March 12, 2026

Mehmet Oz, MD
Administrator
Centers for Medicare and Medicaid Services
7500 Security
Boulevard, Baltimore, MD 21244

Submitted via regulations.gov

Re: CMS–9883–P; Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2027; and Basic Health Program

Dear Administrator Oz:

The undersigned organizations representing patients and providers appreciate the opportunity to respond to the Agency's proposed rule "Patient Protection and Affordable Care Act, HHS Notice of Benefit and Payment Parameters for 2027; and Basic Health Program" as published in the *Federal Register* on February 11, 2026.

Our organizations are united in efforts to improve access to and coverage for specialized formulas and medical foods —which we broadly classify as medically-necessary nutrition — for individuals with gastrointestinal (GI) and inherited metabolic disorders. For patients with these disorders, medically-necessary nutrition is essential. We are therefore deeply concerned with the Agency's proposal to revise current regulations such that any state-required benefits would be considered "in addition to" essential health benefits (EHBs), and, thus, not an EHB, even if those benefits have been embedded in a state's EHB-benchmark plan. This change would apply to any benefits required by a state action taking place after December 31, 2011.

If this proposal is finalized, many patients with GI and inherited metabolic diseases and disorders risk losing coverage and access to medically necessary specialized foods and formulas that are essential to their treatment and disease management. This would put thousands at risk of great physical harm, including potential irreversible brain damage, coma and death.

While CMS asserts states would not be expected to remove the state-mandated benefits from their EHB-benchmark plans, states would need to defray the cost of or repeal state-required benefits that would be considered in addition to EHB if this proposal were finalized. CMS proposes this change would take effect for the 2027 plan year, which could result in an abrupt change in access to specialized foods and formulas for these patients.

MEDICALLY-NECESSARY NUTRITION IS ESSENTIAL

Certain GI and inherited metabolic disorders impair the body's ability to digest, absorb, or metabolize nutrients. For individuals living with these conditions, medically necessary nutrition is an essential component of treatment and disease management. Examples of these conditions and their nutritional requirements are described below.

When these GI and inherited metabolic conditions — that can be effectively managed with medically-necessary nutrition — are left untreated or under-treated, the implications are significant, often permanent and costly (monetarily and in quality of life). The effects are particularly profound in pediatric patients and include inadequate growth, abnormal development, cognitive impairment, and behavioral disorders. In severe cases, without medically-necessary nutrition, the outcomes may include unnecessary surgery, repeated hospitalizations, intellectual disability, or even death— all of which can be prevented with proper medical nutrition. Patients with an unmanaged disease also suffer emotionally and socially.

The 2022 formula shortage demonstrated the essential nature of specialty formulas for those with GI and inherited metabolic conditions and the dire medical consequences that can result when these formulas are inaccessible. During the shortage, physician members of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN) documented medical consequences such as feeding intolerance, weight loss, rectal bleeding, rapid gastric emptying, acute kidney injury, and electrolyte disturbances, all of which resulted in increased physician and emergency department visits. Children with inherited metabolic disorders who were hospitalized due to lack of formula faced similar challenges due to lack of formula supply and had to be placed on IV nutrition.

Treatment for Gastrointestinal Disorders

GI disorders for which specialized (non-standard) formulas may serve as an essential treatment component include: severe protein intolerance, allergies, malabsorption, and poor growth. For example, 2-5 percent of infants are affected by a milk protein allergy and require either hypoallergenic, extensively hydrolyzed or amino acid-based formulas as their sole source of nutrition — the same formulas that were in short supply in 2022.

Specialized formulas are a critical, evidence-based treatment of Crohn's disease. More than 100,000 American youth under the age of 20 are living with Crohn's disease, a life-long condition.[1] Studies[2] have demonstrated that enteral therapy is as effective as conventional and

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[1] Prevalence of Pediatric Inflammatory Bowel Disease in the United States: Pooled Estimates From Three Administrative Claims Data Sources Kappelman, Michael D.Brensinger, Colleen Parlett, Lauren E.Hurtado-Lorenzo, AndresLewis, James D. et al. Gastroenterology, Volume 168, Issue 5, 980 - 982.e2

[2] Levine A, Wine E, Assa A. Crohn's Disease Exclusion Diet Plus Partial Enteral Nutrition Induces Sustained Remission in a Randomized Controlled Trial; *Gastroenterology*, https://doi.org/10.1053/j.gastro.2019.04.02

biologic medication options in achieving remission in children, but with far fewer side effects than immunosuppressive therapies.

Lack of treatment leads to preventable complications, including progressive inflammation, growth failure in children and adolescents, malnutrition, repeated hospitalizations and increased surgical needs — all at considerable cost to patients, their families and the health care system.

Eosinophilic Esophagitis (EoE) illustrates similar concerns. EoE is an allergic disease that affects the entire age spectrum — from children to adults — and causes chronic esophageal inflammation that can progress to scarring and narrowing of the esophagus and food impactions. Children with EoE are oftentimes unable to tolerate a regular diet, making hypoallergenic and elemental formulas the only safe and adequate source of nutrition. Exclusive enteral therapy has been shown to reduce inflammation and resolve symptoms without pharmacologic intervention. When treatment is inaccessible, complications can lead to emergency visits, endoscopic procedures, long-term disability, and costly interventions. Ensuring continued coverage of medically necessary formulas prevents irreversible esophageal damage, supports healthy growth and nutritional adequacy, and significantly reduces the need for acute and procedural care.

Treatment for Inherited Metabolic Disorders

The Federal Government's Recommended Universal Screening Panel (RUSP) has very specific requirements for a disorder's inclusion: that the impacts of the disorder be severe enough to warrant early intervention and that an effective treatment exists when a disorder is detected. For the majority of the Inherited Metabolic Disorders (IMD) on the RUSP, the recognized and accepted treatment is medically-necessary nutrition.

For the approximately 300 infants born each year with Phenylketonuria (PKU), medically-necessary nutrition is their primary—if not only—treatment. PKU is one of 13 aminoacidopathies, in which the body cannot metabolize one or more of the amino acids in protein, and patients must maintain a low-protein diet (often only 3-12 grams of natural protein) and consume a metabolic formula to provide the rest of their essential nutrition, for life. This treatment commences as early as possible after birth: failure to do so results in permanent and catastrophic brain damage. Lifelong treatment is necessary to avoid progressive neurological damage. In women with PKU who become pregnant, inadequate medically-necessary nutrition may lead to fetal brain damage, heart malformation, microcephaly and pre-term mortality.

In individuals with very long-chain acyl-CoA dehydrogenase deficiency (VLCAD), a rare inherited disorder that prevents the body from properly breaking down certain fats for energy, illness or interruptions in access to medically necessary nutrition can trigger life-threatening metabolic crises. Survivors may experience poor growth, liver or heart failure, and episodes of painful muscle breakdown (rhabdomyolysis) that can lead to kidney failure. Consistent access to medically necessary nutrition is therefore essential to prevent these complications.

CONCLUSION

Access to medically necessary specialized foods and formulas are not optional clinical supports —they are essential, cost-saving medical treatments that prevent avoidable morbidity and associated health care costs.

We urge CMS to preserve the current treatment of state-required benefits within EHB, including those incorporated into state EHB benchmark plans. Reclassifying these benefits would put at risk coverage and access to specialized formulas and foods essential for patients with GI and inherited metabolic diseases. Instead, we urge the Administration to support expansion of medically necessary foods and formulas across all insured patient populations.

Sincerely,

The AIP BIPOC Network
Alliance of PKU Families
American College of Gastroenterology
American Gastroenterological Association
American Partnership for Eosinophilic Disorders
American Society for Parenteral and Enteral Nutrition
Association for Creatine Deficiencies
California Coalition for PKU and Allied Disorders
Children's National Hospital
Color of Gastrointestinal Illnesses
Council for Pediatric Nutrition Professionals
Crohn's & Colitis Foundation
CURED Nfp
Feeding Matters
flok Health
FOD Family Support Group
FPIES Foundation
Genetic Metabolic Dietitians International
Georgia PKU Connect
Global Liver Institute
Gut Microbiome Foundation
Healthcare Nutrition Council
Intermountain PKU and Allied Disorders Association
Louisiana Metabolic Disorders Coalition
Maryland Alliance of PKU Families
Michigan PKU and Associated Disorders
MitoAction
MSUD Family Support Group
The National Organization for Rare Disorders

National PKU Alliance
National Urea Cycle Disorders Foundation
The New England Connection for PKU and Allied Disorders, Inc.
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition
The Oley Foundation
Organic Acidemia Association
Pediatric IBD Foundation
PKU Alaska
PKU Organization of IL and Allied Disorders
Propionic Acidemia Foundation
Society for Inherited Metabolic Disorders
Tennessee PKU Foundation
United Mitochondrial Disease Foundation