



July 13, 2022

President Joseph Biden
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500

Vice President Kamala Harris
The White House
1600 Pennsylvania Ave NW
Washington, DC 20500

Dear President Biden & Vice President Harris:

The Patients & Providers for Medical Nutrition Equity Coalition (PPMNE) applauds the Biden-Harris Administration for its efforts — including the planned White House Conference on Hunger, Nutrition and Health — to end hunger and to increase healthy eating and physical activity by 2030 so fewer Americans experience diet-related diseases. As a national coalition of more than 40 patient and provider organizations representing those for whom specialized nutrition is medically necessary for treatment of their digestive or inherited metabolic disorder, we have a unique interest in improving food access and affordability. For the children and adults we represent, food insecurity means not being able to access medically necessary nutrition.

The ongoing formula shortage has demonstrated the essential nature of specialty formulas for those with gastrointestinal (GI) and metabolic conditions and the dire consequences that result when these formulas are inaccessible. We feel strongly the needs of this patient population must be addressed as part of the Administration's efforts to tackle hunger often associated with diet-related diseases, and respectfully request that access to medically necessary nutrition be included among the Conference topics.

Please find our answers to the questions posed as part of the "Convener's Toolkit" below:

How has hunger or diet-related disease impacted you, your family, or your community?

Each year, thousands of children and adults in the United States are diagnosed with certain digestive or inherited metabolic disorders that prevent their bodies from digesting, absorbing or metabolizing food. For them, medically necessary food, which can be administered as a specialty formula or low-protein modified food product, constitutes both their treatment and sustenance.

When these conditions are left untreated, food can become toxic or the body can fail to absorb necessary nutrients. The medical consequences are often significant, permanent, and costly.

The implications of denied or delayed access to medically necessary nutrition in pediatric populations are particularly profound — inadequate growth, abnormal development, cognitive impairment, and behavioral disorders. In severe cases, without medically necessary nutrition, the outcome can result in unnecessary surgery, repeated hospitalizations, intellectual disability, or even death—all of which could be prevented with proper diet. Children with an unmanaged disease also suffer emotionally and socially. We encourage you to visit nutritionequity.org/states to read stories about the Americans of all ages who rely on medically necessary nutrition.

Luckily, there are specialty formulas these patients can consume to treat and manage their conditions and to ensure adequate nutritional intake. The formula shortage crisis has had a profound impact on patients who rely on specialty formulas. **Unfortunately, many of these families were in crisis long before the current formula shortage and will continue to be in crisis unless the Administration and Congress act. The reality is that even when the current formula shortage subsides, many individuals will still struggle to obtain access to specialty formulas because of restrictions that health insurance plans place on coverage for these items, as well as on medically necessary foods and specialty vitamin formulations.**

While private insurance companies and public coverage mechanisms often deny coverage of medically necessary nutrition as the prescribed or recommended treatment of certain GI and metabolic disorders, prescription drugs or biologics are routinely approved as treatments of these diseases. Pharmaceuticals and biologics can be costly and can have undesirable risks such as suppression of the immune system, which can increase a patient's risk of infection or cancer.

For many in our community, this coverage crisis not only impacts the individual with the specific medical condition, but also has a detrimental impact on their families. As families are left to struggle with the overwhelming financial cost of providing medically necessary nutrition, their resources to put food on the table for other family members are also impacted. Medically necessary nutrition is not only not generally available at the grocery store; it is not available at food pantries either. We have heard countless stories from individuals who have had to make the choice between providing medically necessary nutrition for one child versus food for the rest of their family members. Medically necessary nutrition is a gap in our current nutrition and hunger policies that must be addressed. Please see the attachment to read some of the stories about the choices these families have had to make.

What specific actions should the U.S. Federal government, including the Executive Branch and Congress, take to achieve each pillar? What are the opportunities and barriers to achieving the actions? Actions should include specific policy and/or programmatic ideas and changes as well as funding needs.

Changes in law and policies are needed to ensure patients have access to essential specialty formulas and other medically necessary foods. PPMNE is committed to improving access to medical foods and formulas for those with GI and metabolic disorders. We encourage the Biden-Harris Administration to use all regulatory and administrative levers at its disposal to

address this issue and we specifically call for the passage of the *Medical Nutrition Equity Act (S. 2013/H.R. 3783)* this year.

The *Medical Nutrition Equity Act* will ensure that those with certain GI and metabolic disorders and diseases will have access to specialty formulas and other medical necessary nutrition to treat their diseases and disorders. Our estimate is that approximately 2.72 million Americans have one of the diseases or conditions covered by the legislation¹ — many of whom could benefit from its passage. This legislation has strong bipartisan and bicameral support. Further, we ask the Administration to use all existing authorities to ensure coverage of medically necessary foods and formulas for those covered under Medicare, Medicaid, CHIP and the Federal Employees Health Benefits Program.

Treatment of GI and metabolic disorders and diseases are generally considered covered conditions under most insurance plans. However, even when an insurance company does cover medically necessary nutrition, it often comes with the stipulation 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) when the individual is otherwise capable of drinking the formula. Surgery to place a feeding tube is expensive and these tubes carry additional risks. For example, a gastrostomy tube can leak, cause ulcerations, or cause infection at the insertion site. In severe cases, a patient may experience a perforation in the intestinal tract. Medically necessary nutrition, when administered under a physician's order, constitutes life-saving treatment with lower costs and fewer risks.

These types of coverage policies are irrational and interfere with thoughtful medical decision making. Further, without coverage, medically necessary nutrition is unaffordable for many families. For example, some children with Crohn's disease require a pre-digested formula such as Peptamen 1.5, which, at five cans per day, can cost an average of \$1,500 per month. For many patients and their families, the out-of-pocket costs for specialized formulas are prohibitive, particularly when you consider these formulas cost far less than the biologics that are covered for some of these conditions.

We also call your attention to the fact that some of the most vulnerable members of our community face abrupt coverage discontinuation as they age into Medicare, resulting in immediate and severe negative health effects. A reversal of the January 2022 decision on National Coverage Decision 180.2 and a reconsideration of the medical evidence for lifelong treatment of inborn errors of metabolism -- not available when the rule was drafted -- is necessary to protect this population. We would be happy to provide more details on this request.

¹ Vital Statistics Consulting analysis provided to the PPMNE Coalition for the "Medical Nutrition Equity Act Cost Estimate." January 30, 2020.

What are innovative, successful activities already happening at the local, state, territory and tribal levels that could inform action at the federal level?

Nearly 40 states require some level of coverage of medically necessary nutrition, but coverage is highly variable from state to state and does not reach patients enrolled in health plans covered by the Employee Retirement Income Security Act (ERISA).

There is congressional precedent for the *Medical Nutrition Equity Act*. Congress recognized the importance of improving coverage of medically necessary nutrition by including language similar to the MNEA in the 2016 National Defense Authorization Act to mandate coverage under TRICARE. It is time to extend that coverage to other insured populations and to ensure there is a federal coverage floor.

Congress has also recognized the importance of identifying some of these conditions early in life and has passed and repeatedly reauthorized legislation requiring newborn screening for inborn errors of metabolism as recommended by the Secretary of HHS 'Recommended Uniform Screening Panel (RUSP). Diseases are added to the RUSP because they can be treated when diagnosed early. Approximately 2,000 of the babies screened each year via the national newborn screening program are diagnosed with inherited metabolic disorders. For most of these babies, medical nutrition is their only option to survive.

Conclusion

PPMNE appreciates this opportunity to share its unique perspectives on what food insecurity looks like for those with GI and metabolic disorders. Once again, we ask that the Administration's efforts to end hunger and reduce diet-related diseases, as well the White House Conference on Hunger, Nutrition and Health, be inclusive of access to medically necessary nutrition, and, specifically, legislative and policy changes to remove barriers to coverage including those articulated in the *Medical Nutrition Equity Act*.

For more information or questions, please contact PPMNE Executive Director, Megan Gordon Don, at mgdon@mgdstrategies.com or 202.246.8095.

Attachment: *The Ripple Effects of Families' Struggles to Pay for Medically Necessary Nutrition: Select Stories*