FRESENIUS KABI

Instructions for Letter of Appeal Template

- Please complete all applicable fields in the fillable form on the following pages.
- Please ask the physician to include specific details showing that the medical necessity criteria outlined in the insurance policy or the Medicare Local Coverage Determination (LCD) or Article are met.
- The Letter of Appeal should be submitted on the practice's letterhead and signed by the physician.
- Send any supporting documents along with the completed Letter of Appeal.
  - The "Enclosures" form field should list all documents included with this letter, such as the original prior authorization or claim form, denial/Explanation of Benefits, and additional supporting documents (e.g., patient's treatment with Omegaven®, medical history, diagnosis, lab results, Omegaven Important Safety Information, and treatment plan).
  - The "Summary of Patient's History" form field should briefly describe patient's symptoms, therapy to date, and any other pertinent information, including how Omegaven has been effective for this specific patient.

See Full Important Safety Information on page 3.

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

[Date]

Attn: Appeals Department
[Payer Name]
[Payer Street Address]
[Payer City, State, Zip]

Re: [Patient Full Name] [Patient Date of Birth]
[Patient Member ID] [Patient Policy/Group Number]
[Prior Authorization or Claim Number] [Date(s) of Service]
[Patient Diagnosis/ICD-10]

To Whom It May Concern:

This letter serves as a request for reconsideration of payment of a denied [Claim/Prior Authorization] for Omegaven® (fish oil triglycerides) injectable emulsion, for intravenous use, for [Patient Name] on [Date(s) of Service].

This patient has been under my care for the treatment of [patient diagnosis], which increases the patient's risk of [insert condition, e.g., malnutrition]. You have indicated that Omegaven is not covered because [reason for denial].

A brief description of the patient's symptoms, therapy to date, and any other pertinent information including how Omegaven has been effective for this specific patient is provided on the next page.

The attached Important Safety Information provides the approved clinical information for Omegaven. Omegaven has been administered as a medically necessary part of this patient's treatment.

I would appreciate reconsideration of coverage for the [Claim/Prior Authorization] for the dates of service referenced above for [Patient Name].

Please contact my office at the number listed below if you require additional information.

Sincerely,

_____

[Physician Name]
[Physician Street Address]
[Physician City, State, Zip]
[Participating Provider Number]
[Physician Phone Number]

Enclosures:

[List and include supporting documentation. Refer to "Instructions for Letter of Appeal."]
[Continue here if needed]

Summary of Patient’s History

INDICATIONS AND USAGE

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.

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/OmegavenPI.