

Senator Johnny Isakson  
131 Russell Senate Office Building  
Washington, D.C. 20510

Senator Mark Warner  
475 Russell Senate Office Building  
Washington, D.C. 20510

Dear Senator Isakson and Senator Warner,

Thank you for the opportunity to provide feedback on ways to improve outcomes for Medicare patients with chronic conditions.

The importance of proper nutrition in patient care is well established. Patients suffering from inadequate nutritional intake at the point of treatment are more likely to incur higher healthcare costs stemming from poorer health outcomes. Conversely, a patient whose treatment includes specialized nutritional support tailored to address the unique nutritional needs associated with the patient's specific disease or condition should expect better health outcomes and lower health care costs, thus minimizing preventable adverse health complications and enhancing the patient's overall quality of life.

In recent decades, advances in science and emerging research have demonstrated the important role of key nutrients in the dietary management of patients with various diseases and conditions. The discovery of novel techniques to study the pathophysiology of disease states has opened new and exciting opportunities in the nutrition field.

Medical foods play a critical role in our healthcare delivery system by providing patients with safe, high quality nutritional products that are specially formulated to meet the distinctive nutritional requirements of specific disease or conditions. When properly addressed, this improvement of nutritional status is associated with benefits in both patient well-being and health outcomes. Patients with pancreatic insufficiency, for example, lack the digestive enzymes that normally release essential amino acids from the protein in food. Gall bladder disease can lead to reduced capacity to absorb dietary fat when bile salts production is impaired. In both cases, medical foods that provide pre-digested protein sources of peptides and amino acids, or medium-chain triglycerides that bypass typical fat absorption pathways, enable essential nutritional requirements to be met and, thereby, improve the nutritional status and quality of life for these patients.

The inadequate coverage of and reimbursement for medical foods is a significant obstacle to more widespread appropriate use of current products on the market and acts as a barrier to further innovation in this important therapeutic field. Medicare provides only limited coverage of certain medical foods, in particular only those medical foods administered long-term via feeding tube. Ironically, cost reimbursement is linked to the “device delivery system”, not to the actual benefit of the product’s nutritional formulation.

Medicare Part B classifies enteral nutrition therapy (“ENT”) under the prosthetic device benefit, and coverage is only for therapy required due to the absence or malfunctioning body part which normally permits food to reach the digestive tract. Additionally, Medicare requires all of the following conditions to be satisfied in order for patients to qualify for coverage of medical foods: (i) a permanent functional impairment of the gastrointestinal tract; (ii) ENT must be reasonable and necessary for the beneficiary; and (iii) tube feeding is required to maintain weight and strength commensurate with a beneficiary’s overall health status.

This narrow approach to coverage has shortcomings. The most significant is that Medicare does not provide coverage for medical foods that are consumed orally. When the tube fed nutrition benefit was first established, the rationale behind constraining this coverage was that if a formula could be consumed orally, then it was simply food and not a medically-required form of food. Although this benefit design was created with program integrity and cost containment in mind, it has not kept pace with scientific advancement. Such a restriction creates a situation in which innovative oral nutritional products specifically targeting the unique nutritional needs of patients with certain diseases or conditions are denied coverage, thereby undermining patient access and health outcomes. Another challenge is that Medicare does not cover enteral nutrition for patients who have a functioning gastrointestinal tract but nevertheless require tube feeding due to cognitive disorders such as anorexia or Alzheimer’s disease.

The benefits of medical foods outside the narrow scope of currently established reimbursement policies are increasingly clear. As an example, when specially-formulated medical foods are used appropriately to address specific nutritional needs in surgical patients, they have been shown, by a number of scientific meta-analyses of published papers, to reduce health care cost by improving overall patient nutrition, and thereby lowering the incidence of post-op complications, resulting in shorter hospital stays. Other demonstration projects are being planned to document that improving the nutritional support of patients discharged from hospital can reduce the likelihood of being re-admitted for the same condition, avoiding significant financial penalties being imposed on the hospital by the Affordable Care Act for failing to meet quality of care criteria. Such cost-effective, patient-centric, improvements in quality of care measurements should be encouraged and appropriate reimbursement provided, as with any

Page 3

other cost-effective treatment. That would spur further innovation in the ever-changing healthcare landscape.

In order to expand our current understanding of the role specialized nutrition can play in optimizing patient health and achieving better health outcomes, we recommend that the National Academy of Medicine convene a workshop to review how nutrition may reduce adverse patient outcomes and improve the management of diseases and conditions. The nutrition community – including scientists from academia, government, non-profits – and industry can play a key role in identifying and helping to address current data gaps on the benefits nutrition can play in overall health. This can be achieved by applying advanced analytical techniques to better characterize when nutrients, their active metabolites, or precursors are not adequately delivered to a patient with a specific disease or health condition in order to understand the impact of pathology on normal physiology.

As a leader in delivering evidence-based specialized nutrition to help improve patient care, Nestlé Health Science looks forward to working with Congress, CMS, the FDA, and other stakeholders to improve patient access to medical food products and protocols for their appropriate and necessary use to promote optimal health outcomes. Thank you again for the opportunity to provide feedback on these critical issues.

For further information, or to address any questions you may have, please feel free to contact me directly.

Sincerely,



Timothy A. Morck, PhD  
Vice President, Scientific & Regulatory Affairs  
Nestlé Corporate Affairs  
Direct: (202) 292-2925 Cell: (973) 216-6290  
[timothy.morck@us.nestle.com](mailto:timothy.morck@us.nestle.com)