounts on the payer's fee schedule or on a "Per Diem" rate. Per Diem means the facility is paid a daily or monthly amount to provide all services to the patient, which includes their daily nutritional needs. Per Diem rates apply to hospital inpatient or Skilled Nursing Facilities.

Place of Service Code	Place of Service Name	Place of Service Description	Coverage of Parenteral Nutrition
12	Home	Location, other than hospital or other facility, where the patient receives care in a private residence	Billed with HCPCS codes
13	Assisted Living Facility	Congregate residential facility with self-contained living units providing assessment of each resident's needs and on-site support 24 hrs. per day, 7 days a week	Billed with HCPCS codes
21	Inpatient Hospital	A facility, which primarily provides diagnostic, therapeutic, and rehab services by, or under supervision of physicians to patients admitted due to various medical conditions	Considered a "Per Diem" situation. Hospitals are paid a fixed rate that includes parenteral nutrition
24	Ambulatory Surgical Center	A freestanding facility other than a physician's office, where surgical and diagnostic services are provided on an ambulatory basis	Billed with HCPCS codes
31	Skilled Nursing Facility	A facility that provides inpatient skilled nursing to patients but does not provide level of care available in a hospital	Considered a "Per Diem" situation. Skilled facilities are paid a fixed rate that includes parenteral nutrition

Sample CMS 1500 Claim Form

These sample claim forms are for informational purposes only and are not intended to replace a medical provider's professional judgment. It is the sole responsibility of the treating healthcare provider to confirm coverage, coding, and claim submission guidance with the patient's health insurance plan to ensure Omegaven® claims are accurate, complete, and supported by documentation in the patient's medical record. Fresenius Kabi does not guarantee Omegaven® coverage or reimbursement.



Block 21: Diagnosis

Enter appropriate ICD-10-CM diagnosis code(s).

Block 24A: Date(s) of Service

If line item NDC information is required, enter it in the shaded portion of item 24A.

Block 24B: Place of Service

A place of service code (e.g., 12 - Home)

Block 24D: Drug Code

Enter the HCPCS and CPT codes B4185- Parenteral nutrition solution; not otherwise classified, 10 grams of lipids.

Review the medical record and compounding log to determine whether additional TPN components should be billed. These may include amino acids (e.g. B4164-B4178), dextrose (e.g., B4180-B4187), additives (B4220), supply kits (B4224), and the infusion pump (B9004). For complete and accurate code selection, refer to internal coding guidelines or the applicable payer policy. See Reference: Page 5 .

Block 24E: Diagnosis Pointer

Refer to the diagnosis for this service from line 21, enter only 1 diagnosis pointer per line.

Block 24F: $ Charges

Indicate total charges.

Block 24G: Units

Enter the billing unit quantity - B4187 (e.g., 250 mL 50 g lipids ÷ 10 g = 5 units).

Benefit Verification and Authorization

Performing a Benefit Verification

Coverage criteria for each individual patient should be validated by contacting the patient's insurance company directly.

Below is some important information to be gathered from the insurance company during a Benefit Verification:

Questions to Ask During Insurance Verification:

- Confirm eligibility – Is the patient's plan current?
- What is the provider's network status?
- Are the reimbursement codes valid and billable?
- What is the patient's out of pocket cost?
  - Co-payment/Co-insurance
  - Deductible Amount and Accumulation
  - Maximum Out-of-Pocket and Accumulation
- Has the patient met their lifetime benefit max?
- What is the address to submit claims to?

Prior Authorization

Medicare does not require precertification/prior authorization for Parenteral Nutrition. However, it is important that medical documentation include the requirements outlined within the Medicare Parenteral Nutrition LCD L38953 and the related Article A58836.

Some insurance plans, including Medicare Advantage and Commercial, may require a Prior Authorization for Omegaven®.

Questions to Ask Regarding Prior Authorization:

- Is Prior Authorization Required?
- What is the insurer's Prior Authorization process?
- What is the fax or telephone number to the Prior Authorization unit within the insurer?
- What information will the Prior Authorization unit request, including any supporting documentation?
- How long does the Prior Authorization process take?

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Fresenius Kabi is a global healthcare company that specializes in lifesaving medicines and technologies for infusion, transfusion, and clinical nutrition. Our products are used to help care for critically ill and chronically ill patients in hospitals, long-term care facilities, and at home. For more information about Fresenius Kabi, please visit **www.fresenius-kabi.com/us**.

For information on **Omegaven® (fish oil triglycerides) injectable emulsion, for intravenous use**, visit **https://freseniuskabinutrition.com/products/omegaven/**.

For Fresenius Kabi product availability and ordering call **1-888-386-1300**.

For Medical Information call 1-800-551-7176 (option 4)
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