



Submitted to: ENTLCDComments@cgsadmin.com

April 9, 2021

DME MAC Medical Directors
26 Century Blvd Ste ST610
Nashville, TN 37214-3685

Re: Comments on Proposed Local Coverage Determinations (LCD): Enteral Nutrition (DL38955)

Dear Medical Directors:

Introduction

The American Association for Homecare (AAHomecare) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the proposed Local Coverage Determination (LCD) and Policy Article (PA) for Enteral Nutrition (DL38955). AAHomecare is the national association representing durable medical equipment, prosthetics, orthotics and supplies (DMEPOS) suppliers, manufacturers, and other stakeholders in the homecare community. Our members are proud to be part of the continuum of care that assures Medicare beneficiaries receive cost effective, safe and reliable home care products and services. Our membership services a comprehensive range of nutrition management products across the nation. In light of our membership's expertise, we are uniquely qualified to comment on this opportunity. Our comments are in support of Nestlé HealthCare Nutrition, Inc., a leading manufacturer in nutritional science, providing science-based nutritional products.

The proposed language requires patients to try the standard enteral nutrition formula and record the adverse health effects in order to qualify for the specialty formula. Below is the language directly from the LCD and PA.

Proposed Enteral Nutrition LCD (DL38955) states:

The medical necessity for special enteral formulas (B4149, B4153, B4154, B4155, B4157, B4161, and B4162) must be justified in each beneficiary. If a special enteral nutrition formula is provided and the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary. (Refer to the LCD-related Policy Article for policy specific documentation requirements.)

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Proposed Enteral Nutrition LCD-related Policy Article (DL38955) states:

Special nutrient formulas, HCPCS codes B4149, B4153, B4154, B4155, B4157, B4161, and B4162, are produced to meet unique nutrient needs for specific disease conditions. If a special nutrient formula is ordered, the beneficiary's medical records must specify the unfavorable events associated with the standard formula that resulted in prescribing a special enteral formula. A diagnosis alone is not sufficient to support the medical need for a specialty formula.

At a minimum, the medical records must include the following:

- *Beneficiary's diagnosis*
- *Formula(s) tried*
- *Unfavorable events associated with the standard formula*

For example, the treating practitioner ordering a diabetes-specific formula may document in the beneficiary's medical record that the beneficiary has a diagnosis of diabetes mellitus and has experienced severe fluctuations of glucose levels on standard formula.

The requirement for all beneficiaries who need a specialty formula to first try and fail on a standard product can cause serious harm to patients. Standard formulas may be inadvisable for patients with certain conditions such as but not limited to: malabsorptive disorders, chylous leak, pancreatitis, pancreatic surgeries (post-Whipple procedures), inflammatory bowel disease including ulcerative colitis, and renal disease. This requirement could possibly negatively impact the quality of life for the patient and delay their care.

Recommendation

AAHomecare recommends the DME MACs to remove the requirement for all beneficiaries to try and fail on standard formula to protect patients from experiencing potential adverse health effects. We recommend the DME MACs to restore the following language from the retired Enteral Nutrition LCD with a supplementary statement:

*"The medical necessity for special enteral formulas (B4149, B4153, B4154, B4155, B4157, B4161, and B4162) must be justified in each beneficiary. If a special enteral nutrition formula is provided and if the medical record does not document why that item is medically necessary, it will be denied as not reasonable and necessary. **In cases where a trial of standard formula is contraindicated the medical record must document the medical necessity of the specialty formula and why a standard formula trial was not performed.**"*

For the related PA, we recommend removing the statement “[a] diagnosis alone is not sufficient to support the medical need for a specialty formula.” In its place, we recommend adding a statement requiring documentation of medical necessity of the specialty formula:

*“Special nutrient formulas, HCPCS codes B4149, B4153, B4154, B4155, B4157, B4161, and B4162, are produced to meet unique nutrient needs for specific disease conditions. If a special nutrient formula is ordered, the beneficiary’s medical records must specify the unfavorable events associated with the standard formula that resulted in prescribing a special enteral formula. **In cases where a trial of standard formula is contraindicated, the medical record must document the medical necessity of the specialty formula and why a standard formula trial was not performed.**”*

If the DME MACs choose not to eliminate the statement “[a] diagnosis alone is not sufficient to support the medical need for a specialty formula,” we request that the DME MACs modify that sentence to state: **“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.”**

Conclusion

For the reasons stated above, AAHomecare recommends the DME MACs to remove the requirement for all beneficiaries to try standard enteral nutrition formula and record the adverse health effects in order to qualify for the specialty formula. This requirement could cause unnecessary adverse health effects that could have simply been avoided. We recommend replacing the requirement with documentation of medical necessity by the prescriber for specialty enteral formula.

We appreciate the opportunity to provide comments on the proposed LCD for enteral nutrition. Please contact me at kimb@aaahomecare.org with any questions, or if you would like additional information.

Sincerely,



Kimberley S. Brummett
VP, Regulatory Affairs