FRESENIUS KABI

Instructions for Letter of Medical Necessity 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 Medical Necessity should be submitted on the practice's letterhead and signed by the physician.
- Send any supporting documents along with the completed Letter of Medical Necessity.
  - The "Enclosures" form field should include all supporting documents submitted with this letter. These may include:
    - The patient's diagnosis, condition, and medical history
    - A list of previous therapies the patient has received
    - The patient's response to those therapies
    - A brief summary of the patient's current symptoms and condition
    - The physician's professional opinion on the patient's likely prognosis without this specific product
  - The "Summary of Patient's History" form field should briefly describe patient's symptoms, therapy to date, and any other pertinent information, including how product has been effective for this specific patient.

SMOFlipid®
(lipid injectable emulsion), for intravenous use

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

Intralipid®
20% (lipid injectable emulsion), for intravenous use

Kabiven®
(amino acids, electrolytes, dextrose, and lipid injectable emulsion), for intravenous use

Perikabiven®
(amino acids, electrolytes, dextrose, and lipid injectable emulsion), for intravenous use

[Date]
[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:

I am writing to provide additional information to support my [Claim/Prior Authorization] for the treatment of [Patient Name] with [Product Name].

In brief, treatment of [Patient Name] with [Product Name] is medically appropriate and necessary and should be a covered and reimbursed service. This letter outlines medical history, prognosis, and treatment rationale.

Rationale for Treatment

Based on the patient's medical history — including a summary of symptoms, prior therapies, and other relevant details provided on the following page — along with current condition and the published clinical data supporting the use of [Product Name], I believe that treatment for [Patient Name] is warranted, appropriate, and medically necessary.

Please contact my office at the number listed below if you require additional information. I look forward to receiving your timely response and approval of this [Claim/Prior Authorization].

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 Medical Necessity."]
[Continue here if needed]

Summary of Patient’s History

INDICATIONS AND USAGE

SMOFlipid is indicated in adult and pediatric patients, including term and preterm neonates, as a source of calories and essential fatty acids for parenteral nutrition (PN) when oral or enteral nutrition is not possible, insufficient, or contraindicated.

IMPORTANT SAFETY INFORMATION

For intravenous infusion only into a central or peripheral vein. Use a non-vented non-DEHP 1.2 micron in-line filter set during administration. Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize and eliminate lipids, and consideration of additional energy given to the patient. The recommended dose for adults and pediatrics is shown in Table 1. For information on age-appropriate infusion rate, see the full prescribing information. SMOFlipid Pharmacy Bulk Package is only indicated for use in pharmacy admixture programs for the preparation of three-in-one or total nutrition admixtures. Protect the admixed PN solution from light.

Table 1: Recommended Adult and Pediatric Dosage

Age	**Nutritional Requirements**	
	Initial Recommended Dosage	Maximum Dosage
Birth to 2 years of age (including preterm and term neonates)	0.5 to 1 g/kg/day	3 g/kg/day
Pediatric patients 2 to <12 years of age	1 to 2 g/kg/day	3 g/kg/day
Pediatric patients 12 to 17 years of age	1 g/kg/day	2.5 g/kg/day
Adults	1 to 2 g/kg/day	2.5 g/kg/day

SMOFlipid is contraindicated in patients with known hypersensitivity to fish, egg, soybean, peanut, or any of the active or inactive ingredients, and severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglycerides >1,000 mg/dL).

Clinical Decompensation with Rapid Infusion of Intravenous Lipid Emulsion in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of intravenous lipid emulsions have been reported.

Parenteral Nutrition-Associated Liver Disease: Increased risk in patients who received parenteral nutrition for greater than 2 weeks, especially preterm neonates. Monitor liver tests; if abnormalities occur, consider discontinuation or dosage reduction.

Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reactions occur.

Risk of Infections, Fat Overload Syndrome, Refeeding Syndrome, Hypertriglyceridemia, and Essential Fatty Acid Deficiency: Monitor for signs and symptoms; monitor laboratory parameters.

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

Most common adverse drug reactions (≥5%) from clinical trials in adults were nausea, vomiting, and hyperglycemia. Most common adverse drug reactions (≥5%) from clinical trials in pediatric patients were anemia, vomiting, increased gamma-glutamyltransferase, and nosocomial 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 SMOFlipid safely and effectively. Please see full prescribing information for SMOFlipid (lipid injectable emulsion), for intravenous use at www.FreseniusKabiNutrition.com/SMOFlipidPI.

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.

INDICATIONS AND USAGE

Intralipid is indicated as a source of calories and essential fatty acids for patients requiring parenteral nutrition (PN) and as a source of essential fatty acids for prevention of essential fatty acid deficiency (EFAD).

IMPORTANT SAFETY INFORMATION

Intralipid 20% Pharmacy Bulk Package (lipid injectable emulsion), for intravenous use and Intralipid 30% Pharmacy Bulk Package (lipid injectable emulsion), for intravenous use are for admixing use only and are **not** intended for direct intravenous administration.

Intralipid 30% (lipid injectable emulsion) Pharmacy Bulk Package must be combined with other PN fluids. Diluting Intralipid 30% with an intravenous fluid such as normal saline or other diluent does not produce a dilution that is equivalent in composition to Intralipid 10% or 20% intravenous lipid emulsions. Therefore, diluents other than dextrose and amino acids should not be used to prepare admixtures for direct intravenous administration. When Intralipid 30% is diluted, strictly adhere to the recommended total daily dosage; the hourly infusion rate should not exceed 0.125 g/kg/hour for neonates and infants.

Recommended dosage depends on age, energy expenditure, clinical status, body weight, tolerance, ability to metabolize and eliminate lipids, and consideration of additional energy given to the patient. Protect the admixed PN solution from light. Use a 1.2 micron in-line filter during administration.

Dosage for Intralipid 20%

Age	**Nutritional Requirements**	
	Initial Recommended Dosage	Maximum Dosage
Birth to 2 years of age (including preterm and term neonates)	0.5 g/kg/day	3 g/kg/day
Pediatric patients 2 to <12 years of age	1 to 2 g/kg/day	2.5 g/kg/day
Pediatric patients 12 to 17 years of age	1 g/kg/day	2 g/kg/day
Adults	1 g/kg/day (stable) ≤1 g/kg/day (critically ill)	2.5 g/kg/day

Intralipid is contraindicated in patients with:

- Known hypersensitivity to egg, soybean, or peanut, or any of the active ingredients or excipients
- Severe disorders of lipid metabolism characterized by hypertriglyceridemia (serum triglyceride >1,000 mg/dL)

Risk of Clinical Decompensation with Rapid Infusion of Lipid Injectable Emulsion in Neonates and Infants: Acute respiratory distress, metabolic acidosis, and death after rapid infusion of lipid injectable emulsions have been reported. When Intralipid 30% is diluted, strictly adhere to the recommended total daily dosage; the hourly infusion rate should not exceed 0.125 g/kg/hour for neonates and infants.

Risk of Parenteral Nutrition-Associated Liver Disease (PNALD): Increased risk in patients who receive PN for extended periods of time, especially preterm neonates. Monitor liver function tests; if abnormalities occur, consider discontinuation or dosage reduction.

Hypersensitivity Reactions: Monitor for signs or symptoms. Discontinue infusion if reactions occur.

Risk of 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 neonates.

Most common adverse drug reactions (≥5%) from clinical trials in adults were nausea, vomiting, and pyrexia. Most common adverse drug reactions (≥5%) from clinical trials in pediatric patients were anemia, vomiting, increased gamma-glutamyltransferase, and cholestasis.

Vitamin K Antagonists (e.g., Warfarin): Anticoagulant activity may be counteracted; increase monitoring of coagulation parameters.

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 Intralipid safely and effectively. Please see full prescribing information, for intravenous use at www.FreseniusKabiNutrition.com/Intralipid20PI and www.FreseniusKabiNutrition.com/Intralipid30PI.

INDICATIONS AND USAGE

KABIVEN and PERIKABIVEN are each indicated as a source of calories, protein, electrolytes, and essential fatty acids for adult patients requiring parenteral nutrition when oral or enteral nutrition is not possible, insufficient, or contraindicated. KABIVEN and PERIKABIVEN may be used to prevent essential fatty acid deficiency or treat negative nitrogen balance in adult patients.

Limitations of Use

Neither KABIVEN nor PERIKABIVEN is recommended for use in pediatric patients <2 years including preterm infants because the fixed content of the formulation does not meet nutritional requirements in this age group.

IMPORTANT SAFETY INFORMATION

KABIVEN is indicated for intravenous infusion into a **central vein**. PERIKABIVEN is indicated for intravenous infusion into a **peripheral or central vein**. It is recommended to mix the contents thoroughly by inverting the bags upside down to ensure a homogenous admixture. Ensure the vertical seals between chambers are broken and the contents of all three chambers for KABIVEN and PERIKABIVEN are mixed together prior to infusion. The dosage of KABIVEN and PERIKABIVEN should be individualized based on the patient's clinical condition (ability to adequately metabolize amino acids, dextrose, and lipids), body weight, and nutritional/fluid requirements, as well as additional energy given orally/enterally to the patient. Prior to administration of KABIVEN and PERIKABIVEN, correct severe fluid, electrolyte, and acid-base disorders. Before starting the infusion, obtain serum triglyceride levels to establish the baseline value. Do not exceed the recommended maximum infusion rate of 2.6 mL/kg/hour for KABIVEN and 3.7 mL/kg/hour for PERIKABIVEN.

KABIVEN and PERIKABIVEN are contraindicated in:

- Concomitant treatment with ceftriaxone in neonates (28 days of age or younger)
- Known hypersensitivity to egg, soybean, peanut, or any of the active or inactive ingredients
- Severe disorders of lipid metabolism characterized by hypertriglyceridemia (with serum triglyceride concentration >1,000 mg/dL)
- Inborn errors of amino acid metabolism
- Cardiopulmonary instability
- Hemophagocytic syndrome

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.

Parenteral Nutrition-Associated Liver Disease: Increased risk in patients who receive parenteral nutrition for greater than 2 weeks. Monitor liver tests; if abnormalities occur, consider discontinuation or dosage reduction.

Pulmonary Embolism and Respiratory Distress due to Pulmonary Vascular Precipitates: If signs of pulmonary distress occur, stop the infusion and initiate a medical evaluation.

Hypersensitivity Reactions: Monitor for signs or symptoms and discontinue infusion if reactions occur.

Precipitation with Ceftriaxone: Do not administer ceftriaxone simultaneously with KABIVEN or PERIKABIVEN via a Y-site.

Infection, Fat Overload, Hyperglycemia, and Refeeding Complications: Monitor for signs and symptoms; monitor laboratory parameters.

The most common adverse reactions for KABIVEN (≥3%) are nausea, pyrexia, hypertension, vomiting, decreased hemoglobin, decreased total protein, hypokalemia, decreased potassium, and increased gamma glutamyltransferase. The most common adverse reactions for PERIKABIVEN (≥3%) are hyperglycemia, hypokalemia, pyrexia, and increased blood triglycerides.

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.

Coumarin and Coumarin Derivatives, Including Warfarin: Anticoagulant activity may be counteracted; monitor laboratory parameters.

This Important Safety Information does not include all the information needed to use KABIVEN and PERIKABIVEN safely and effectively. Please see full prescribing information for KABIVEN and PERIKABIVEN (amino acids, electrolytes, dextrose, and lipid injectable emulsion), for intravenous use at www.FreseniusKabiNutrition.com/KabivenPI and www.FreseniusKabiNutrition.com/PerikabivenPI.