
Healthcare Nutrition Council

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

The Honorable William J. Lippert Jr.
Chair
House Committee on Health Care
2751 Baldwin Road
Hinesburg, VT 05461

The Honorable Anne B. Donahue
Vice Chair
House Committee on Health Care
Vermont Psychiatric Survivors Inc.
1 Scale Ave., Suite 54
Rutland, VT 05701

The Honorable Timothy Briglin
Ranking Member
House Committee on Health Care
459 Tucker Hill Road
Thetford Center, VT 05075

RE: HNC Support for Vermont House Bill 65 – Health Coverage for Elemental Enteral Formula for Home Use

Dear Representatives Lippert Jr., Donahue and Briglin:

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 Vermont House Bill 65, which would expand health insurance coverage for nonprescription elemental enteral formulas for home use. HNC supports the bill because it will ensure that all patients are provided home access to elemental enteral nutrition formulas in cases of impaired absorption of nutrients caused by a medical disorder or chronic disease, when such formulas are prescribed, or when the formulas are an essential source for a patient's nutritional requirements.

Patients with chronic diseases and gastrointestinal (GI) medical conditions often suffer from malnutrition or other medical complications. Many of these patients' anatomy requires a specially formulated or specialized diet that is referred to as an elemental amino acid-based or peptide-based diet. Such diets are specifically 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 enteral products provide to patients when their use is indicated, many families face significant financial burdens or lack access to elemental enteral formulas when such formulas are not covered by their insurance provider for home use.ⁱⁱ HNC supports the increased access to elemental enteral formulas for home use, due to the fact that elemental enteral formulas contribute to the intervention for malnutrition and may help manage GI disorders and conditions. To help ensure patients with complex GI conditions receive access and can afford these formulas, HNC encourages the House Committee on Health Care to bring House Bill 65 up

for Committee consideration, quickly pass this legislation and ensure this important bill is signed into Vermont State law. Enactment of this legislation will directly benefit these patients and their families while also preemptively addressing the complications and added medical expenses associated with the management of these conditions.

Importance of Elemental Enteral Formulas

Interventions recommended by healthcare providers for patients with impaired or compromised GI function typically include some type of specialized nutritional support.ⁱⁱⁱ 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.^{iv} Because of how they are formulated, these products require minimal digestive function to be broken down and absorbed, making it easy to digest in patients in a malabsorptive state.^v Many patients rely on elemental formulas in the intervention for malnutrition and the management of 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, 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) in 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.^{vi} 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.^{vii} Although these 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 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.^{viii ix}

Without legislation like House Bill 65, 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 elemental enteral formula provides patients, 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.

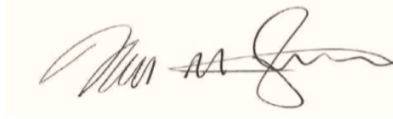
Conclusion

Given the importance of elemental enteral formulas for certain patient populations, HNC supports Vermont House Bill 65 and enthusiastically encourages its enactment into law. We commend the Vermont State Legislature for recognizing the gap in insurance coverage for these important elemental enteral formulas that are needed for malnutrition intervention and the management of many chronic medical conditions, complications and comorbidities. We believe that by passing this legislation and making home administration of these elemental enteral formulas affordable for numerous Vermont patients, there will be an immediate and meaningful impact on patient access to critical therapies.

HNC welcomes the opportunity to work with the House Committee on Health Care, relevant stakeholders, doctors, and patient groups to identify additional types of enteral formula for home use and additional disease states that would be deemed clinically necessary by a health care professional for use as a treatment 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@kellenccompany.com or 202-207-1116.

Sincerely,

A handwritten signature in black ink on a light yellow background. The signature is cursive and appears to read 'Nicholas M. Gardner'.

Nicholas M. Gardner
Executive Director
Healthcare Nutrition Council

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} 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.

^v Id.

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

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

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

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