

Support the Medical Foods & Formulas Access Act of 2025 (S. 3304/H.R. 5684)



The **Healthcare Nutrition Council (HNC)** is an association representing manufacturers of enteral nutrition (EN) formulas and oral nutrition supplements (ONS), including those categorized as medically necessary nutrition, and parenteral nutrition (PN).

What is MFFA?

Medical Foods & Formulas Access Act of 2025 (MFFAA) would expand coverage for medically necessary food, vitamins, individual amino acids, and related equipment and supplies under Medicare, Medicaid, CHIP, and the Federal Employees Health Benefits Program (FEHB) for individuals with digestive and inherited metabolic disorders. The bill builds on Congress's previous action to improve access to medical nutrition for military families enrolled in TRICARE and helps ensure consistent coverage across federal health programs.

MFFAA is limited to vitamins, individual amino acids, and medically necessary nutrition for the management of certain digestive and metabolic disorders and conditions:

Inherited metabolic disorders

Medical and surgical conditions of malabsorption

Immunoglobulin E and non-Immunoglobulin E-mediated allergies to food proteins

Inflammatory or immune mediated conditions of the alimentary tract (i.e. inflammatory bowel disease, Crohn's disease)

Any other disease or condition determined appropriate by the Secretary in consultation with appropriate scientific entities



Coverage of medically necessary foods today

Health insurance coverage for medically necessary foods varies across the United States. Typically, insurance companies will cover drugs or biologics, which are better known therapeutic categories, but medically necessary foods are not covered. In some cases, such as with PKU, the approved drugs are covered, but some insurers will not cover the medical foods for the same condition, even where medically necessary foods are recognized as a primary therapy. Individuals with PKU rely on more than 80% of their diet from medically necessary foods. Even when an insurance company does cover medically necessary foods, it often comes with the stipulation that the formula be administered through a feeding tube (for example, a nasogastric tube, placed through the nose into the stomach or a gastrostomy tube, surgically placed directly into the stomach; and coverage is denied if consumed through a bottle).

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Why support MNEA?

- MNEA will close gaps in health insurance coverage of medically necessary nutrition not covered by state laws.
- Infants, children, and adults use these specialized foods to help reduce their risks of developing adverse health consequences such as hospitalization, inadequate growth, nutrient deficiencies, permanent cognitive impairment, and even death.
- Pharmaceuticals to treat a condition that are covered by insurance companies are costly and may not be recommended by the treating physician as first-line therapy. In contrast, specialized formulas, when administered under a physician's order, are life-saving treatments with lower costs and fewer risks.
- The bill recognizes research showing specialized foods are medically necessary for safe and effective management of certain digestive diseases and inherited metabolic disorders that impact the digestion, absorption, and/or metabolism of nutrients.
- Passage of the bill will help patients access the products they need.

Who will MFFAA help?

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