

## HNC Statement of Support for Local Coverage Determination Clarification Act

The Healthcare Nutrition Council (HNC) is pleased to express its strong support for the *Local Coverage Determination Clarification Act* (S. 794). This bipartisan legislation is needed to improve the transparency and efficiency of the process by which Medicare Administrative Contractors (MAC) set local coverage determination policies for physician services provided to Medicare beneficiaries. These local coverage determinations and corresponding reimbursement codes set by MACs impact millions of Americans, including patients, physicians, manufacturers and insurance companies, who participate in the Medicare program. Currently, 12 MACs have the authority to process claims and make reimbursement decisions on a range of items and services, including medical procedures, office visits, imaging, drugs, specialized nutrition products, and laboratory tests. With just a slight change in local coverage determinations, patients could lack access and no longer be able to afford the lifesaving treatments they need to survive.

S. 794 was introduced in the U.S. Senate by Senators Johnny Isakson (R-GA), Tom Carper (D-DE), Debbie Stabenow (D-MI), and John Boozman (R-AZ). **HNC strongly encourages Members of Congress to cosponsor S. 794 and express their support for this commonsense legislation.** Passing this bill into law will ensure that key stakeholder input is included in the Medicare process and will provide expertise and guidance for future Medicare contractors.

As an example of the impact of alterations in local coverage determinations, this past spring, a change was made to a Durable Medical Equipment (DME) Local Coverage Determination Article (policy article A52493) that directly impacts the coding determination for enteral nutrition products. This coding revision altered the reimbursement for specialty enteral nutrition formulas to be nearly equivalent to those products which are not formulated to address metabolic conditions or gastrointestinal diseases. While not all enteral formulas were impacted by these revised codings, no additional explanation of this downcoding was provided by the Pricing, Data Analysis, and Coding (PDAC) system and DME MAC Medical Directors. Additionally, the Centers for Medicare and Medicaid Services (CMS) have reversed some of their decisions on the codes they assign, which impacts the petition process for products.

Maintaining access to specialized enteral nutrition formulas is critical for these reasons:

- Specialized enteral nutrition formulas can be lifesaving for individuals with digestive diseases, metabolic disorders, and other medical conditions who cannot maintain their nutrition and health through a regular diet.
- Specialized enteral nutrition formulas are fundamentally different in composition from other enteral nutrition formulas that contain intact macronutrients, such as intact whole proteins, and availability of specialized enteral nutrition formulas can be vital to a patient's health.
- With reduced access to the specialized enteral nutrition formulas patients need, many can experience adverse health consequences that lead to nutrient deficiencies, hospitalization, medical complications, disability, inadequate growth, or even death. For example, for children with maldigestion or malabsorption diseases/disorders, or severe food allergies, consuming an enteral nutrition formula with intact whole proteins can cause pain, chronic diarrhea, weight loss, and nutrient deficiencies, and ultimately may not adequately support their growth and development and put their health at risk.

Because of their unique ingredients and complex formulas, specialized enteral nutrition products are extremely difficult and costly to research, develop, and manufacture. The current LCD procedures which have resulted in the downcoding of specialized enteral nutrition formulas will stifle the innovation of new products to treat highly complex and specific diseases and could impact other lifesaving products, such as parenteral solutions. Ultimately, the coding revision for specialty enteral nutrition formulas will have a negative effect on product access and could reduce patient safety, and overall patient outcomes. HNC members' are committed to keeping specialized enteral nutrition formulas available to those who need them to manage their medical conditions, positively contribute to their overall health, and improve their quality of life.

HNC is pleased to join the College of American Pathologists, Advanced Medical Technology Association, American Society of Clinical Oncology, and more than 75 state and national physician organizations,

patient advocacy groups and national cancer centers in their support of S. 794. We strongly encourage Congress to pass this critical legislation and for President Trump to sign S. 794 into law. The speedy passage of this legislation will have an immediate impact on hundreds of thousands of Americans who rely on specialized enteral nutritional products and similar critical therapies.

**About HNC:** The Healthcare Nutrition Council (HNC) is an organization dedicated to raising awareness of malnutrition and the profound impact nutritional status has on overall health and treatment outcomes. Our work is focused on promoting malnutrition screening, assessment and intervention in all healthcare settings, and encouraging policymakers to preserve and expand access to nutritional therapies that patients need. We are a group of medical nutrition manufacturers, representing the manufacturers of enteral formulas and parenteral solutions, supplies and equipment, working together to help healthcare professionals improve the experience of care, improve the health of populations, and reduce the costs of care.