Letter of Medical Necessity

Date:(MM/DD/YYYY) _____

To: (Insurance company) _____

From: (Physician name) _____

Subject: Request for coverage of Kate Farms® Renal Support 1.8

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® Renal Support 1.8. 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, BMI/BMI percentile (pediatrics)_____, and history of weight loss. The pertinent labs that support the use of this product include: (list out any lab work or delete this section if not applicable)_____. The potential health of this patient will decline if this formula is not covered, and could result in (List out health outcomes associated with denial)_____.

Kate Farms® Renal Support 1.8 is specifically designed to meet the nutritional needs of patients on dialysis, due to conditions such as the following [select appropriate]:

- ❑ Chronic Kidney Disease (N18)
- ❑ Chronic Kidney Disease, unspecified (N18.9)
- ❑ Injury of Kidney (S37.0)
- ❑ Acute Kidney Failure, unspecified (N17.9)
- ❑ Post-procedural (acute/chronic) kidney failure (N99.0)
- ❑ Other acute Kidney Failure (N17.8)
- ❑ Dependence on Renal Dialysis (Z99.2)
- ❑ Other disorders of electrolyte and fluid balance, not elsewhere classified (E87.8)

The unique formulation of Kate Farms® Renal Support 1.8 provides a complete nutrition profile and may be the *sole source of nutrition* for this patient to be taken orally or via a tube feeding.

Renal Support 1.8 contains optimized amounts of sodium, potassium, and phosphorus to support the needs of patients on dialysis. This product can be used as an oral supplement or for exclusive enteral nutrition.

Renal Support 1.8 is recognized by the Centers for Medicare and Medicaid Services (CMS) as "an enteral formula, nutritionally complete special metabolic needs, excludes inherited disease

of metabolism, includes altered compositions of proteins, fats, carbohydrates, vitamins and/or minerals, may include fiber, administered through an enteral feeding tube" within the B4154 HCPCS category.

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® Renal Support 1.8 can be taken orally or via a feeding tube, it can support the nutritional management of patients with malnutrition and chronic conditions to help decrease overall health care costs. Literature on the use of nutritional supplements in adult hospitalized patients has displayed an overall decrease in readmission (6.7%), overall episode cost (21.6% decrease), and in length of stay (21% decrease).[3]

(Optional information to include) In addition to the above, to date, my patient has *failed* to tolerate other formulas including: (insert failed formulas 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® Renal Support 1.8 is made without the top 8 allergens including gluten, dairy, soy, peanuts, tree nuts, eggs, fish, and shellfish. 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 help improve markers of oxidative stress.[4]

For the above-outlined medical reasons, I am prescribing the following:
Kate Farms® Renal Support 1.8

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

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 health.

Sincerely,

_____ _____

Signature of prescribing provider *Date*

_____

Printed Name of prescribing provider

_____

Title

_____

Title – Center/Hospital/Institution/Practice

Encouraged Enclosures to be attached: Relevant Clinical Notes, 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 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 Bauer, JD., Isenring, E., Torma, J., Horsely, P., Martineau, J. (2007). Nutritional Status of patients who have fallen in an acute care setting. J Human Nutrition and Dietetics;20(6):558-564.

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