

September 9, 2021

The Honorable Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Boulevard  
Baltimore, MD 21244

Re: File Code CMS–1751–P. Proposed Rule – Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements.

Dear Administrator Brooks-LaSure:

The American College of Medical Genetics and Genomics<sup>i</sup> appreciates the opportunity to provide feedback on a specific section of the proposed rule for Medicare Program; CY 2022 Payment Policies Under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Provider Enrollment Regulation Updates; Provider and Supplier Prepayment and Post-Payment Medical Review Requirements (CMS-1751-P).

In section III.G.1. of the proposed rule, CMS proposes to retire National Coverage Determination (NCD) 180.2, Enteral and Parenteral Nutritional Therapy citing external feedback suggesting that the NCD is outdated. Existence of an appropriate national coverage policy is critical for ensuring that access to medical nutrition is accessible for Medicare beneficiaries. For this reason, we urge CMS to reconsider NCD 180.2 so that the outdated coverage policies can be updated based on current evidence to support coverage of medical nutrition.

Medical nutrition is necessary for survival of patients with certain inherited metabolic conditions who cannot metabolize normal foods, examples of which include ornithine transcarbamylase (OTC) deficiency, maple syrup urine disease (MSUD), phenylketonuria (PKU), homocystinuria. This includes many conditions on the Recommended Uniform Screening Panel (RUSP), a national list approved by the Secretary of Health and Human Services to guide state newborn screening programs. Many of these conditions would not be on the RUSP if it weren't for the availability of medical nutrition treatments.

NCD 180.2 currently limits coverage of medical nutrition to those delivered enterally or parenterally. CMS defines enteral feeding as excluding oral intake and specifies that enteral nutrition therapy can be given by nasogastric, jejunostomy, or

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gastrostomy tubes. However, coverage issues for medical nutrition are not limited to just those patients who require enteral (as defined by CMS) or parenteral delivery. Patients who can consume medical nutrition orally still struggle financially due to the lack of coverage for their nutritional therapy. Access issues resulting from the lack of coverage for medical nutrition can result in expensive hospitalizations charged to Medicare that could have otherwise been avoided. Patients with metabolic conditions who cannot consistently access medical nutrition suffer serious and irreversible complications such as organ failure, severe cognitive decline, and even death. Further, covering medical nutrition only when it is delivered by the enteral or parenteral routes described in NCD 180.2 may lead some patients to pursue this route of delivery even though it is more expensive to Medicare, invasive, and not without risks to the patient.

Our ability to treat patients with inherited metabolic conditions has significantly changed since this current NCD policy was established over 37 years ago. Ample evidence exists to support the national coverage of medical nutrition for all patients who rely on it for survival regardless of how it is delivered, and a national coverage policy is the best way to avoid unnecessary disparities in access that could result from local coverage decisions. For these reasons, we urge CMS to reconsider NCD 180.2 in light of current available evidence.

For questions or additional information, please contact Dr. Michelle McClure, ACMG Public Policy Director at [mmcclure@acmg.net](mailto:mmcclure@acmg.net).

Sincerely,



Marc Williams, MD, FACMG  
President  
American College of Medical Genetics and Genomics

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<sup>1</sup> Founded in 1991, the American College of Medical Genetics and Genomics (ACMG) is the only nationally recognized medical professional organization solely dedicated to improving health through the practice of medical genetics and genomics, and the only medical specialty society in the US that represents the full spectrum of medical genetics disciplines in a single organization. The ACMG is the largest membership organization specifically for medical geneticists, providing education, resources and a voice for more than 2,300 clinical and laboratory geneticists, genetic counselors and other healthcare professionals, nearly 80 percent of whom are board-certified in the medical genetics specialties. ACMG's mission is to improve health through the clinical and laboratory practice of medical genetics as well as through advocacy, education and clinical research, and to guide the safe and effective integration of genetics and genomics into all of medicine and healthcare, resulting in improved personal and public health.

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