Healthcare Nutrition Council

529 14th Street, NW • Suite 750 • Washington, DC 20045

The Honorable Jene Vickrey Chair House Committee on Insurance State Capitol #372-W 300 SW 10th Street Topeka, KS 66612

The Honorable Willie Dove Vice-Chair House Committee on Insurance 300 SW 10th Street Room 149-S Topeka, KS 66612

RE: HNC Support for Kansas House Bill 2103 – Amino Acid Based Elemental Formula Insurance Coverage

Dear Representatives Vickrey and Dove:

The Healthcare Nutrition Council (HNC), representing the manufacturers of enteral formulas and parenteral solutions, supplies, and equipment, is writing to express our strong support for Kansas House Bill 2103, which would provide insurance coverage for amino acid-based elemental formula if clinically indicated by a health care professional. HNC supports the bill because it will ensure patients have access to amino acid-based elemental formulas, which is used for the treatment of food protein-induced enterocolitis syndrome, eosinophilic disorders, short bowl syndrome, and other gastrointestinal conditions.

Patients with these chronic diseases and medical conditions often suffer from malnutrition or other medical complications. Many of these patients' anatomy require a specifically formulated or specialized diet that is referred to as an elemental amino acid-based or peptide-based diet. Such diets are specially designed to help them properly digest essential nutrients stay healthy, and to support growth and development in children. Malnutrition and other complications can arise in these vulnerable patients as a result of their underlying conditions that may impair their ability to absorb nutrients from conventional foods. When patients become malnourished, they are at a significantly higher risk for negative complications, including mortality.ⁱ

Despite these potential complications and the clear benefits such specialized products provide to patients when their use is indicated, many families face significant financial burdens or lack access to amino acidbased elemental formulas when such formulas are not covered by their insurance provider.ⁱⁱ HNC supports the increased access to amino acid-based elemental formulas, due to the fact that elemental formulas contribute to the intervention for malnutrition and may help manage GI disorders and conditions. To help ensure patients with complex GI conditions, such as food protein-induced enterocolitis syndrome, eosinophilic GI disorders and short bowl syndrome, receive access and can afford these formulas, HNC encourages the House Committee on Insurance to bring House Bill 2103 up for Committee consideration, quickly pass this legislation and ensure this important bill is signed into Kansas State law. Enactment of this legislation will directly benefit these patients and their families and will also preemptively address the complications.

Importance of Amino Acid-Based Elemental Formulas

Interventions recommended by healthcare providers for patients with impaired or compromised GI function typically include some type of specialized nutritional support.ⁱⁱⁱ Amino acid-based elemental formulas are deemed necessary by many health care providers for those patients who cannot tolerate hydrolyzed protein or need an amino acid-based medical food.^{iv} Without these specialized formulas, which include elemental formulas for various life stages, infants, children, and adults can suffer adverse health consequences, including hospitalization, inadequate growth, nutrient deficiencies, or even death.^v Because of how they are formulated, these products require minimal digestive function to be broken down and absorbed, making it easy to digest for patients in a malabsorptive state.^{vi} Many patients rely on amino acid-based elemental formulas to help intervene with and manage chronic medical conditions, complications and comorbidities related to the poor absorption of nutrients because such nutrients would be otherwise unavailable to them through a conventional diet.

Depending on the patient's disease state and other underlying medical conditions, amino acid-based elemental formulas may be fed directly into the GI tract through a nasogastric, gastrostomy, jejunostomy or other type of feeding tube. Elemental formulas may also be administered orally as oral nutrition supplements (ONS) for patients who are able to swallow normally. For example, elemental formulas provide infants with short bowel syndrome, who often cannot absorb protein unless it is broken down into its component amino acids, with essential nutrients as a specialized nutritional formula.^{vii} Similarly, almost all infants suffering from severe food allergies can tolerate hypoallergenic amino acid-based formulas, while some infants with milk protein allergies cannot properly digest alternative formula options, such as hydrolyzed formulas.^{viii} Although amino acid-based elemental formulas are essential to patients suffering from specified digestive and inherited metabolic disorders, they are often too expensive if not reimbursed by health insurance. If these infant, pediatric, and adult populations do not receive treatment with elemental formula as a result of financial hardships of the family or lack of access, malnutrition and associated severe medical complications can occur, which can be life-threatening. Additionally, the growth and development of infants and children can be compromised.^{ix x}

Without legislation like House Bill 2103, these families can be left with a huge financial burden just for providing the nutrition interventions needed to support their loved one's health. Due to the critical nutrition that amino acid-based elemental formulas provides patient, HNC believes that these products should be made available to all patients, including those receiving care at home, if they have a diagnoses or condition for which such products are clinically indicated.

Conclusion

Given the importance of amino acid-based elemental formulas for certain patient populations, HNC supports Kansas House Bill 2103 and enthusiastically encourages its enactment into law. We commend the Kansas State Legislature for recognizing the gap in insurance coverage for these important amino acid-based elemental formulas that are needed to help intervene with and manage many chronic medical conditions, complications and comorbidities. We believe that by passing this legislation and making these elemental formulas affordable for numerous Kansas patients, there will be an immediate and meaningful impact on patient access to critical nutrition.

HNC welcomes the opportunity to work with the House Committee on Insurance, relevant stakeholders, doctors, and patient groups to identify additional disease states where amino acid-based elemental formula would be deemed clinically necessary by a health care professional for use as a nutritional intervention method.

Thank you for the opportunity to comment on this bill. If you have any questions or would like additional information, please contact me at ngardner@kellencompany.com or 202-207-1116.

Sincerely,

Nicholas M. Gardner Executive Director Healthcare Nutrition Council

^v Coleman MS, Kellermann A, Andersen R, et. al: Health Insurance is a Family Matter. *Insurance Health*. Institute of Medicine of the National Academies. National Academy of Sciences. 2002; 122-123.

^{vi} Id.

^{vii} Cuffari C, Ziegler, T. Short Bowel Syndrome. The National Institute of Diabetes and Digestive and Kidney Diseases. 2015.

viii Latcham et al, A consistent pattern of minor immunodeficiency and subtle enteropathy in children with multiple food allergy. J Pediatric. 2003.

^{ix} Thompson JS, Rochling FA, Weserman RA, Mercer DF. Current management of short bowel syndrome. *Current Problems in Surgery*. 2012;49(2):52-115.

^x Thompson JS, Rochling FA, Weserman RA, Mercer DF. Current management of short bowel syndrome. *Surgical Clinics of North America*. 2011;91(3):493-510.

ⁱ White JV, Guenter P, Jensen G, Malone A, Shofield M. Consensus Statement: Academy of Nutrition and Dietetics and American Society for Parenteral and Enteral Nutrition: Characteristics Recommended for the Identification and Documentation of Adult Malnutrition (Undernutrition). Journal of Parenteral and Enteral Nutrition. 2012;36 (3):275-283.

ⁱⁱ Walia, C, Van Hoorn, M, Edlbeck, A, et. al.: The Registered Dietician Nutritionist's Guide to Homemade Tube Feeding. *Journal of the Academy of Nutrition and Dietetics*, 2017; 117: 1: 15-16.

ⁱⁱⁱ Id.

^{iv} Latcham et al, A consistent pattern of minor immunodeficiency and subtle enteropathy in children with multiple food allergy. J Pediatric. 2003.