



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 Intralipid®, medical history, diagnosis, lab results, Intralipid 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 Intralipid has been effective for this specific patient.



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

See Full Important Safety Information on page 3.

Attn: Appeals Department

Re:

To Whom It May Concern:

This letter serves as a request for reconsideration of payment of a denied
for Intralipid® 20% (lipid injectable emulsion), for intravenous use,
on .

This patient has been under my care for the treatment of ,
which increases the patient's risk of . You have indicated
that Intralipid is not covered because .

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

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

I would appreciate reconsideration of coverage for the
for the dates of service referenced above for .

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

Sincerely,

Enclosures:

Summary of Patient's History

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 ($\geq 5\%$) from clinical trials in adults were nausea, vomiting, and pyrexia. Most common adverse drug reactions ($\geq 5\%$) 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.