Report to Congress on Medical Nutrition Therapy

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I. Introduction

This report conducts a further review of medical literature on the efficacy and effectiveness of medical nutrition therapy for certain diseases. Medical nutrition therapy (MNT) is comprised of the assessment of nutritional status and the provision of nutritional counseling by a licensed dietitian or nutritional professional. The first review of medical literature regarding MNT was conducted by the Institute of Medicine (IOM). In 2000, they published the report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly" that outlined the medical literature they found concerning the use of MNT for undernutrition, cardiovascular disease, diabetes mellitus, renal disease, and osteoporosis. IOM recommended that MNT should be covered by the Medicare program for the five conditions identified in its report; it should be provided by a dietitian or qualified nutrition professional; and that enteral and parenteral nutrition-related services continue to be a covered benefit.

When Congress made MNT provided by a qualified dietitian or nutrition professional a Medicare benefit, they selected two of the diseases reviewed in the IOM report for coverage: diabetes and renal disease, and required that DHHS make recommendations for extending coverage for nutritional assessment and counseling to other diseases. Our literature search for any articles regarding nutrition assessment and counseling was done on PubMed, a comprehensive listing of all available medical literature. In evaluating that literature, we ranked the literature from the highest, those that described randomized controlled trials to the lowest, editorials or articles based on anecdotal information. The ranking of the medical literature is based on the quality of the study using standards accepted in the scientific community and how well the findings will apply to the Medicare population.

In our current review, we found the same literature that was identified in the IOM report. Therefore, our review follows the same pattern as the IOM report. Enteral and parenteral nutrition or the types of nutrition professionals are not covered in this report, however, because the statute only directed us to make recommendations regarding MNT or nutritional assessment and counseling. We also reviewed the use of nutritional assessment and counseling in dialysis centers in response to a subsequent Congressional request.

II. Summary of Findings

We conducted an exhaustive medical literature search to determine the availability of literature about nutrition therapy for different diseases and found literature concerning the same diseases outlined in the IOM report. Cardiovascular disease is divided into hypertension, hyperlipidemia, and heart failure as it is in the IOM report. The literature for undernutrition focused almost exclusively on enteral and parenteral nutrition and was therefore, excluded from this review because the purpose of this report is to review the evidence regarding MNT. However, in response to interest from the American Dietetic Association, we did review the provision of MNT for cancer patients with undernutrition. At the request of Congress, we have included a review of nutritional assessment and counseling in dialysis centers. Our analysis and findings are based solely on the quality and amount of supportive evidence found in our medical literature search.

Our review suggests that there may be a benefit resulting from dietary modification using medical nutrition therapy for patients with hyperlipidemia and hypertension. Supportive studies were not found for patients with heart failure. We evaluated the nature of the interventions (counseling sessions) and outcomes (dietary modification and the effect on the symptoms of disease) in each of the studies. A large number of randomly controlled trials using dietitians or nutritionists demonstrated that dietary modification was effective in treating hyperlipidemia and hypertension. However, the studies were not designed to show if dietitian/nutritionist interventions were more effective than interventions provided by physicians during office visits. Two articles did state that there was evidence that dietary modification may be more successful when patients are counseled by dietitians/nutritionists (medical nutrition therapy) in addition to receiving dietary counseling routinely provided in physician office visits. We did not find supportive evidence for dietary modification in the treatment of osteoporosis or undernutrition for cancer patients in the medical literature.

Our research into the adequacy of MNT provided in renal dialysis centers found that the MNT provided in that setting was comparable to the MNT provided under the fee-for-service benefit.

The American Dietetic Association did provide comments to DHHS. They recommended that the MNT benefit be expanded (to cardiovascular disease, malnutrition, pharmacoptherapy), and that DHHS be given the authority to further expand the benefit under the national coverage determination process. They also made a recommendation regarding reimbursement for MNT which is not covered in this report.

II. Background

Section 4108 of the Balanced Budget Act of 1997 included a provision that required the Secretary of the Department of Health and Human Services (DHHS) to contract with National Academy of Sciences to examine the benefits and costs associated with

extending Medicare coverage for some preventive services including MNT. As a result of that study, the Institute of Medicine (IOM) report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly" was published in 2000. The report examined the use of MNT for managing disease in beneficiaries with undernutrition, cardiovascular disease, diabetes mellitus, renal disease, and osteoporosis. It recommended that MNT should be a reimbursable benefit for Medicare beneficiaries.

Effective January 1, 2002, Congress created a Medicare benefit for MNT for beneficiaries with diabetes or a renal disease (except for those receiving dialysis) in section 105 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act (BIPA). MNT services are defined in statute as "nutritional diagnostic, therapy, and counseling services for the purpose of disease management which are furnished by a registered dietitian or nutrition professional ... pursuant to a referral by a physician..." The benefit is further defined in CMS's final rule dated November 1, 2001 (CMS-1169-FC), as face-to-face nutritional assessments and interventions in accordance with nationally accepted dietary or nutritional protocols. (The protocols currently recognized by CMS as nationally accepted are the protocols developed by the American Dietetic Association and the National Kidney Foundation.)

Enrollment of dietitians/nutritionists as a new provider group started in December of 2001 and Medicare contractors started paying Medicare claims for MNT for diabetes and renal disease for services provided on or after January 1, 2002, the statutory effective date.

BIPA also required the Secretary of the DHHS to recommend expansions of the MNT benefit to other Medicare beneficiary populations by July 1, 2003. This report fulfills that mandate. We also have included the results of our study of the adequacy of MNT provided to dialysis patients.

III. Diseases Reviewed

A. Undernutrition

The Institute of Medicine (IOM) report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly"[1] discusses undernutrition in terms of markers and syndromes. The markers they note are:

- Weight loss and morphometric measures of undernutrition,
- Poor nutritional intake, and
- Biochemical markers of malnutrition (albumin, transferrin, retinol binding protein).[2]

[1] Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, pp. 65-92.
[2] Ibid.

The syndromes noted are:

- Body composition changes with aging or sarcopenia,
- Cachexia,
- Wasting,
- Protein-energy undernutrition, and
- Failure to thrive.[3]

All of these conditions except for poor nutritional intake are not specific for undernutrition. They are symptoms of disease states such as cancer. In this report, we will focus on undernutrition for patients with cancer.

Malnutrition may be defined as a condition caused by inadequate intake or inadequate digestion of nutrients. It is a general term that indicates a lack of some or all nutritional elements, and may occur with various conditions, especially digestive conditions, malignancies and chronic infections. Malnutrition may range from mild with no symptoms to severe with considerable detriment to health.

In cancer, diet and nutrition play important roles in prevention and the subsequent treatments. Since dietary recommendations for cancer prevention are similar to general dietary recommendations, we will focus on malnutrition and nutrition services for patients diagnosed with cancer. Since weight loss and malnutrition are fairly common in patients with cancer due to the nature of the disease and treatments, weight loss may be considered a surogate marker for malnutrition in some instances. It has been reported that "40% of cancer patients are already malnourished, before the onset of any medical or surgical treatment." [4]

As noted earlier, the 2000 Institute of Medicine (IOM) Report, "The Role of Nutrition in Maintaining Health in the Nation's Elderly written by the Institute of Medicine is used as a baseline for this report.

We define undernutrition as inadequate nutrition from any cause. Undernutrition markers include weight loss, poor nutritional intake, and biochemical markers of malnutrition (albumin, transferrin, and the reintol binding protein). The weight loss for undernutrition has varying definitions that include the amount and duration of the weight loss.[5] The IOM report uses a definition for outpatient settings of 10 pounds in 6 months, 4 to 5 percent of body weight in 1 year, or 7.5 percent of total weight in 6 months. For nursing home residents the Omnibus Budget Reconciliation Act of 1987 mandates the use of Minimum Data Set (MDS) and Resident Assessment Protocols (RAPs) to ensure prompt identification and response to problems in nursing home residents. The MDS defines undernutrition as weight loss that is greater than or equal to 5 percent of body weight in

[3] Ibid.
[4] Cohen and Lefor, 2001.
[5] Ibid.

the past month or greater than or equal to 10 percent in the last 6 months.[6] Involuntary weight loss is associated with an increased risk of mortality.[7] The report also notes however, that no randomized clinical trial data had evaluated any relationships between nutrition therapy and better health outcomes.

Poor nutritional intake is defined as average or usual intake of servings of food groups, nutrients, or energy below recommended amounts. The IOM report states that poor nutritional intake is between 66 and 75 percent of the Recommended Dietary Allowance.[8] Poor nutrient intake for patients translates into higher rates of in-hospital and 90-day mortality.[9]

As individuals age, nutritional assessment methods may be affected. Notable changes take place in body composition that also affect the nutrient requirements of older individuals. Not all changes have been shown to have a relationship with undernutrition.[10]

However, wasting is a direct result of poor dietary intake that results in weight loss.[11] Wasting is a clinically observed in patients with marasmus, cancer, advanced AIDS with opportunistic infection, critical illness without nutrition support, and chronic organ failure syndromes such as renal failure.[12] Treatment of wasting has focused on supplementing nutrient intake and drug therapy to stimulate appetite. However, the wasting and inability to accumulate lean body mass appears to be a result of the underlying disease process, not from poor dietary intake.[13] Protein-energy undernutrition or PEU is defined by conditions like wasting and by biochemical markers such as albumin. Prealbumin has been shown to be of value in predicting mortality of patients in nursing homes. Treatment of PEU has focused on improving nutritional intake but there is no evidence to support this practice.

The IOM report notes that undernutrition is very common among hospitalized and nursing home residents. However, there is no evidence that the undernutrition resulting from aging and disease processes can be effectively treated with nutrition therapy or that increased normal nutrient intake (not enteral or parenteral nutrition) would be effective

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[6] Ibid.
[7] Wallace JI, Schwarts RS, LaCroix AZ, Uhlmann RF, Pearlman RA, "Involuntary weight loss in older outpatients: Incidence and clinical significance." J Am Geriatr Soc 1995;43:329-337.
[8] Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, pp. 65-92.
[9] Sullivan, et al., "Protein-energy undernutrition among elderly hospitalized patients: A prospective study." J Am Med Assoc 1999;47:710-715.
[10] Baumgartner, et al., "Epidemiology of sarcopenia among the elderly in New Mexico." Am J Epidemiol 1998;147:755-763.
[11] Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, pp. 65-92.
[12] Roubenoff, et al., "Standardization of nomenclature of body composition in weight loss." Am J Clin Nutr 1997;66:192-1966.
[13] Institute of Medicine, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*, Washington, D.C.:National Academy Press;2000, pp. 65-92.

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