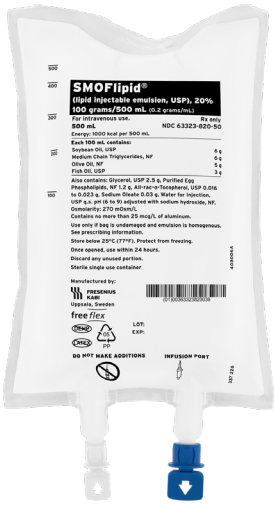
FRESENIUS KABI

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



See Full Important Safety Information on page 3.

SMOFlipid®
(lipid 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 SMOFlipid® (lipid 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 SMOFlipid 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 SMOFlipid has been effective for this specific patient is provided on the next page.

The attached Important Safety Information provides the approved clinical information for SMOFlipid. SMOFlipid 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

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.