



## **COVERAGE OF SPECIALIZED FORMULAS AND FOODS FOR GI CONDITIONS & INHERITED METABOLIC DISORDERS SAVES LIVES & COSTS**

Thousands of children and adults in our country live with digestive (i.e. gastrointestinal, liver or pancreatic disease) or inherited metabolic disorders (IMDs) that inhibit their bodies from digesting or metabolizing typical foods. When these conditions are left untreated, patients suffer avoidable medical complications. Risks in pediatric populations with these conditions are particularly profound and when medically-necessary nutrition is delayed or cannot be obtained the results are often severe: inadequate growth, abnormal development, cognitive impairment, and behavioral disorders. Specialized medical nutrition is standard-of-care therapy for these patients and is necessary to prevent debilitating, costly, and potentially fatal outcomes.

Medically-necessary nutrition typically must be ordered through a pharmacy or durable medical equipment company (DME); formula, even for an infant, can run \$1500/month and low-protein modified foods are 4-5 times the cost of “normal” food. These costs put significant strain on individuals and families in the best of times. The formula shortages in 2022 had a profound impact on affected children and adults and underscore the essential nature of specialized formulas.

**Policy changes are needed to give these patients access to these critical treatments.  
Please cosponsor the bipartisan *Medical Foods and Formulas Access Act of 2025*  
introduced by Sens. Wicker, Klobuchar, Grassley and Whitehouse and  
Reps. McGovern, Rutherford and Dingell.**

### **INSURANCE COMPANIES DO NOT GENERALLY COVER MEDICALLY-NECESSARY NUTRITION**

- Insurance companies, both public and private, will typically cover pharmaceuticals or biologics to treat a digestive or metabolic condition. These treatments can be hundreds of times more costly than medical nutrition and can have undesirable risks such as suppression of the immune system, which can increase a patient’s risk of infection and certain cancers. Patient exposure to these risks can be compounded because many of these treatments begin in childhood and must be continued long-term or even lifelong.
- Even when an insurance company does cover medically-necessary nutrition, it often comes with the arbitrary stipulation the formula be administered through a nasogastric tube (a tube placed in the nose and into the stomach) or through a gastrostomy tube (a surgically placed tube directly in the patient’s stomach), which is expensive and carries additional risks. Specialized formulas, when administered orally under a physician’s order, are life-saving treatments with lower costs and fewer risks.

### **STATE LAWS ARE INSUFFICIENT: TOO MANY PATIENTS STILL FALL THROUGH THE CRACKS**

Most states have implemented some level of protection for patients who rely on medical nutrition in state-run programs or state-regulated private insurance. The fact that so many states have passed legislation on this issue demonstrates its importance. Unfortunately, state laws vary considerably: they regularly eliminate coverage for affected individuals on the basis of age, gender, income, insurance type, disorder, and treatment delivery method (oral versus g-tube or ng-tube).

### **CONSIDER THE FOLLOWING SCENARIOS THAT SHOW HOW CURRENT COVERAGES POLICIES FAIL PATIENTS:**

- An eight-month old in fragile health with a liver defect needs to gain weight to survive an upcoming liver transplant. Insurance will only cover the \$450/month cost of his required formula if it’s delivered via g-tube when he could consume it orally. He is therefore subjected to an additional, invasive, and unnecessary procedure to satisfy his insurance carrier.
- Disorders are added to Newborn Screening’s Recommended Uniform Screening Panel (RUSP) only if treatment is available for the disorder. While up to 60% of newborns with NBS-identified inherited metabolic

disorders are eligible for Medicaid, many states' programs do not cover medical or low-protein-modified foods, which are 4-5x the cost of standard nutrition, undermining the premise and promise of Newborn Screening.

- A woman with PKU who becomes pregnant and cannot obtain adequate medically-necessary nutrition risks fetal brain damage, heart malformation, microcephaly and pre-term mortality. Her state, like many others, cuts off insurance coverage at an arbitrary age, despite the fact that these disorders are genetic, and lifelong, discriminating against her as a woman.
- A child with Crohn's disease—a lifelong illness—can be effectively treated with enteral therapy or nutritional formulas. Although enteral therapy will result in few or no side effects, the child's insurance company will only cover a biologic medication which is more expensive when factoring the cost of induction, infusion center, and nursing costs, and which carries the risk of medical complications, including suppression of the immune system.

### **THERE IS PRECEDENT FOR THIS LEGISLATION, BUT IT DOESN'T GO FAR ENOUGH**

- In December 2016, Congress passed legislation that improved coverage for medical nutrition for military families enrolled in TRICARE. Prior to the passage of the new statute, TRICARE medical nutrition coverage policies were inconsistently applied and fell short of meeting the needs of TRICARE beneficiaries.
- As of 2023, the Federal Employee Health Benefit Program (FEHBP) covers medical food for IMD regardless of age.
- The *Consolidated Appropriations Act, 2023* recognized medical foods, including the types of medically necessary nutrition covered under the *Medical Foods and Formulas Access Act*, as “critical food.”

### **THE MEDICAL FOODS AND FORMULAS ACCESS ACT CLOSES CRITICAL COVERAGE GAPS**

- The *Medical Foods and Formulas Access Act* would require coverage of medically necessary foods and formulas as treatment under Medicare, Medicaid, CHIP and the FEHBP.
- The legislation is narrowly drafted to ensure it only covers patients for whom the physician- prescribed or - ordered medically necessary nutrition constitutes the treatment.
- Recognizing the importance of understanding the costs of implementing this legislation, the Patients and Providers for Medical Nutrition Equity Coalition commissioned an independent firm to complete a cost analysis of the legislation. The conservative cost projection for Medicare and the Medicaid federal contribution was \$128.3 million per year to improve access to medically necessary nutrition for these vulnerable patient populations.

**You have the power to provide a lifeline to your constituents**

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**with digestive and metabolic disorders.**

Contact the following offices to co-sponsor the *Medical Foods and Formulas Access Act*.

Rep. McGovern — [Isabella.Edo@mail.house.gov](mailto:Isabella.Edo@mail.house.gov)  
Rep. Rutherford — [Kevin.Alkinburg@mail.house.gov](mailto:Kevin.Alkinburg@mail.house.gov)  
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