

Letter of Medical Necessity

Date:

To:

From:

Subject: Request for coverage/reimbursement TRILITY®, ACEND®, Medical Food, Chronic Inflammation

I am requesting insurance coverage and reimbursement for my patient, _____, _____, DOB: ____/____/____ as (today's date) ____/____/____, for whom I have prescribed the use of ACEND, oral feeding enteral formula. 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 (pediatrics/adults): _____ and history of weight loss/gain: _____. The pertinent labs that support the use of this product include: _____. The potential health of this patient will decline if this formula is not covered, and could result in _____.

The unique formulation of ACEND provides an important nutrition profile for those patients ages 18 years and up and may be the *sole source of critical chronic inflammation reducing phyto-nutrients* for this patient to be taken orally or via a feeding tube.

Clinical chronic inflammation due to 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 malnutrition have been reported to be between 6-51%. It is known that with the diagnosis of malnutrition in 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 ACEND® can be taken orally or via a feeding tube, it can support the nutritional management of patients with chronic inflammation due to 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

ACEND® is specifically designed to meet the nutritional needs of patients with chronic inflammation, intestinal inflammation, gut dysbiosis and mitochondrial dysfunction. The composition of ACEND does not contain gluten, dairy, sugar, soy (traces may exist due to vitamin K2 being derived from fermented soy), corn, and nuts. ACEND® is formulated with 9 peer-reviewed polyphenols, prebiotics, probiotics and essential vitamins, minerals and micro-nutrients showing evidence in supporting gut health, mitochondrial function and inflammatory response due to chronic conditions.

ACEND® is currently recognized by the Centers for Medicare and Medicaid Services (CMS) in **HCPCS Category A9153**: a valid 2023 HCPCS code for *Multiple vitamins, with or without minerals and trace elements, oral, per dose, not otherwise specified* or just "**Multi-vitamin nos**" for short, used in Other medical items or services.

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

TRILITY®, **ACEND®**, **medical food for the dietary management for chronic inflammation (flavor)**_____

Based on my patient’s current medical condition, I am prescribing 2 packets per day. One in the morning and one in the afternoon.

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

TRILITY P.B.C. is providing this template to assist medical providers in communicating with insurance companies when a medical provider determines that TRILITY’s products should be part of a patient’s care. TRILITY P.B.C. 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., Pietrzowski, 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>