Optum

Dietary supplements and their role in injury recovery

September 4, 2024

Questions about continuing education credits

- If you have any questions regarding your continuing education credits received from Optum webinars, please contact rosters@ceuinstitute.net.
- CE credits are only available for those who qualify during the live version of this webinar held on 09/04/2024 from 2:00-3:00 p.m. ET.

This course has been approved for 1-hour of CE for the following license types: Pre-approved Adjuster (AK, AL, AR, CA, DE, FL, GA, ID, IN, KY, LA, MS, NC, NH, NM, NV, OK, OR, TX, UT, WV, WY); National Certified Case Manager (CCM); National Nurse; Certified Disability Management Specialists (CDMS); and Certified Rehabilitation Counselor (CRC). For states that do not require prior approval, the adjuster is responsible for submitting their attendance certificate to the appropriate state agency to determine if continuing education credits can be applied.

This course has NOT been approved for Certified Medicare Secondary Payer (CMSP) credits.

Optum

Disclosure

No planner, presenter or content expert has a conflicting interest affecting the delivery of this continuing education activity. Optum does not receive any commercial advantage nor financial remittance through the provided continuing education activities.

Medical disclaimer

Medicine is an ever-changing science. As new research and clinical experience broaden our knowledge, new treatment options and approaches are developed. The authors have checked with sources believed to be reliable in their efforts to provide information that is complete and generally in accord with the standards accepted at time of publication.

However, in view of the possibility of human error or changes in medical sciences, neither Optum nor any other party involved in the preparation or publication of this work warrants the information contained herein is in every respect accurate or complete and are not responsible for errors or omissions or for the results obtained from the use of such information. Readers are encouraged to confirm the information contained herein with other sources.

This educational activity may contain discussion of published and/or investigational uses of agents that are not approved by the Food and Drug Administration (FDA). We do not promote the use of any agent outside of approved labeling. Statements made in this presentation have not been evaluated by the FDA.

Disclaimer

The display or graphic representation of any product or description of any product or service within this presentation shall not be construed as an endorsement of that product by the presenter or any accrediting body. Rather, from time to time, it may facilitate the learning process to include/use such products or services as a teaching example.

Accreditation of this continuing education activity refers to recognition of the educational activity only and does not imply endorsement or approval of those products and/or services by any accrediting body.

CE credits for this course are administered by the CEU Institute. If you have any issues or questions regarding your credits, please contact rosters@ceuinstitute.net.

Presenters

Tron Emptage, BS Pharm, MA, RPh
Chief Clinical Officer

Tania Smiley, BS Pharm, RPh
Clinical Pharmacist, Clinical Services

Optum

Learning objectives

- Define and review what a dietary supplement is
- Define and review medical foods
- Discuss use of nutrition and medical foods post-injury and post-surgery
- Review commonly discussed supplements and/or conditions and their place in therapy

OTC meds

Over the counter (OTC) drugs are medications sold directly to a consumer without a requirement for a prescription from a healthcare professional, as opposed to prescription drugs, which may be supplied only to consumers possessing a valid prescription.

There are over 80 non-prescription (OTC) drug classes like:

- Laxatives
- Antacids
- Antidiarrheal
- Cough medications

Regulation

To market an OTC drug product in the United States, the manufacturer may follow one of two pathways.

A manufacturer can either (1) submit a new drug application (NDA) for approval, to the Food and Drug Administration (FDA) or (2) use the OTC drug monograph process.

Both the NDA and monograph pathways involve a scientific decision by FDA; however, the two mechanisms are different.

NDA process
Approval of an NDA results in the approval to sell a specific finished drug product.

OTC monograph process
Focuses on the safety and effectiveness of one or more active ingredients within a drug category.

Optum

Dietary supplements

What is a dietary supplement?

- It is intended to supplement the diet.
- It contains one or more dietary ingredients (including vitamins, minerals, herbs or other botanicals, amino acids, and other substances) or their constituents.
- It is intended to be taken by mouth as a tablet, capsule, or liquid.
- It is labeled (clearly, on the front of the container) as being a dietary supplement.

Are dietary supplements different from foods and drugs?

- Dietary supplements are regulated by the FDA as foods.
- Intended use is the differentiator between the classification of a dietary supplement, conventional food, or drug.

Regulation of dietary supplements

- Ingredients sold prior to October 15, 1994 are not required to be reviewed by the FDA.
- For a new dietary ingredient, the manufacturer must notify the FDA of its intent to market a dietary supplement containing the new dietary ingredient.
- FDA may refuse to allow new ingredients or remove existing ingredients from the marketplace.
- Difference between dietary supplements and drug products:
  - Dietary supplements – FDA has to prove that the product is not safe prior to removal from the market.
  - Drug products – Manufacturers must obtain FDA approval before being allowed to market a drug product.

Optum

Claims that manufacturers make for dietary supplements and drugs

Drug manufacturers may claim:

- Diagnose
- Cure
- Mitigate
- Treat
- Prevent

Label of a dietary supplement or food product may contain one of three types of claims:

- Health claim
- Nutrient content claim
- Structure/function claim

Optum

Required labeling

General Information

- Product name
- Net quantity
- Name and place of business of manufacturer, packer, or distributor
- Directions for use

Supplement Facts Panel

- Serving size, list of dietary ingredients, amount per serving size (by weight)
- If botanical – scientific name of the plant or the common or usual name
- If a proprietary blend, the total weight of the blend and the components of the blend

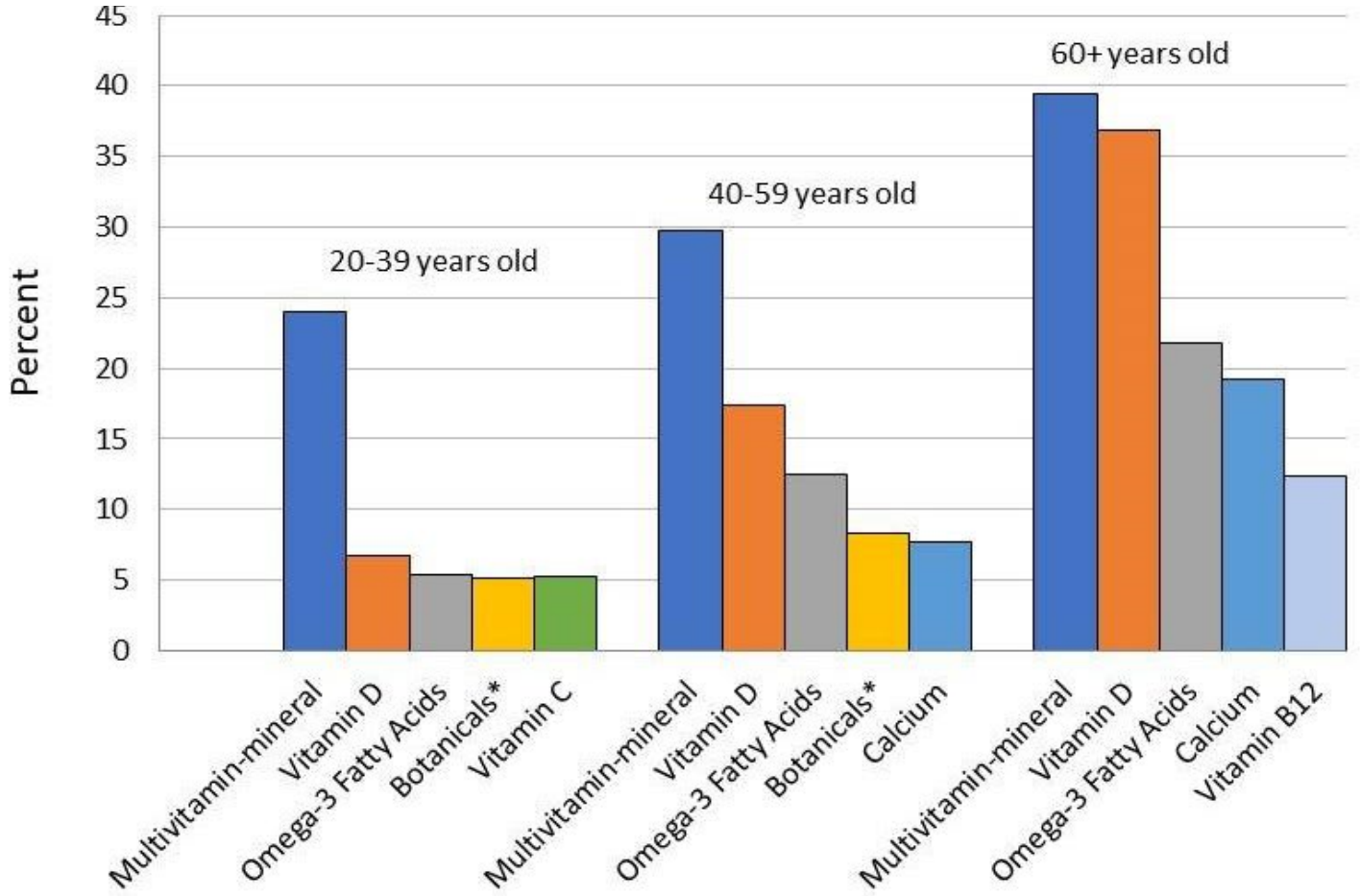
The label of the supplement may contain a cautionary statement but the lack of a cautionary statement does not mean that no adverse effects are associated with the product.

Optum

Quality, standardization, and safety

- Quality control depends on the manufacturer, the supplier, and others in the production process.
- Manufacturers are expected to guarantee the identity, purity, strength, and composition of their dietary supplements.
- Dietary supplements **are not required** to be standardized in the U.S.; therefore, standardization may mean many different things.
- Dietary supplements are not required by federal law to be tested for safety and effectiveness prior to marketing.

Most common types of dietary supplements used by adults in the US, 2017-2018



Statistics

- Among adults 20 years or older in the US from 2017-2018, nearly 60% reported using a dietary supplement in the previous month.
- Females tend to use more supplements than males and overall dietary supplement use increases with age.
- Females 60 years or older are among the greatest users of dietary supplements.
- In 2020, supplement sales in the US surpassed ten million dollars for the first time.

Medical foods

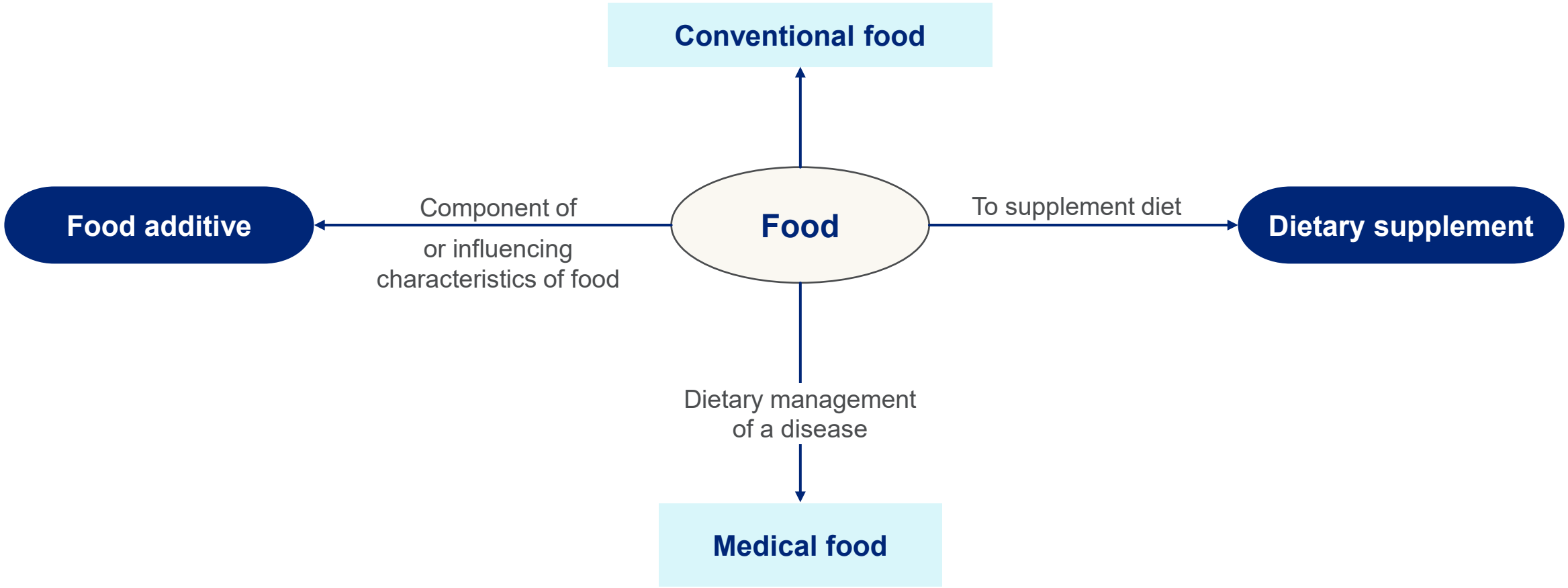
General description of foodstuffs

Term	General description
Nutraceuticals	Food bioactives, functional foods or supplements, dietary natural product or its ingredients with biofunctionality
Functional food	Naturally occurring foods with biofunctionalities, modified foods (fortified, enriched, or enhanced whole foods) or ingredients
Dietary supplement	Orally consumed products consisting of dietary ingredients, such as multi-vitamins, minerals, amino acids, peptides, herbal extracts
Fortified food	Conventional foods enriched with biofunctional ingredients, such as vitamins and/or minerals
Enriched food	Conventional foods enriched with functional ingredients existing in the original foods
Medical food	Foods formulated and consumed enterally under medical supervision of physicians and intended for the dietary management of a disease or condition

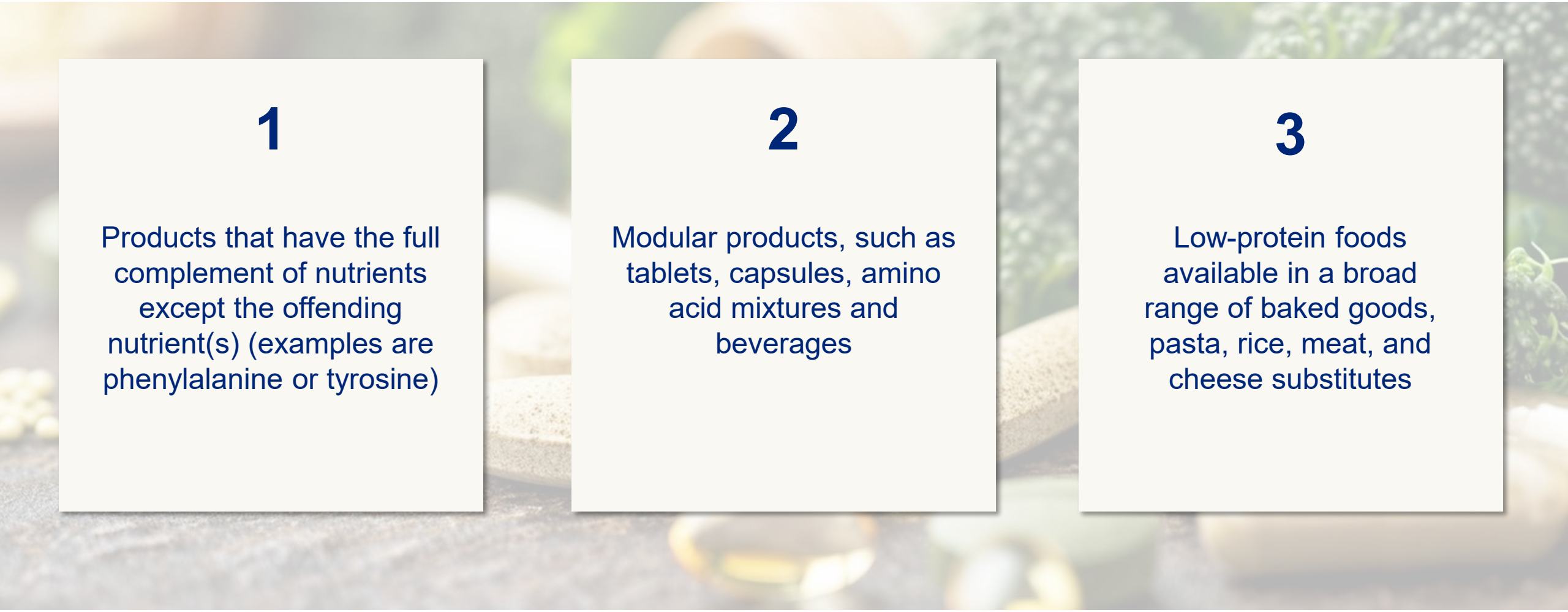
What is a medical food?

- According to the FDA, “a food which is formulated to be consumed or administered enterally under the supervision of a physician and which is intended for the specific dietary management of a disease or condition for which distinctive nutritional requirements, based on recognized scientific principles, are established by medical evaluation.”
- Patients may suffer from nutrient deficiencies as a result of genetic conditions, chronic conditions, and/or adverse effects from drug treatment.

Types of foods



Three general categories of medical foods



1

Products that have the full complement of nutrients except the offending nutrient(s) (examples are phenylalanine or tyrosine)

2

Modular products, such as tablets, capsules, amino acid mixtures and beverages

3

Low-protein foods available in a broad range of baked goods, pasta, rice, meat, and cheese substitutes

Optum

Examples of medical foods

Lipisorb	Nutritional management of AIDS patients with fat malabsorption
Carb Zero	Use in the ketogenic diet or in the dietary management of other conditions requiring a source of long-chain triglycerides
Ketonex-2	Nutrition support of children and adults with maple syrup urine disease
Limbrel	Clinical dietary management of the metabolic processes associated with osteoarthritis
Foltx	For the distinct nutritional requirements of individuals under a physician's treatment for hyperhomocysteinemia, homocystinuria, or nutrient malabsorption; with particular emphasis for individuals with or at risk for: cardiovascular disease, peripheral vascular disease, arteriosclerotic vascular disease, and vitamin B12 deficiency
Nepro	For people on dialysis with specific nutrient needs and altered metabolism
Oxepa	For the dietary management of critically ill patients with lung injury

Medical food and nutritional supplement use post-injury and post-surgery

Medical food uses post-surgery

Medical nutrition is a critical part of the recovery process. Prescribed under medical supervision, medical nutrition products provide the body with nutrients when normal food is not possible or efficient. They can be medical foods such as bars or drinks that provide extra nutrients in an easy-to-eat form.

.

Optum

Nutritional supplement uses post-injury

Injuries are a normal and expected part of exercise participation. Regardless of severity, injuries typically result in short- or long-term removal from participation.

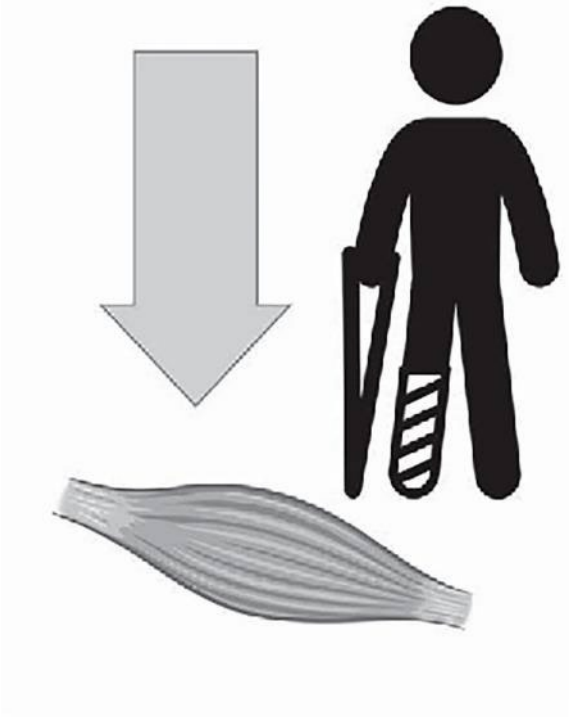
The initial healing stage that occurs immediately after trauma involves an inflammatory response and may last from a few hours to several days, depending on the nature of the injury.

This inflammatory response is essential to initiate optimal healing; as a result, nutritional interventions intended to control inflammation in this acute phase may be contraindicated for optimal healing.

Key concerns in injury and immobilization

Concerns

- Muscle atrophy
- Reduced muscle protein synthesis
- Development of anabolic resistance
- Proteolysis
- Loss of strength



Nutritional targets

- Calories
- Protein/amino acids
- Carbohydrates
- Fatty acids
- Supplements
  - Creatine monohydrates
  - HMB
  - Fish oil/omega-3
  - Vitamin D
  - Probiotics
  - Multivitamin

Nutritional supplement uses post-surgery

Recent studies have led to rekindled efforts to introduce the roles of specific immunonutrients, and we now have a better understanding of the role of nutrients such as arginine, which becomes essential in certain clinical situations such as for the trauma patient or patients at high risk for malnutrition.

Immunonutrition in its current formulation usually includes supplementation with arginine, glutamine, omega-3 fatty acids, vitamins, and trace minerals, and its use has often been associated with decreased infectious complications and sometimes with improvements in wound healing.

Optum

What nutrients are considered immunonutrition?

Amino Acids

Essential amino acids are: histidine, isoleucine, leucine, lysine, methionine, phenylalanine, threonine, tryptophan, and valine.

Foods high in amino acids are quinoa, turkey, cottage cheese, eggs, mushrooms, fish, and legumes.

Antioxidants

Vitamin C, vitamin E, flavonoids, curcuminoids (found in turmeric), and oleocanthal (found in olive oil).

Foods high in antioxidants are kale, blueberries, dark chocolate, Gogi berries, artichokes, and pecans.

Omega 3 Polyunsaturated Fatty Acids

Eicosapentaenoic acid (EPA), alpha-linolenic acid (ALA), docosahexaenoic acid (DHA), omega-3, omega-6, and omega-9 fatty acids are all essential dietary fats.

Foods like fatty fish, eggs, flax seeds, soybeans, and walnuts are high in omegas.

Dietary supplements and their place in therapy

Supplements for specific purposes

Condition	Supplements*
Alzheimer's Disease	Fish Oil/Omega-3s, Ginkgo, B-vitamins, Curcumin, Melatonin
Exercise and athletic performance	Antioxidants, arginine, beet juice, beta-alanine, HMB, branched chain amino acids, caffeine, creatine, DHEA, ginseng, glutamine, iron, protein, ribose, sodium bicarbonate
Eye Conditions	Selenium, vitamin E, antioxidants, zinc, omega-3s beta-carotene
Diabetes	Alpha-lipoic acid, berberine, chromium, apple cider vinegar, magnesium, omega-3s, selenium, vitamins
Immune function	Vitamins A, B6, B12, C, D, E, K; minerals – folate, copper, iodine, iron, magnesium, selenium, zinc; botanicals – echinacea, elderberry, garlic, ginseng
Osteoarthritis	Glucosamine and chondroitin, DMSO and MSM, SAMe, oral herbal remedies, topical herbal remedies

*studied in recent years

Optum

Vitamins and their uses

Vitamin	Main Functions
Vitamin A	Helps the body's immune system work properly; helps vision in dim light; maintains skin health
Vitamin C	Protects and maintains cell health; facilitates wound healing; maintains healthy bone, skin, blood vessels and cartilage
Vitamin D	Regulates the amount of calcium and phosphate in the body
Vitamin E	Maintains healthy skin and eyes; strengthens the immune system
Riboflavin (B2)	Maintains health of the skin, eyes, and nervous system; helps the body release energy from food

B-group vitamins

B-group vitamins are essential to the body's stress response. Vitamin B1, B2, B3, B6 and B12 help to maintain a healthy nervous system that allows the body to effectively fight the symptoms of stress. Other B vitamins are needed for energy production to aid the body's stress response.

Kubala, Jillian. “B-Complex Vitamins.” *Healthline*, Healthline Media, 21 Apr. 2023, www.healthline.com/nutrition/vitamin-b-complex.

Minerals and their uses

Mineral	Main Functions
Calcium	Helps build bones; regulates muscle contractions (including heartbeat)
Fluoride	Helps prevent tooth decay and maintains bone strength
Iron	Important in the production of red blood cells, which carry oxygen throughout the body
Potassium	Helps control the balance of fluids in the body; helps the heart work properly
Sodium	Needed to keep the level of fluids in the body balanced

Top selling herbal supplements

Supplement	Promoted use
Apple cider vinegar	Weight loss, regulation of blood sugar, blood pressure, digestive health, immune support, skin care
Ashwagandha	Anti-inflammatory, neuroprotection, sleep induction, anxiolytic
Echinacea	Preventing the common cold
Elderberry	Support immune health
Tumeric	Osteoarthritis, rheumatoid arthritis

Cranberry

- Historically used for bladder, stomach, and liver disorders, as well as diabetes, wounds and other conditions
- Today, cranberry is commonly promoted for urinary tract infections (UTIs)
- Studies in people who are at increased risk for UTIs or those who have had recurrent UTIs show that cranberry products decrease the risk of UTIs by about one-third
- Studies in certain populations at increased risk of UTIs have had inconsistent results or have not been found to be beneficial at all
  - Elderly people in long-term care
  - Pregnant women studies
  - Multiple sclerosis patients

In 2020, the U.S. Food and Drug Administration announced that it would permit manufacturers to claim on product labels that there is “limited” evidence that daily consumption of specified amounts of cranberry dietary supplements may reduce the risk of recurrent UTI in healthy women who have had a UTI.

Magnesium – “the miracle mineral”

- Magnesium does play a key role in processes such as bone development, blood pressure regulation, regulation of muscle and nerve function, and regulation of blood sugar levels
- Magnesium can be recommended for hypomagnesemia
- Magnesium is an old “standby” for constipation or heartburn
- Conditions patients ask about
  - Migraine
  - Leg cramps
  - Insomnia

Magnesium absorption varies on the source, available stores in the body, and intake

Optum

Summary

- Dietary supplements and medical foods are reviewed and approved in a different manner than prescription medications/drugs
- The types of claims that can be made by the manufacturers of dietary supplements and medical foods also differ from medications – legally
- Some products are commonly seen post-injury (typically for catastrophic claims); however, others may be more challenging to “tie” to the injury, and it is important to assess what products are reasonable for a given injury
- Use available resources – literature, clinicians – to answer questions

References

Center for Drug Evaluation and Research (no date) *OTC drug review process: OTC drug monographs,* U.S. Food and Drug Administration. Available at: https://www.fda.gov/drugs/otc-drug-review-process-otc-drug-monographs (Accessed: 23 January 2024).

(No date a) *Frequently asked questions about medical foods; third edition*. Available at: https://www.fda.gov/media/97726/download (Accessed: 23 January 2024).

Understanding Medical Foods under FDA regulations - Venable. Available at: https://www.venable.com/files/Publication/9fcd4938-922e-48e3-a1f1-9b7cb84543d9/Preview/PublicationAttachment/01120516-562f-4cfe-af40-a9dc75119bdf/Understanding_Medical_Foods_under_FDA_Regulations.pdf (Accessed: 23 January 2024).

Office of dietary supplements - dietary supplements: What you need to know (no date) NIH Office of Dietary Supplements. Available at: https://ods.od.nih.gov/factsheets/WYNTK-Consumer/ (Accessed: 23 January 2024).

Vitamins and minerals (2023) The Nutrition Source. Available at: https://www.hsph.harvard.edu/nutritionsource/vitamins/ (Accessed: 23 January 2024).

International over counter OTC medicines regulators forum. Available at: https://www.tga.gov.au/sites/default/files/international-over-counter-otc-medicines-regulators-forum-2017-usa.pdf (Accessed: 25 January 2024).

References

Long SJ, Benton D. Effects of vitamin and mineral supplementation on stress, mild psychiatric symptoms, and mood in nonclinical samples: a meta-analysis. Psychosom Med. 2013 Feb;75(2):144-53. doi: 10.1097/PSY.0b013e31827d5fbd. Epub 2013 Jan 29. PMID: 23362497.

Chow O, Barbul A. Immunonutrition: Role in Wound Healing and Tissue Regeneration. Adv Wound Care (New Rochelle). 2014 Jan 1;3(1):46-53. doi: 10.1089/wound.2012.0415. PMID: 24761344; PMCID: PMC3900114.

Rask DMG, Puntel MR, Patzkowski JC, Patzkowski MS. Multivitamin Use in Enhanced Recovery After Surgery Protocols: A Cost Analysis. Mil Med. 2021 Aug 28;186(9-10):e1024-e1028. doi: 10.1093/milmed/usaa505. PMID: 33242075.

Holmes JL, Biella A, Morck T, Rostorfer J, Schneeman B. Medical Foods: Science, Regulation, and Practical Aspects. Summary of a Workshop. Curr Dev Nutr. 2021 Jan 1;5(Suppl 1):nzaa172. doi: 10.1093/cdn/nzaa172. PMID: 33409445; PMCID: PMC7775186.

Chmielecki K, Dockter B, Johnson W, Jurch M, Pacht P, Rostorfer J. What is a "Distinctive Nutritional Requirement"? A Position Paper of the Healthcare Nutrition Council. Curr Dev Nutr. 2023 Oct 7;7(11):102013. doi: 10.1016/j.cdnut.2023.102013. PMID: 37954136; PMCID: PMC10637874.

References

Sarris J, Mehta B, Óvári V, Ferreres Giménez I. Potential mental and physical benefits of supplementation with a high-dose, B-complex multivitamin/mineral supplement: What is the evidence? Nutr Hosp. 2021 Dec 9;38(6):1277-1286. English. doi: 10.20960/nh.03631. PMID: 34530623.

Li, Shiming, et al. “Medical Foods in USA at a glance.” *Journal of Future Foods*, vol. 1, no. 2, Dec. 2021, pp. 141–145, https://doi.org/10.1016/j.jfutfo.2022.01.003.

“Oxepa®.” *Abbott Nutrition Ireland*, www.abbottnutrition.ie/products/oxepa. (Accessed 3 Feb. 2024).

“Perative.” *CWI Medical*, www.cwimedical.com/ready-to-feed/perative-perat#tab_1. (Accessed 3 Feb. 2024).

Optum

Thank you

About Optum Workers' Compensation and Auto No-Fault Solutions

Optum Workers' Compensation and Auto No-Fault Solutions collaborates with our clients to lower costs while improving health outcomes for the injured persons we serve. Our programs include pharmacy, ancillary, medical bill review, and PPO network solutions, and combine data, analytics, and extensive clinical expertise with innovative technology so injured persons receive safe, appropriate, and cost-effective care throughout the lifecycle of a claim. For more information, email us at expectmore@optum.com.