Letter of Medical Necessity

Date: MM/DD/YYYY
To: Insurance company
From: Physician's name

Subject: Request for coverage of Kate Farms® Pediatric Standard 1.2 Vanilla, Chocolate

I am requesting insurance coverage and reimbursement for my patient, Patient's name, Patient's DOB (MM/DD/YYYY), for whom I have prescribed the use of Kate Farms® Pediatric Standard 1.2. Based on this patient's clinical history, and diagnosis of _____, I have determined that the formula indicated above is medically necessary.

My patient's current measurements are:

Weight: _____
Height: ____
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

_____

The nutritional profile of Kate Farms Pediatric Standard 1.2 is formulated to meet the nutrition needs of children ages 1 to 13 years. The product may be used in children over the age of 13 and through adulthood, in volumes deemed appropriate by the prescribing clinician. The formula is calorically dense at 1.2kcal/mL to meet needs with less volume. Kate Farms® Pediatric Standard 1.2 is Clinically demonstrated to improve tolerance, weight gain, and adherence.[1,2*] It contains ingredients such as prebiotic fiber from organic agave inulin for gut microbiome support, as well as organic medium chain triglycerides (MCT from coconut) for easy fat absorption. Kate Farms® Pediatric Standard 1.2 is recognized by the Centers for Medicare

and Medicaid Services in the category of B4160 as an "enteral formula, for pediatrics, nutritionally complete, calorically dense (equal to or greater than 0.7kcal/mL with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an enteral feeding tube, 100 calories = 1 unit."

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.[3] 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. [4]

Since Kate Farms® Pediatric Standard 1.2 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.[5]

In addition to the above, to date, my patient has *failed* to tolerate other products including: _____ 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 Standard 1.2 is made without the top 9 allergens including milk, eggs, fish, shellfish, tree nuts, peanuts, wheat, soybeans, and sesame and is gluten free. Kate Farms® medical products contain all nine essential amino acids from pea protein with additional L-Cysteine and L-Tryptophan 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.[6]

For the above-outlined medical reasons, I am prescribing the following:

- ❑ **Kate Farms®** Pediatric Standard 1.2 Vanilla

❑ **Kate Farms®** Pediatric Standard 1.2 Chocolate

Based on my patient's current medical condition, I am prescribing _____ calories or _____ ounces per day, which equates to ____% of daily caloric needs.
This equates to ____ Tetra pack 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,

_____ MM/DD/YYYY

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, etc.

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 Cohen, SA, et al. JPGN. 2020;71(suppl 1):S454-456.
2 Cohen SA, et al. JPEN. 2020;44(3):275.
3 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.
4 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.
5 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.
6 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

* Formulas included in these studies were Pediatric Standard 1.2 Vanilla, Standard 1.0 Vanilla/Chocolate, Pediatric Peptide 1.5 Plain, and Peptide 1.5 Plain