Submitted via Email

April 9, 2021

DME MAC Medical Directors
900 42nd St S
Fargo, ND 58103-2119
Enteral Nutrition (DL38955): ENTLCDComments@cgsadmin.com

Re: Organization Comments on Proposed Enteral Nutrition Local Coverage Determinations

Dear DME MAC Medical Directors,

The Healthcare Nutrition Council (HNC) and undersigned organizations are providing comments on the Proposed Enteral Nutrition (EN) Local Coverage Determinations (LCDs) and our concerns with the language outlined in the Local Coverage Article: Enteral Nutrition - Policy Article related to starting a patient on a standard formula before prescribing a specialty formula.

We urge the DME MAC Medical Directors to modify the Proposed Enteral Nutrition Local Coverage Determinations to ensure patients have access to the enteral nutrition formula most appropriate for their individual needs, and not require a patient to try a standard formula before moving to a specialty formula. Requiring patients to start a trial of standard formula risks:

- **Serious harm to the patient,**
- **Costly medical complications, and**
- **Inappropriate and/or delayed care and healing.**

The Proposed EN LCD states *"specialty formulas (B4149, B4153, B4154, B4155, B4157, B4161 and B4162) must be justified in the medical record through documentation of specific events associated with the standard formula that resulted in prescribing a special enteral formula…(and) a diagnosis alone is not sufficient to support the medical need for specialty formula."* In addition to a beneficiary's diagnosis, the medical records must also include *"formula(s) tried [and] unfavorable events associated with the standard formula."* This language in the Proposed EN LCD mandates a failed trial of standard formula before specialty formula will be considered for coverage. We are concerned about the implications of this language, since standard formulas may be contraindicated for certain conditions, such as malabsorptive disorders and/or allergies, and their mandated use could cause serious harm to the patient.

Specialized formulas are uniquely created specifically to address the nutrition needs of individuals who are not able to digest or metabolize a standard formula. Starting a patient on a standard formula that is clinically contraindicated and will not be tolerated by the patient will delay the patient's ability to recover and heal, negatively impact quality of life for the patient, and add significant costs to the health care system. Standard formulas may be contraindicated or suboptimal for certain patients and conditions, such as malabsorptive disorders, chylous leak, pancreatitis, pancreatic surgeries (post-Whipple procedures), gastroparesis, inflammatory bowel disease (IBD) including ulcerative colitis, food protein allergies, inherited disorders, inborn errors of metabolism, renal disease, among others. Unfavorable symptoms could include emesis, malabsorption with uncontrolled diarrhea, and/or a life-threatening allergic reaction. A better clinical approach is to identify the unique nutrition needs of the individual and start them on the specialized formula when it is indicated instead of potentially forcing an adverse event from using an inappropriate formula.

This proposed change impacts adults, older adults, and pediatric patients who qualify as Medicare beneficiaries. We have included some patient advocacy group feedback and commentary on the proposed changes:

"Having had to fail three different formulas and experiencing unpleasant and painful side effects before ending up on a peptide-based formula, I know a change like this would make a huge difference in the lives of the consumers/patients." -Oley Foundation's Vice President, Joy McVey Hugick

In the pediatric home tube-fed community, specialty formulas are needed for a wide range of medical conditions. Eosinophilic GI Disorders and Food Protein-Induced Enterocolitis Syndrome (FPIES) are conditions where children may not have safe standard formula options and must use a specialty hypoallergenic formula. Many children of families involved with the Feeding Tube Awareness Foundation have been on a specialized formula at some point for conditions such as severe food allergies, Eosinophilic Esophagitis, dysmotility/gastroparesis, and an unknown metabolic condition. For any one of these conditions, use of a standard formula could be unsafe and lead to negative clinical outcomes.

For those living with eosinophil associated gastrointestinal disease such as eosinophilic esophagitis, gastritis, gastroenteritis and colitis (collectively known as "EGIDs"), the importance of elemental formulas for treatment are well-documented. For certain individuals with EGIDs, specialized elemental formulas are the primary or sole treatment for the disorder. For many, proper nutritional therapy has been established as being critical to a good outcome. Elemental formulas have over a 90% success rate for symptom and esophageal disease resolution in eosinophilic esophagitis and may be more important than prescription medications. A subset of these patients will require long term medical therapy with amino acid-based formulas.[1]

If these patients were mandated to be trialed on a standard formula, there would be serious health complications such as malnutrition[2] as one example. Risks associated with malnutrition in pediatric populations are particularly profound and often severe: inadequate growth, abnormal development, cognitive impairment, behavioral disorders, and repeat hospitalizations. Malnourished adults and older adults experience increased morbidity, complications and mortality, longer hospitalizations, more readmissions, and institutionalizations and need for ongoing services. These complications may result in increased healthcare costs as well as increased risks for functional disability, frailty, and falling.[3]

The COVID-19 Public Health Emergency poses a particularly unique need for individualized care as some patients require specialty enteral formula from their transition from hospital to home and trialing a standard formula might not be possible. It is essential for these patients to receive the correct product throughout their unique care and treatment.

Additionally, there are significant healthcare costs and product waste implications to consider when requiring a patient to try a standard formula before moving to a specialized formula. These costs, for example, could include using costly pharmaceuticals to compensate for the patient's intolerance of the standard formula and/or throwing away the remaining supply after the trial period was found to be unsuccessful. The prescribing physician, registered dietitian, or healthcare provider understands how to select the most appropriate formula based on the patient's condition. Knowingly placing a patient on an inappropriate formula is likely to cause the patient's condition to worsen (such as elicit a severe allergic reaction or impact a malabsorptive condition), increasing medical costs, and risking complications and potential re-hospitalization.

Our Recommendations

We recommend removing the language in the Proposed EN LCDs requiring every patient to start on a standard formula, and replacing it with the following language: "*In cases that a trial of standard formula is contraindicated, the medical record must document the medical necessity of the specialty formula including why a standard formula trial was not performed."*

We also recommend changing the line from the policy article from: *"A diagnosis alone is not sufficient to support the medical need for a specialty formula."* to: *"A diagnosis alone is not sufficient to support the medical need for a specialty formula, a written justification is required for why a standard formula trial was not performed."*

Our recommendations align with the oral comments presented during the March 30 public meeting by the American Society for Parenteral and Enteral Nutrition (ASPEN) and the National Home Infusion Association (NHIA).

We appreciate the opportunity to comment on this Proposed EN LCD. If you have any questions, please contact Berit Dockter, Healthcare Nutrition Council, at bdockter@healthcarenutrition.org or 202-207-1112.

Respectfully,

AAHomecare
Academy of Nutrition and Dietetics
American Partnership for Eosinophilic Disorders
American Society for Parenteral and Enteral Nutrition
Crohn's & Colitis Foundation
Feeding Tube Awareness Foundation
Healthcare Nutrition Council
National PKU Alliance
The Oley Foundation

[1] Groetch M, Venter C, Skypala I, Vlieg-Boerstra B, Grimshaw K, Durban R, Cassin A, Henry M, Kliewer K, Kabbash L, Atkins D, Nowak-Węgrzyn A, Holbreich M, Chehade M; Eosinophilic Gastrointestinal Disorders Committee of the American Academy of Allergy, Asthma and Immunology. Dietary Therapy and Nutrition Management of Eosinophilic Esophagitis: A Work Group Report of the American Academy of Allergy, Asthma, and Immunology. *J Allergy Clin Immunol Pract.* 2017 Mar-Apr; 5(2): 312-324.e29.
[2] Saunders J, Smith T. Malnutrition: causes and consequences. *Clin Med (Lond)*. 2010; 10(6): 624-627.
[3] Goates, Scott; Kristy Du, Carol Braunschweig, and Mary Beth Arensberg. Economic Burden of Disease-Associated malnutrition at the State Level. *PLOS ONE*. 2016; 11(9): 1-15.