



September 10, 2021

The Honorable Xavier Becerra
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

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

RE: NORD Comments on CMS-1751-P: 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 Secretary Becerra and Administrator Brooks-LaSure,

Thank you for the opportunity to submit comments on CMS-1751-P related to the proposed removal of the National Coverage Determination (NCD) 180.2 made on July 11, 1984, for patients requiring enteral and parenteral medical nutrition. NORD is a unique federation of voluntary health organizations dedicated to helping the 25-30 million Americans living with a rare disease. We believe that all patients should have access to quality, accessible and affordable health coverage that is best suited to meet their medical needs, which includes comprehensive coverage of medically necessary nutrition for patients living with digestive or inherited metabolic disorders.

Currently thousands of adults are living with digestive or inherited metabolic disorders that inhibit their bodies from digesting or metabolizing most food. Examples of these rare diseases include Gastroparesis, Homocystinuria, Maple Syrup Urine Disease, and Phenylketonuria. For those with certain digestive or inherited metabolic disorders, regular food can become toxic, or the body can fail to absorb necessary nutrients. As a result, these patients must turn to medically necessary nutrition, such as highly specialized formulas and genetically modified medical foods that are given enterally, parenterally, or orally to treat their condition.

The method of delivery for this medically necessary nutrition is best determined between the patient and provider, however the health care coverage for medical nutrition and its different delivery methods varies greatly. Inconsistent coverage decisions amongst Medicare Administrative Contractors often leaves patients without adequate coverage and with high out of

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pocket costs. For example, the annual cost of oral formula for the Phenylketonuria is on average \$7,753 per year for adults, depending on factors such as age and weight¹.

We thank the Centers for Medicare and Medicaid (CMS) for bringing this issue of medically necessary nutrition coverage to the forefront in the recent proposed rule. However, instead of simply removing the NCD for enteral and parenteral nutritional therapy, NORD respectfully requests that a national coverage analysis be opened for Medicare coverage of all three types of medical nutritional therapy: oral, enteral and parenteral. Since 1984 when the last NCD was determined, there have been significant strides in science for patients requiring medically necessary nutrition. There are now more oral medical food options available, and the standard of care for some diseases has shifted to oral delivery of these medically necessary foods², instead of the more invasive enteral and parenteral delivery methods. CMS should take this opportunity to evaluate the updated medical evidence for the care and treatment of those with digestive or inherited metabolic disorders to ensure the thousands of rare disease patients that are covered by Medicare have clear, uniform access to the medical nutrition and delivery mode for that medically necessary nutrition as determined by their provider. NORD urges CMS to conduct a national coverage analysis that considers all the options for patients to obtain medically necessary nutrition safely.

We are deeply concerned that if the proposed rule is implemented and removes the current NCD, there will be a decrease in access to this specialized type of care. Without an NCD, more denials could occur and place rare disease patients at greater risk for health complications, which could also potentially increase the costs for the Medicare program.

We respectfully urge you to open a new national coverage analysis that evaluates all the medically appropriate methods to administer medically necessary nutrition including enterally, parenterally, and orally and ultimately make a NCD that will increase affordable access to this medically necessary care for Medicare beneficiaries.

If you have any questions, please contact Rose Gallagher with the National Organization for Rare Disorders at Rgallagher@rarediseases.org.

Sincerely,

Rose Gallagher

Associate Director of Policy
National Organization for Rare Disorders

¹ <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6807265/>

² <https://pediatrics.aappublications.org/content/145/3/e20192261>