



# COVERAGE OF MEDICAL FOODS FOR INHERITED METABOLIC DISORDERS (IMD) AND GI CONDITIONS CAN SAVE LIVES & COSTS

Thousands of children and adults in our country live with digestive (i.e. gastrointestinal, liver or pancreatic disease) or inherited metabolic disorders (IMD) that inhibit their bodies from digesting or metabolizing typical foods. When these conditions are left untreated, food can become toxic or the body can fail to absorb necessary nutrients. These individuals must rely on medically-necessary nutrition, such as highly specialized formulas, as a treatment for their condition and to maintain growth and health.

Without medically-necessary nutrition, individuals risk unnecessary surgery and repeated hospitalizations, intellectual disability or even death. Risks in pediatric populations 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. While these costs put significant strain on individuals and families in the best of times, the burden worsened during the COVID-19 pandemic. *The ongoing formula shortages that began in 2022 have had a profound impact on affected children & adults, and highlight the essential nature of medical nutrition.*

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

- Insurance companies will typically cover pharmaceuticals or biologics for treatment of 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. For example, a gastrostomy tube can leak, cause ulcerations, or a patient may experience infection at the insertion site. In severe cases, some patients with feeding tubes experience a perforation in the intestinal tract. In contrast, 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).

*Furthermore, the majority of Americans get their health coverage through federally-regulated insurance plans or programs that are not subjected to state benefit mandates. As a result of varied, ambiguous—or in some cases non-existent—state-based coverage, many patients still face obstacles when trying to access-medically necessary nutrition, even in states that have passed comprehensive laws.*

*(continued on reverse)*

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

- A patient with PKU lives in a state with medical nutrition coverage but is insured under his employer's plan in another state without coverage. This patient has no coverage for his metabolic formula, which he needs to survive. A young child with PKU who lives in a state with full coverage for metabolic formula & low-protein foods but is insured under a self-insured plan has no guaranteed coverage due to the ERISA exception.
- 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 now covers medical food for IMD regardless of age.
- The Biden Administration's National Strategy on Hunger, Nutrition, and Health stated that “the Administration also recognizes that for children and adults with digestive and inherited metabolic disorders, ensuring access to the right types of nutritional supports, such as infant formula, can prevent hospitalizations and be lifesaving. Still, there are often systematic barriers making access to these specialized nutritional supports challenging. CMS will evaluate coding, payment and administrative requirements in order to support access to nutritional supports for individuals with digestive and inherited metabolic disorders.”
- The Consolidated Appropriations Act, 2023 recognized medically-necessary nutrition as a “critical food,” and CMS accepted comments in January 2023 on the question of whether medically-necessary nutrition should be considered an essential health benefit.

## **THE MEDICAL NUTRITION EQUITY ACT WOULD CLOSE THE GAPS**

- The Medical Nutrition Equity Act would ensure both public and private insurance cover medically necessary foods as a treatment option, which are required to support proper growth and development and to prevent medical complications, severe disabilities and death.
- 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 PPMNE Coalition commissioned an independent firm to complete a cost analysis of the legislation. The conservative cost estimate was \$132 million per year to improve access to medically necessary nutrition for this vulnerable patient population. The bill champions have also requested a Congressional Budget Office cost estimate.

**You Have the Power to Provide a Lifeline to Your Constituents  
with Rare Digestive and Metabolic Conditions.  
#EquityRequiresAccess**

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Please contact the offices of Representative McGovern, Senator Casey, or Senator Ernst to co-sponsor the MNEA in 2023.  
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