



July 17, 2023

Ms. Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244–1850

Dear Administrator Brooks-LaSure:

The Patients & Providers for Medical Nutrition Equity Coalition (PPMNE) greatly appreciated the April 3 conversation with Center for Consumer Information and Insurance Oversight representatives to provide more background on why medically necessary foods and formulas are essential to the care and treatment of patients with gastrointestinal (GI) and metabolic disorders. This conversation was a follow up to the January 31 letter we submitted to the Centers for Medicare and Medicaid Services (CMS) in response to the Agency's request for information on Essential Health Benefits as published in the *Federal Register*.

As stated in our January 31 letter, certain GI and inherited metabolic disorders prevent the body from digesting, absorbing or metabolizing food. PPMNE has collected [patient and provider stories](#) that explain the tremendous cost burden associated with non-coverage of medically-necessary nutrition.

Insurance coverage of medical foods is currently handled by a state-by-state basis, which create inconsistencies, variabilities, and inequitable access. The majority of states have adopted legislation to help facilitate access, and the federal government has recognized the need for coverage through the extension of benefits to TRICARE recipients. However, many Americans who are prescribed medical foods as treatment are still being denied coverage.

While TRICARE has provided coverage for medically necessary foods and formulas since 2017 and the Biden-Harris Administration has taken action to require all Federal Employee Health Benefit (FEHB) carriers to provide coverage of foods specifically formulated and prescribed to treat inborn errors of metabolism (IEMs) for the 2023 plan year, coverage of medically necessary foods and formulas remains a patchwork of policies and our patients are falling through the gaps. Our January 31 letter also provided an analysis of the current EHB policies and showed there is wide variability among current EHB plans and even some that do not cover medically necessary nutrition at all.

As discussed during the April 3 meeting, patients would benefit from a model policy that creates a uniform and robust benefit for all patients with these diseases/disorders regardless of the state in which they reside. We were asked to review existing state and

federal coverage policies and provide recommendations for an ideal national coverage policy for CMS' consideration.

We feel strongly a national policy must follow the key principles outlined below to adequately cover the needs of the patients with GI and metabolic disorders who rely on medically-necessary foods and formulas for treatment:

1. First and foremost, it is critical that any coverage policy include the full range of GI and metabolic disorders for which medical nutrition is necessary. Please see the attachment, which lists the conditions that should be included.
2. There should be no age restrictions. While many patients are diagnosed as infants or children, diagnosis can occur at any age and most of the conditions persist throughout the patient's life.
3. Further, coverage should not be limited to individuals who require medically-necessary nutrition as their sole source of nutrition and should extend to those who require it for partial nutrition. Many patients with certain GI and metabolic disorders are able to supplement medical foods and specialized formulas with other sources of nutrition on a limited basis; however, they still rely on medical food and specialized formulas as their treatment and for a majority of their nutrition.
4. Specialized formulas must also be covered for both oral consumption and administration through an enteral feeding tube. While patients may prefer oral consumption as the preferred route of administration, insurance companies often require administration through a nasogastric or jejunostomy tube. Surgical placement of a jejunostomy tube is invasive and has higher associated costs and risk of infection. The decision of the best route of administration should be left to patients in consultation with their treating physicians.
5. It is absolutely critical that any coverage policy include the full range of medically necessary foods and formulas, including specialized vitamin formulations, for the treatment and management of GI and metabolic diseases and disorders.

We have engaged in a review of the most robust state coverage policies, as well as the current TRICARE policy. Based on that review, with some enhancements, the TRICARE policy serves as a gold standard. Please see our suggestions for gold standard model language in the attachment, which is based on the TRICARE policy.<sup>1</sup>

Our organizations are committed to ensuring equitable, fair and comprehensive coverage of medically-necessary nutrition to individuals with GI and metabolic disorders across payers and coverage policies. We are grateful for the continued opportunity to engage in dialogue with you about how CMS can help implement steps toward this goal. For questions or additional information, please contact Camille Bonta, NASPGHAN policy advisor, at (202) 320-3658 or [cbonta@summithealthconsulting.com](mailto:cbonta@summithealthconsulting.com), Sarah Chamberlin, Executive Director, National PKU News at [sarah@pkunews.org](mailto:sarah@pkunews.org) or (973) 619-9160, or Megan Gordon Don, PPMNE at [mgdon@mgdstrategies.com](mailto:mgdon@mgdstrategies.com) or (202) 246-8095.

Sincerely,

American Academy of Allergy, Asthma & Immunology

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<sup>1</sup> [https://manuals.health.mil/pages/DisplayManualHtmlFile/2022-12-05/AsOf/TPT5/C8S7\\_1.html](https://manuals.health.mil/pages/DisplayManualHtmlFile/2022-12-05/AsOf/TPT5/C8S7_1.html)

American Academy of Pediatrics  
American College of Gastroenterology  
American College of Medical Genetics and Genomics  
American Gastroenterological Association  
American Partnership for Eosinophilic Disorders  
American Society for Parenteral and Enteral Nutrition  
Children's National Hospital  
Color of Crohn's and Chronic Illness  
Crohn's & Colitis Foundation  
CURED Nfp (Campaign Urging Research for Eosinophilic Diseases)  
Feeding Matters  
Genetic Metabolic Dietitians International  
Georgia PKU Connect  
HCU Network America  
International FPIES Association (I-FPIES)  
MSUD Family Support Group  
National Organization for Rare Disorders  
National PKU Alliance  
National PKU News  
Nationwide Children's Hospital  
Network of Tyrosinemia Advocates  
North American Society for Pediatric Gastroenterology, Hepatology and Nutrition  
Organic Acidemia Association  
Propionic Acidemia Foundation  
Society for Inherited Metabolic Disorders  
Super T's Mast Cell Foundation  
The FPIES Foundation  
The New England Connection for PKU and Allied Disorders, Inc.  
The Oley Foundation  
United Mitochondrial Disease Foundation

Attachments:

- List of GI and metabolic disorders that should be included in any national policy
- Suggested Gold Standard Model Coverage Policy