Letter of Medical Necessity

Date:(*MM/DD/YYYY)*
To: *insurance company*
From: *Physician name*

Subject: Request for coverage/reimbursement Kate Farms® Pediatric Peptide 1.5 vanilla/plain

I am requesting insurance coverage and reimbursement for my patient, *NAME*, *DOB as MM/DD/YYY*, for whom I have prescribed the use of Kate Farms® Pediatric Peptide 1.5. Based on this patient's clinical history, and diagnosis of *medical condition/diagnosis*, I have determined that the formula indicated above is medically necessary.

My patient's current measurements are:
Weight: _____
Height/Length: _____
BMI/BMI Percentile:_____
Weight History: _____

Pertinent Labs and/or Medications (if applicable): _____
_____

The potential health of this patient will decline if this formula is not covered and could result in LIST OUT POTENTIAL HEALTH OUTCOMES IF DENIED.

The nutritional profile of Kate Farms® Pediatric Peptide 1.5 is formulated to meet the nutrition needs of children ages 1 to 13 years and may be the sole source of nutrition or supplemental nutrition for this patient to be taken orally or via tube feeding. The product may be used in children over the age of 13 and through adulthood, in volumes deemed appropriate by the prescribing clinician. It contains ingredients such as prebiotic fiber from organic agave inulin, as well as organic MCT oil. MCT oil is an easily digestible plant-based fat source. It is a nutritionally complete peptide-based formula that may be used to support the nutrition of patients that experience gastrointestinal disease (GI), GI dysfunction, maldigestion, malabsorption, or symptoms of GI intolerance. It is calorically dense at 1.5cal/mL to meet needs with less volume. Kate Farms® Pediatric Peptide 1.5 contains organic agave inulin as a source of prebiotic fiber for gut microbiome support. The formula is recognized by the Centers for Medicare and Medicaid Services (CMS) as "Enteral formula, for pediatrics, hydrolyzed/amino acids and peptide chain proteins, includes fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit" found in the HCPCS Category B4161.

Clinical malnutrition is becoming a growing problem in our country, and more than 50% of those adults who are hospitalized, are estimated to be malnourished.[1] Estimations for pediatric malnutrition have been reported to be between 6-51%. It is known that with the diagnosis of malnutrition in pediatric patients, comes a three-fold increase in overall hospital cost. With malnutrition comes a two-and-a-half time increase in hospital length of stay, increase in comorbidities, and 3.5-fold increase in home care needs following discharge. [2]

Since Kate Farms® Pediatric Peptide 1.5 can be taken orally or via a feeding tube, it can support the nutrition of patients with malnutrition and chronic conditions and may help decrease overall health care costs. Malnutrition-related inpatient stays are up to twice as costly in comparison to all inpatient stays. The 30-day readmission rates for malnourished patients were 50% higher than a patient without malnutrition.[3]

[OPTIONAL INFORMATION TO INCLUDE] In addition to the above, to date, my patient has *failed* to tolerate other products including: [insert failed products here], as evidenced by:

☐ Failure to meet weight gain goals
☐ Nausea and/or vomiting
☐ Diarrhea
☐ Constipation
☐ Heartburn/GERD
☐ Excessive gas and/or bloating
☐ Abdominal pain/cramps
☐ Increased mucus production
☐ Early Satiety
☐ Abnormal Labs
☐ __Add additional symptoms, if applicable___
☐ __Add additional symptoms, if applicable___

The composition of Kate Farms® Pediatric Peptide 1.5 is made without the top 9 allergens including wheat, dairy, soy, peanuts, tree nuts, eggs, fish, shellfish, and sesame and is gluten free. Kate Farms® medical products contain all nine essential amino acids from pea protein with additional l-cysteine to provide a Protein Digestibility Corrected Amino Acid Score (PDCAAS) of 1.0. The formula includes organic ingredients as well as an organic phytonutrient blend designed to improve markers of oxidative stress in adults.[4]

For the above-outlined medical reasons, I am prescribing the following:
☐ **Kate Farms®** Pediatric Peptide 1.5 Vanilla
☐ **Kate Farms®** Pediatric Peptide 1.5 Plain

Based on my patient's current medical condition, I am prescribing:
_____CALORIES (_____OUNCES per day)

_____% of daily caloric needs
This equates to [number of 250 mL Tetrapack cartons] Tetrapack cartons daily.

Your approval of this request for assistance with medical care and reimbursement of the formula would have a significant positive impact on this patient's nutrition.

Sincerely,

_____ _____

Signature of prescribing provider *Date*

_____

Printed Name of prescribing provider

_____

Title

_____

Title – Center/Hospital/Institution/Practice

Encouraged Enclosures to be attached: Current Growth Chart, Letter of Dictation, Reports, Prescription

Kate Farms, Inc. is providing this template to assist medical providers in communicating with insurance companies when a medical provider determines that Kate Farms' products should be part of a patient's care. Kate Farms, Inc. does not evaluate individual patients and does not participate in the determination of what constitutes proper care. Health Care providers should evaluate each of their patients to determine the best treatment plan for the patient's condition, which may include prescribing Kate Farms' products.

1 Robinson, MK., Trujillo, EB., Mogensen, KM., Rounds, J., McManus K., Jacobs, DO. (2003). Improving nutritional screening of hospitalized patients: the role of prealbumin. Journal of Parenteral and Enteral Nutrition;27(6):389-395.

2 Abdelhadi, R., Bouma, S., Bairdain, S., Wolff, J., Legro, A., et al. (2016). Characteristics of Hospitalized Children with a Diagnosis of Malnutrition. J Parenteral and Enteral Nutr;40(5):623-635.

3 Barrett ML, Bailey MK, Owens PL. Non-maternal and Non-neonatal Inpatient Stays in the United States Involving Malnutrition, 2016. ONLINE. August 30, 2018. U.S. Agency for Healthcare Research and Quality. Available: www.hcup- us.ahrq.gov/reports.jsp.

4 Nemzer, B., Chang, T., Xie, Z., Pietrzkowski, Z., Reyes, T., & Ou, B. (2014). Decrease of free radical concentrations in humans following consumption of a high antioxidant capacity natural product. Food Science & Nutrition, 2(6), 647–654. http://doi.org/10.1002/fsn3.146