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

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, 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 Pediatric Peptide 1.5 is specifically designed to meet the nutritional needs of children ages 1-13 years with malabsorption, maldigestion or GI impairment due to conditions such as the following [select appropriate]:

- ❑ Intestinal Malabsorption (K90.9)
- ❑ Regional enteritis (Crohn's Disease) (K50.0)
- ❑ Ulcerative Colitis (K51.0-51.9)
- ❑ Pancreatitis (K85.1-85.9)
- ❑ Short bowel syndrome (K91.2)
- ❑ Cystic Fibrosis (E84.19)
- ❑ Celiac Disease (K90.0)
- ❑ Lactose sensitivity (E73.9)
- ❑ Human Immunodeficiency Virus infection (B20.0-20.9)
- ❑ Liver Transplant (Z94.4)
- ❑ Trauma (S36.0)
- ❑ Sepsis (A41.9)
- ❑ Burn (T31.0-31.9)

- ❑ Functional digestive disorders, not elsewhere classified (K59.0-59.9)
- ❑ Other and unspecified noninfectious gastroenteritis and colitis (K52.9)
- ❑ Other conditions in which an elemental peptide-based formulation would be beneficial (e.g., tube feeding-associated GI intolerance, critical illness-associated GI dysfunction, early enteral feeding, transition from TPN)

The unique formulation of Kate Farms Pediatric Peptide 1.5 provides a complete nutrition profile for pediatric patients and may be the *sole source of nutrition* for this patient to be taken orally or via a tube feeding. Kate Farms Pediatric Peptide 1.5 is a nutritionally complete peptide-based elemental formula for the nutritional management of pediatric patients experiencing gastrointestinal (GI) disease, GI dysfunction, maldigestion, malabsorption, or symptoms of GI intolerance.

In comparison with formulas containing only free amino acids or intact protein, peptide-based formulas provide better absorption, better tolerance, and better maintenance of GI-tract function[1-4]. This formula contains prebiotic fiber from agave inulin which increases the production of short chain fatty acids, which is helpful in the management of diarrhea[4]. This formulation also contains medium chain triglycerides, a well-tolerated and absorbed fat[5-6].

In addition to the above, to date, my patient has *failed* to tolerate conventional cow milk, soy-based, hydrolysate and/or amino-acid based formulas including: (insert failed formulas here) _____ as evidenced by failure to meet (include only those which are applicable: weight gain goals, GI discomfort, emesis, diarrhea, constipation, heartburn/GERD, bloating, excessive gas, stomach aches/pains, increased mucus production, etc.)_____. Kate Farms® Pediatric Peptide 1.5 is specifically designed to meet the nutritional needs of patients with intestinal inflammation, severe cow milk protein, multiple food protein allergies and/or are unable to tolerate conventional cow milk, soy-based, hydrolysate formulas and/or amino-acid based formula. The composition of Kate Farms Pediatric Peptide 1.5 is made without gluten, dairy, soy, corn and nuts. Kate Farms products are formulated with organic pea protein and a complete amino-acid profile, include organic ingredients and are fortified with evidence-based protein-free phytochemical extracts to support the body's ability to fight inflammation and oxidation[7]. I believe this product is ideally suited for my patient with compromised gastrointestinal function and/or food allergy-related symptoms.

Based on my patient's current medical condition, I am prescribing _____CALORIES, kcal / _____OUNCES per day. This equates to (number of 325 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 health.

Sincerely,

_____ _____

Signature of prescribing MD, PA-C, ARNP *Date*

_____

Printed Name of prescribing MD, PA-C, ARNP

_____

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.

References

1. Daniel H. Molecular and integrative physiology of intestinal peptide transport. Annu Rev Physiol 2004; 66:361-384.
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3. Brinson RR, Kolts BE. Diarrhea associated with severe hypoalbuminemia: a comparison of a peptide-based chemically defined diet and standard enteral alimentation. Crit Care Med 1988; 16:130-136.
4. Brinson RR, Kolts BE. Hypoalbuminemia as an indicator of diarrheal incidence in critically ill patients. Crit Care Med 1987; 15:506-509.
5. Bowling TE, Raimundo AH, Grimble GK, Silk DB. Reversal by short-chain fatty acids of colonic fluid secretion induced by enteral feeding. Lancet 342, 1266-1268. 1993.
6. McKenna MC, Hubbard VS, Bieri JG. Linoleic acid absorption from lipid supplements in patients with cystic fibrosis with pancreatic insufficiency and in control subjects. J Pediatr Gastroenterol Nutr 1985; 4:45-51.
7. 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