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

See Full Important Safety Information on page 3.

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]

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 Kabiven® (amino acids, electrolytes, dextrose, and 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 Kabiven 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 Kabiven has been effective for this specific patient is provided on the next page.

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

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.