
Healthcare Nutrition Council

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

The Honorable Jim Justice
Governor, State of West Virginia
State Capitol, 1900 Kanawha Blvd E.
Charleston, WV 25305

RE: HNC Support of West Virginia Senate Bill 299 – Mandatory Insurance Coverage for Medical Foods

Dear Governor Justice:

The Healthcare Nutrition Council (HNC), representing the manufacturers of enteral and parenteral nutrition formulas, solutions, supplies, and equipment, is writing to express our strong support for West Virginia Senate Bill 299, which would provide insurance coverage, up to the age of 20, for certain medical foods for amino acid-based formulas. HNC supports the bill because it will ensure patients have access to amino acid-based formulas, which are used for the treatment numerous diseases and medical conditions, such as severe protein-allergic conditions or impaired absorption of nutrients caused by disorders affecting the gastrointestinal track.

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 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. Additionally, decades of research shows that specialized foods are medically necessary for the safe and effective management of digestive diseases and inherited metabolic disorders that impact the digestion, absorption, and/or metabolism of nutrients. Therapeutic nutrition products, like medical foods, are critical products for individuals with a variety of underlying medical conditions who cannot maintain their nutritional health through their regular diets. 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 acid-based formulas when such formulas are not covered by their insurance provider.ⁱⁱ HNC supports the increased access to amino acid-based formulas, due to the fact that these formulas contribute to the intervention for malnutrition and may help manage GI disorders and conditions. Additionally, infants, children and adults use these specialized formulas to reduce their risks of developing adverse health consequences, including hospitalization, inadequate growth, nutrient deficiencies, or even death. To help ensure patients with complex GI conditions, such as severe food protein-induced enterocolitis syndrome, eosinophilic GI disorders and short bowel syndrome, receive access and can afford these formulas, HNC encourages the Governor to quickly sign this bill into West Virginia state law. Enactment of this legislation will directly benefit these patients and their families and will also preemptively address the complications and added medical expenses associated with the management of these conditions.

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 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 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 formulas may be fed directly into the GI tract through a nasogastric, gastrostomy, jejunostomy or other type of feeding tube. For example, amino acid-based 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 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 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 Senate Bill 299, 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 formulas provides patient, HNC believes that these products should be made available to all patients, adults and children alike, if they have a diagnoses or condition for which such products are clinically indicated.

Conclusion

Given the importance of medical foods for amino acid-based formulas for certain patient populations, HNC supports West Virginia Senate Bill 299 and encourages its enactment into law. We commend the West Virginia State Legislature for recognizing the gap in insurance coverage for these important medical foods for amino acid-based formulas that are needed to help intervene with and manage many chronic medical conditions, complications and comorbidities.

HNC welcomes the opportunity to work with the Governor's office, relevant stakeholders, doctors, and patient groups to identify additional disease states where medical foods for amino acid-based formulas would be deemed clinically necessary by a health care professional for use as a nutritional intervention method. Legislation is needed to ensure that patients with varying medical conditions and a variety of different ages can receive these medical foods when deemed medically necessary by a healthcare professional.

Thank you for the opportunity to support this bill. If you have any questions or would like additional information, please contact me at mjurch@kellencompany.com or 202-207-1122.

Sincerely,



Madeline Jurch
Healthcare Nutrition Council

¹ 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 Walla, 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.

^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.

