Letter of Medical Necessity

| Date: |
|--|
| To: |
| From: |
| Subject: Request for coverage of Kate Farms® Standard 1.4 Vanilla, Chocolate, Plain |
| I am requesting insurance coverage and reimbursement for my patient,, for whom I have |
| prescribed the use of Kate Farms® Standard 1.4. 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 |
| |

Kate Farms® Standard 1.4 provides a balance of macronutrients for those patients ages 14 years and up through adulthood and may be the sole source of nutrition or supplemental nutrition for this patient to be taken orally or via tube feeding. Calorically dense at 1.4kcal/mL to meet needs with less volume. Standard 1.4 has a low glycemic index. Kate Farms® Standard 1.4 is made for toleranceTM and 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, nutritionally complete with intact nutrients, includes proteins, fats, carbohydrates, vitamins and minerals, may include fiber, administered through an

enteral feeding tube, 100 calories = 1 unit" found in the HCPCS Category B4150.

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. 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® Standard 1.4 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

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 | |
| ☐ Hyperglycemia or uncontrolled blood glucose | |
| ☐ Abnormal Labs | |
| Add additional symptoms, if applicable: | |
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The composition of Kate Farms® Standard 1.4 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.⁴

| □ Kate Farms® Standard 1.4 Vanilla □ Kate Farms® Standard 1.4 Chocolate □ Kate Farms® Standard 1.4 Plain 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, | | | |
| Signature of prescribing provider | Date | | |
| Printed Name of prescribing provider | | | |
| Title | | | |
| Title – Center/Hospital/Institution/Practice | | | |

For the above outlined medical reasons. Lam proscribing the following:

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