

Medical Foods — Learn How They Manage Disease and Ways to Incorporate Them in Practice

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As dietitians, we strive to offer nutrition interventions that will help our clients manage chronic medical conditions and maximize their health and well-being. Our rapidly evolving knowledge of nutrition science has allowed us to meet these goals in ways that were impossible even a few years ago. One of the most significant additions to the dietitian's arsenal of therapeutic tools has been the emergence of medical foods, nutritional products developed specifically for the dietary management of disease.

The idea of a medical food may conjure images of arcane herbal remedies or strange dietary regimens. But medical foods are specially formulated products defined and regulated by the FDA as follows¹:

- Medical foods aren't regular foods. They're orally administered dietary products formulated for the management of diseases for which specific nutritional requirements have been established.
- Medical foods aren't drugs or dietary supplements and are monitored separately by the FDA.
- All efficacy claims for medical foods must be based on recognized scientific principles and sound laboratory and clinical data.
- Medical foods must be comprised of components designated as Generally Regarded as Safe.
- Ingredients in medical foods must be listed on the product label in descending order of content.
- Medical foods may be used only under medical supervision.

This continuing education activity will provide an overview of medical foods and how they're used in the management of disease, explain the nutrition professional's role in using these products, and offer strategies on how to begin incorporating them in practice.

History and Background

The use of medical foods originated in the 1940s when formulas consisting of whey protein, carbohydrate, and lipids were administered to convalescing elderly patients in hospitals and nursing homes, according to Bruce P. Bennett, director of medical education and scientific and

regulatory affairs at Primus Pharmaceuticals in Scottsdale, Arizona (written communication, February 20, 2012). The first commercially developed medical food debuted in the late 1960s with the introduction of Lofenalac, an infant formula created by Mead Johnson to treat the inborn error of metabolism phenylketonuria (PKU).²

Medical foods were classified and managed as drugs until passage of the Orphan Drug Act of 1983, which defined them as specially formulated mixtures of nutrients and phytochemicals to be used under physician supervision. Medical foods, per Bennett, often are developed and brought to market by pharmaceutical companies, but they don't need to be approved or registered by the FDA.

Although medical foods are used only under medical supervision, patients don't need a prescription to obtain them. Many healthcare practitioners including dietitians currently use them in their practices under a physician's direction.

It's important to note that medical foods can't prevent or cure illness; they're meant only to manage the course of a disease, according to Bennett.

Medical Foods vs. Dietary Supplements and Nutraceuticals

Medical foods often are confused with dietary supplements and nutraceuticals. Each is very different and serves different purposes. Dietary supplements are intended to enhance wellness among healthy adults and consist of vitamins, minerals, and/or herbs and botanicals. Nutraceuticals are nutrients, foods, or parts of foods that provide health benefits and combat disease. Like dietary supplements and nutraceuticals, medical foods are composed of combinations of vitamins, minerals, and botanicals, but they're formulated specifically to manage nutritional deficiencies that affect disease progression. While many nutrients contained in medical foods are also commonly taken as supplements, medical foods contain specific formulations designed to improve risk factors associated with disease.

Evidence supporting the effectiveness of supplements and nutraceuticals may vary widely; there's no legal distinction between the two, and the terms often are used interchangeably. In contrast, medical foods are tested for effectiveness in clinical trials and deemed safe by panels of experts before they're brought to the marketplace.¹

Current Marketplace

Since the introduction of Lofenalac, the use of medical foods has grown steadily to include various products for the treatment of illnesses and disorders that have a nutritional association. These include chronic conditions such as diabetes, cardiovascular disease, and osteoporosis; inborn errors of metabolism; mitochondrial disease; wound healing; pain management; gastrointestinal disorders; and neurological and psychological disorders such as Alzheimer's disease and depression. Medical foods are created for both pediatric and adult use and are available in a variety of forms, including powders, liquids, capsules, tablets, and bars. They may be specialized blends of macronutrients, vitamins, minerals, phytochemicals, and botanicals or preparations composed of a single nutrient. Moreover, today's medical foods are much more palatable than the metabolic formulas of the past.

Following is a brief overview of some of the diseases and conditions for which medical foods are used and their clinical efficacy.

Inborn Errors of Metabolism

There are numerous inborn errors of metabolism that must be controlled with nutrition intervention. These include amino acid and protein metabolism disorders, which are among the most frequently encountered in the clinical setting. All require lifelong dietary management from infancy onward, with emphasis on providing adequate nutrition for growth and development. The control of these disorders focuses on minimizing or eliminating intake of specific amino acids as well as restriction of dietary protein.³

PKU is the most common amino acid metabolism disorder.³ Medical foods created to manage PKU often are used in conjunction with moderately restricted PKU diets based on reduced intakes of protein and phenylalanine.⁴ These products are predominantly composed of large neutral amino acids (LNAAs) that compete with phenylalanine and block its absorption in the gut. LNAAs include tyrosine, tryptophan, threonine, methionine, valine, isoleucine, leucine, and histidine.⁵ A typical medical food dose used to treat PKU consists of 0.41 g of protein equivalent per 1 kg of body weight.⁶

Treatment with a medical food containing LNAAs was found to significantly reduce both brain and plasma concentrations of phenylalanine among patients with PKU in a double-blind clinical study conducted in seven metabolic treatment centers in the United States, Europe, and South America.^{5,7} Although the participants didn't adhere to the phenylalanine-restricted diet, their blood phenylalanine levels declined on average by 39% after one week of treatment.⁷ These findings suggest that LNAA therapy may be beneficial in controlling PKU even when dietary compliance is poor.⁵

Medical foods also have been developed for managing other amino acid metabolism disorders, such as tyrosinemia, leucinemia, maple syrup urine disease, homocystinuria, glutaric acidemia, and urea cycle disorders. Formulated to meet the specific nutritional needs of infants, children, and adults, these products are free of the offending amino acids, supply about 30% to 40% of energy as fat, and typically are supplemented with linoleic acid, carnitine, and taurine.⁸

Metabolic Syndrome, Type 2 Diabetes, and Cardiovascular Disease

Medical foods used for managing metabolic syndrome, type 2 diabetes, and cardiovascular disease are designed to improve lipid profiles and blood sugar levels, combat insulin resistance, and support favorable changes in body composition (ie, increased lean body mass). These products generally have a low glycemic index and often contain folic acid, vitamin B6, and soy fiber, nutrients that help normalize serum homocysteine levels, a known risk factor for cardiovascular disease. In addition to these nutrients, medical foods promoting cardiometabolic health may contain formulated blends of plant sterols, dietary fiber, herbal extracts, and soy protein. They also may consist of single nutrients, such as folic acid or chromium, known to be effective in improving cardiovascular risk factors.

A randomized double-blind clinical trial demonstrated that use of a medical food containing extracts from the herb hops (*Humulus lupulus*) and the acacia plant (*Acacia nilotica*) significantly decreased serum triglyceride and insulin levels in individuals with metabolic syndrome (defined as a BMI of 25 to 42.5, hypertriglyceridemia, and fasting insulin levels greater than 71.74 pmol/L) compared with those in the placebo group.⁹ Phytochemicals present in these plant extracts (rho-iso-alpha acids and proanthocyanidins) appear to improve cardiovascular and diabetes risk factors by exerting favorable effects on lipid and glucose metabolism.⁹

Medical foods also may improve other cardiovascular risk factors. Deficiencies of the omega-3 fatty acids EPA and DHA have been implicated in an increased risk of sudden death from myocardial infarction.¹⁰ An open clinical trial that involved subjects with clinical deficiencies of omega-3 fatty acids showed marked improvement in blood levels of omega-3s after two weeks of using medical food consisting of 680 mg of EPA and 110 mg of DHA derived from fish oils four times per day.¹¹

Osteoporosis

Medical foods used to treat osteoporosis aim to return bone metabolism to a normal balance of resorption and formation to improve bone mineralization.¹² Typically, they're composed of vitamin D, zinc, and genistein, an isoflavone derived from soy that's been found to repress the activity of osteoclasts (cells responsible for bone loss) and stimulate the development of osteoblasts (cells that build bone matrix).¹² A randomized double-blind controlled clinical trial of postmenopausal women with osteoporosis found that those who received genistein in conjunction with calcium and vitamin D had significantly greater rates of bone mineralization, compared with subjects taking a placebo, calcium, and vitamin D.¹²

Mitochondrial Disorders

Mitochondrial disorders result from mutations in mitochondrial DNA and affect about one in 4,000 to 8,000 people.¹³ Mitochondrial diseases present diverse symptoms and clinical manifestations, including neurological, hematological, cardiovascular, respiratory, and autoimmune disorders, which appear early in life and are sometimes fatal. The underlying pathology often involves disturbances in creatine metabolism.¹⁴

Medical foods used to manage mitochondrial disorders are composed primarily of ubiquinol, a form of coenzyme Q10, which is found in high concentrations in mitochondria and is responsible for energy production.¹⁵ Other components include B complex vitamins, vitamin E, lipoic acid, biotin, L-carnitine, and zinc picolinate.¹⁶ This formulation has been found to increase muscle strength and exercise tolerance, inhibit free radical production, and boost glycogen, amino acid, and lipid metabolism via stimulation of mitochondrial activity.¹⁷

A randomized double-blind multicenter clinical trial investigating the safety and effectiveness of coenzyme Q10 in improving motor and neurological symptoms among children aged 12 months to 17 years with mitochondrial energy metabolism disease is under way at the University of Florida.¹⁸

Wound Healing

Healing of surgical wounds, chronic foot ulcers caused by diabetes, and pressure ulcers due to prolonged bed rest often is difficult because of increased metabolic needs and poor dietary intake. Nutrition intervention for wounds and pressure ulcers involves increasing intake of protein and energy and other nutrients known to promote healing.¹⁹

Medical foods used to treat wounds and pressure ulcers generally contain 1.2 to 1.5 g of hydrolyzed collagen protein per 1 kg of body weight, along with vitamin C, zinc, copper, and the amino acids arginine, glutamine, proline, hydroxyproline, glycine, and cystine, which are essential for tissue repair.¹⁹ Some also contain citrulline, an arginine precursor that's converted to nitric oxide in the body.²⁰ Formulas containing nitric oxide have been shown to facilitate healing by increasing the transport of oxygen and stimulating collagen synthesis at wound sites.^{20,21}

A randomized prospective controlled multicenter trial conducted among elderly residents in long-term care facilities found that the use of a collagen protein hydrolysate formula significantly increased healing of pressure ulcers when compared with those who received the placebo.²¹

Pain Management

Acute and chronic pain affects millions of Americans and can be difficult to manage. Typical treatment involves the use of nonsteroidal anti-inflammatory drugs, which may have serious adverse effects such as liver damage and renal complications, or potentially addictive narcotic drugs.^{22,23}

Research has shown that individuals experiencing chronic pain often have depressed serum levels of choline, tryptophan, arginine, glutamine, and histidine, nutrients that serve as precursors to neurotransmitters involved in the control of inflammation and pain.²⁴ Medical foods developed to alleviate pain and inflammation from disorders such as fibromyalgia, arthritis, headache, and back and joint problems contain specialized formulations of these nutrients as well as gamma-aminobutyric acid, an inhibitory neurotransmitter that slows pain response; antioxidants (gingko biloba, grapeseed extract, and cinnamon); and anti-inflammatory peptides (provided by whey protein hydrolysate). Researchers found that this formulation significantly reduced pain symptoms in a crossover study of patients with fibromyalgia, trigeminal neuralgia, back pain, headache, osteoarthritis, and tendonitis.²⁴

Gastrointestinal Disorders

Inflammatory bowel disease (Crohn's disease and ulcerative colitis), irritable bowel syndrome, and leaky gut syndrome are chronic debilitating disorders associated with pain, diarrhea, weight loss, and nutrient malabsorption.²² During acute stages, these diseases usually are treated with low-residue diets as well as corticosteroid and antibiotic therapies.²⁵

Medical foods designed to lessen the symptoms of gastrointestinal disorders contain specialized blends of soluble fibers, vitamins, minerals, amino acids, and/or hydrolyzed protein.²⁶⁻²⁸ Other ingredients may include extracts of ginger, rosemary, turmeric, hops, plantain (herbs and plants containing phytochemicals with anti-inflammatory properties), medium-chain triglycerides (MCTs), rice, and oats. Formulations with these ingredients are developed to strengthen the intestinal mucosa, lessen free radical formation, and boost the immune response.²⁵

Probiotic medical foods also are used to relieve the symptoms of gastrointestinal disease. These products are composed of select strains of beneficial bacteria (eg, *Bifidobacterium longum*, *Bifidobacterium infantis*, *Lactobacillus acidophilus*) in a formulation and potency designed to restore optimal levels of normal gut flora.²⁶

Emerging studies are providing evidence that the components of these medical foods are effective in managing the symptoms of gastrointestinal disorders.²⁷⁻²⁹ In addition, clinical trials are under way to evaluate the effectiveness of these products in easing the symptoms of ulcerative colitis and Crohn's disease.

Neurological and Psychological Disorders

Medical foods have been developed to treat various neurological and psychological disorders, including Alzheimer's disease and depression.

Alzheimer's disease is characterized by the death of brain cells due to the formation of plaques (deposits of a protein called beta amyloid) and tangles (clumps of a protein called tau) in the brain.³⁰ The accumulation of plaques and tangles is linked with the loss of cognitive ability and memory seen in Alzheimer's disease.³⁰ Two medical foods (one consisting of EPA, DHA, uridine, choline, B vitamins, vitamin E, selenium, and vitamin C; the second containing MCTs), significantly increased cognitive scores in two randomized, double-blind clinical trials involving elderly subjects with early Alzheimer's disease.^{31,32}

Folic acid deficiency has been linked with the onset of depression because of its positive effect on the biosynthesis of the neurotransmitters serotonin, dopamine, and norepinephrine.³³ A medical food consisting of methylfolate, the active form of folic acid, significantly improved symptoms of depression in a retrospective study of clients at an outpatient psychiatric clinic.³³

Insurance Reimbursement

For all the good associated with medical foods, insurance reimbursement for their use in the United States has been inconsistent. This results from several factors: Health professionals, insurance companies, and patients are unfamiliar with the use and the expense of medical foods (a medical food can exceed \$7,000 per year), and there are tighter controls on insurance claims although the rate of compensation is greater for pediatric medical foods than for adult products.³⁴

Currently, 33 states have mandated private insurance coverage of medical foods; however, the type of products covered and the amount of financial reimbursement differs significantly from state to state.³⁴ In addition, employer-provided health plans are exempt from state insurance regulations, which excludes individuals enrolled in these plans from third-party reimbursement benefits for medical foods.³⁴ As a result, patients who need a medical food that isn't covered by private insurance must pay out of pocket or seek coverage from Medicaid or Medicare, which have strict eligibility guidelines.³⁴

Medical foods have unique Healthcare Common Procedure Coding System and National Drug Code billing codes that healthcare practitioners should use when seeking reimbursement from insurance companies.³⁵ Physicians, dietitians, and other healthcare providers who send letters to insurance companies documenting the necessity for medical foods increase reimbursement for these products.³⁶ Many medical food manufacturers' websites provide these letters for consumer use.³⁵

Some federal agencies offer free or reduced-cost medical foods to eligible individuals. The WIC program provides pediatric medical foods to qualified participants.³⁷ In addition, advocacy groups such as the National Organization for Rare Disorders (NORD) work with patients to obtain coverage for medical foods, and some pharmaceutical companies provide them for free to those who aren't covered by private insurance and can't afford to pay for them.³⁴

RD's Role in Medical Food Use

The use of medical foods was once the sole territory of physicians, but RDs working in various clinical settings are now overseeing and promoting them.

Sarah Morgan, MD, MS, RD, FAND, FACP, CCD, a professor of medicine at the University of Alabama, has a unique perspective on medical foods. A physician and an RD as well as a pioneer in the use of medical foods, Morgan directs the university's Osteoporosis Prevention and Treatment Clinic, where she authorizes and monitors the medical foods patients use.

“I use medical foods often with my patients in the metabolic bone clinic,” Morgan says. “I certainly see them as a viable treatment option due to their low toxicity and the limited success of some drugs in managing disease. Many of the enteral supplements are considered to be medical foods, so RDs have a lot of opportunity to recommend medical foods in both inpatient and outpatient settings. For example, the patient educator in the clinic is a PhD/RD. She teaches a class for all new osteoporosis patients before they see the physicians and presents the medical foods we use in the clinic.”

At Tulane University in New Orleans, patients with various metabolic diseases, such as PKU, tyrosinemia, maple syrup urine disease, and acidemias are treated. Amy Cunningham, MS, LDN, RD, a metabolic dietitian at the Hayward Genetics Center at the university and a founding member of Genetic Metabolic Dietitians International (GMDI), the professional organization for metabolic nutritionists, says an interdisciplinary approach is an integral part of patient care at her center. “All of our patients are seen by each member of the clinical team, which consists of physicians, genetic counselors, and metabolic dietitians,” she says. “The medical foods chosen are based on the patients’ clinical needs, taste tolerances, and lifestyles. We use only products backed by evidence-based research. The RDs choose the formulas and write the orders, which are signed by the physicians.”

Kathleen Huntington, MS, RD, LD, chief dietitian at the Metabolic Clinic at the Oregon Health & Science University, a member of the board of directors of the GMDI, an active member of the NORD, and a key player in establishing Oregon’s reimbursement regulations for medical foods, says, “Oregon has a very good medical foods law—it covers all inborn errors of metabolism, all ages, all types of medical foods, and there are no financial caps. In addition, our medical food dispensing system is somewhat unique in Oregon. After I design the therapeutic diet and choose the medical food, then I file the product order in the medical record for physician review. The medical food is then dispensed from a centralized inventory program and billed directly to the insurance company. This helps our patients get the products they need in a timely fashion.”

Working under the auspices of her clinic’s managing physician, Sheila Dean, DSc, RD, LD, CCN, CDE, a private practitioner at the Palm Harbor Center for Health & Healing in Florida, who routinely incorporates medical foods into her patients’ care plans, sets up accounts with medical food manufacturers, orders products directly, and sells them to clients in her office, says, “Any registered dietitian can set up an account—free of charge—with pharmaceutical companies. This is a real advantage for me because I can maintain a close relationship with the reps, who keep me informed about the medical foods I recommend in my practice.”

Morgan, Cunningham, Huntington, and Dean agree that educating both patients and medical staff is essential to effectively using medical foods. Although they all have support staff to assist with patient instruction, each provides one-on-one teaching to their clients.

“I educate all my patients about the medical foods they’re using,” Dean says. “I’m ultimately responsible for understanding what nutrients, herbs, and botanicals the medical food product contains; what patient population it’s indicated for; and if there are any drug-nutrient interactions. The education can potentially be quite extensive, depending on the interest and needs of the patient. To keep on top of all of it, I follow up with each patient at least once per month.”

As might be expected, advocacy for insurance reimbursement is an ongoing concern among dietitians. “My coworkers and I often see patients from states that don’t have good medical food laws,” Huntington notes. “We spend a lot of time working with their insurance companies to get approval. The clinic RDs spend time coaching families on their appeal letters as well.”

Incorporating Medical Foods in Practice

Dietitians interested in introducing medical foods into their practices can take the following steps:

- **Learn about the medical foods that can help your patients.** Areas to focus on are protocols for use, benefits, contraindications, and potential drug and nutrient interactions.
- **Visit the FDA’s website on medical foods** at www.fda.gov/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/MedicalFoods/ucm054048.htm.
- **Get a copy of your state’s insurance medical food reimbursement policy** and become familiar with the regulations and available resources.
- **Visit the websites of medical food manufacturers.** These sites often provide useful information about reimbursement for their products.
- **Follow clinical trials evaluating the effectiveness of medical foods.** Information about federally and privately funded clinical trials can be found at <http://clinicaltrials.gov>.
- **Network with other RDs who use medical foods.** Groups such as the GMDI (www.gmdi.org) and the NORD (www.rarediseases.org) provide opportunities to share knowledge and information about medical foods.
- **Increase awareness of the benefits of medical foods** among colleagues by presenting educational in-service programs.
- **Develop relationships with pharmaceutical representatives** and meet with them regularly for product education and updates.

— *Written by Mary Franz, MS, RD, LDN, a research dietitian at Harvard University and a freelance medical and science writer.*

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Examination

1. If insurance reimbursement for a medical food has been denied to your patient, what is the appropriate plan of action?

- A. Send an appeal letter with signatures from all healthcare team members to the insurance company documenting medical necessity.
- B. Call the insurance company.
- C. Contact the manufacturer of the medical food and inquire about the availability of discounted or free medical foods.
- D. A and C

2. A medical food developed to treat inflammatory bowel disease might contain which of the following?

- A. Soluble fiber
- B. Hydrolyzed protein
- C. Turmeric
- D. All of the above

3. The FDA regulates medical foods under which law?

- A. Nutrition Labeling and Education Act
- B. Dietary Supplement Health and Education Act
- C. Orphan Drug Act
- D. Prescription Drug Marketing Act

4. An RD wants to introduce a medical food for hyperlipidemia to a patient in the cardiac rehab clinic where she works. The patient's physician is not familiar with the product and believes use of a lipid-lowering medication is sufficient. Which of the following is NOT an appropriate action for the RD to pursue:

- A. Order the food, document it in the patient's medical record, and ask the physician to sign the order.
- B. Present an inservice to the doctor and clinical staff about the medical food.
- C. Arrange an informational meeting with the medical food's product rep and the physician to discuss the product's use and benefits.
- D. Recommend use of a nutritional supplement instead.

5. A medical food used to manage phenylketonuria (PKU):

- A. can be used only when the patient is in strict dietary compliance.
- B. contains 0.8 g/kg protein equivalent.
- C. contains serine, cysteine, and aspartic acid.
- D. None of the above

6. A medical food containing the isoflavone genistein promotes which of the following physiologic effects?

- A. Increased bone resorption
- B. Increased bone mineralization
- C. Increased osteoclast activity
- D. Decreased osteoblast activity

7. Which of the following is true about medical foods?

- A. They sometimes may be substituted for prescription drugs.
- B. They always require a prescription.
- C. They can be used without medical supervision.
- D. They may contain some of the same components found in dietary supplements.

8. A medical food containing a precursor to nitric oxide would be used for which condition?

- A. Pressure ulcers
- B. Fibromyalgia
- C. Homocystinuria
- D. Aciduria

9. One of the treatment goals for managing type 2 diabetes with a medical food is to do which of the following?

- A. Restore blood glucose to normal levels
- B. Eliminate the need for oral hypoglycemic agents
- C. Reduce insulin resistance
- D. Allow the patient to eat more carbohydrate

10. Clinical trials investigating the efficacy of medical foods in Alzheimer's disease management have found which of the following?

- A. Significant improvement in cognitive scores
- B. Reversal of dementia symptoms
- C. Increased long-term memory
- D. All of the above