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September 13, 2021

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
P.O. Box 8016
Baltimore, MD 21244-8016

Re: 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]

Dear Administrator Brooks-LaSure:

The American Association for Homecare (AAHomecare) is pleased to submit comments to the Centers for Medicare and Medicaid Services (CMS) on the above captioned Proposed Rule [CMS-1751-P] ("Proposed Rule"). 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 pertain to CMS' request for comments on removing the National Coverage Determination (NCD) for Enteral and Parenteral Nutritional Therapy (NCD 180.2).

In the Proposed Rule, CMS states that the Agency periodically reviews NCDs and removes outdated NCDs that do not reflect current clinical information. CMS has identified two NCDs, Enteral and Parenteral Nutritional Therapy (180.2) and Positron Emission Tomography (PET) Scans (220.6), that may be considered for removal in future rule making or NCD process. CMS explains that stakeholders have previously suggested that the NCD for enteral nutrition (EN) is outdated and therefore believes allowing the DME MACs to determine coverage decision better serves the Medicare Program.

AAHomecare is opposed to removing NCD 180.2. Instead, we urge CMS to revise the current NCD, consistent with its current procedures to do so. We believe maintaining national level coverage criteria is important because the process will provide a more comprehensive forum and better involve all stakeholders. Instead of removing the NCD, AAHomecare recommends that CMS update and revise the NCD, consistent with its established process (see 78 Fed. Reg. 48164, Aug. 7, 2013).

We agree with and appreciate CMS' statements in the Proposed Rule that parts of the NCD 180.2 are outdated. The NCD has not been updated in almost 40 years and there have been many clinical advancements in the delivery of EN in that time. The NCD's coverage criteria should be based on currently available clinical evidence and any criteria that is not supported by clinical evidence should be reconsidered or removed. AAHomecare recommends that CMS work with the clinical and DMEPOS community to update the NCD 180.2. An updated NCD with current information and objective criteria will improve compliance and interpretation of coverage requirements for prescribers and DMEPOS suppliers.

AAHomecare supports the improvements the DME MACS made in the newly updated EN LCD (LCD 38955) that went into effect on September 5, 2021. This revised EN LCD, however, references the current NCD. Without the NCD language, we are concerned that certain coverage criteria may be unclear, potentially resulting in beneficiary access issues.

Specifically, the newly revised DME MAC EN LCD references language in the current NCD that describe patients with non-functioning structures that normally permit food to reach the digestive tract:

1) L38955: Home Enteral Nutrition (HEN), Summary of Evidence, paragraph 5

   Coverage of HEN for patients with non-function of the structures that normally permit food to reach the digestive tract has been established in the Medicare National Coverage Determinations (NCD) Manual (CMS Pub. 100-03), Chapter 1, Part 4, Section 180.2. Additionally, benefit category and billing guidance for enteral nutrition are outlined in the Medicare Benefit Policy Manual (CMS Pub. 100-02), Chapter 15, Section 120 and the Medicare Claims Processing Manual (CMS Pub. 100-4), Chapter 20, Section 30.7. The guidance outlined in these manuals are reflected in the remainder of the LCD.

2) And again, referenced in L38955: Conclusion, Home Enteral Nutrition

   Based on review of the best available evidence, HEN is appropriate for the management of; and, improves health outcomes for individuals with a diagnosis of maldigestion/malabsorption. Therefore, the Enteral Nutrition LCD will include coverage of EN as reasonable and necessary as nutritional support therapy for the management of Medicare beneficiaries with a diagnosis of maldigestion and malabsorption. As previously noted, coverage of HEN for patients with non-function of the structures that normally permit food to reach the digestive tract has been established in the Medicare National Coverage Determinations Manual (CMS Pub. 100-03), Chapter 1, Part 4, Section 180.2.

We therefore urge CMS to update the NCD and not remove it entirely. A revised NCD is important to ensure continued beneficiary access to medically necessary EN therapy.

If CMS elects to update the NCD 180.2, or if CMS instead elects to have the Medicare contractors be responsible for revising the coverage criteria, AAHomecare recommends including language that will expand coverage for beneficiaries. More specifically, CMS should include language that reflects current clinical practice of EN therapy for beneficiaries with short-term need. The current language in the NCD 180.2 limits EN therapy coverage only for patients with, "permanently inoperative internal body organ or function thereof." This limitation creates a barrier for beneficiaries that can greatly benefit from shorter duration of EN therapy.

AAHomecare understands that due to EN therapy being covered under the prosthetic device benefit, CMS currently does not have the legal authority to expand coverage for short-term use. Therefore, AAHomecare recommends CMS to seek legal authority to make this change. Beneficiaries with head and neck cancer, such as esophageal cancer, stroke recovery, and post-surgical gastrointestinal (GI) complications with temporary impairment to the GI tract that have short-term inability to swallow are some examples of conditions where short-term EN therapy will be beneficial.[1,2] The National Academy of Sciences has also supported coverage for short-term feedings and has recommended a reevaluation of the current regulation in their report from 2000.[3] Recently, European Society for Clinical Nutrition and Metabolism (ESPEN) published a report on nutritional management for patients with COVID-19 and includes a recommendation for COVID-19 patients with dysphagia to have EN administered to help with their difficulty swallowing.[4] ESPEN states such swallowing complications can last up to 21 days, which is notably shorter than the current Medicare coverage policy.[5] These reports highlight how short-term coverage of EN therapy is helpful in treating patients with many different types of health issues. The L38955 also references the use of short-term EN therapy to treat pancreatitis. It states, "[Specialized nutrition support] should be used in patients with acute or chronic pancreatitis to prevent or to treat malnutrition when oral energy intake is anticipated to be inadequate for 5 to 7 days. (B)"[6] In addition, short-term EN therapy can be helpful for patients with mood disorders or failure to thrive.

Due to the significance of the potential changes to the NCD, we recommend CMS to thoroughly consider all the clinical information available on the therapy. AAHomecare supports comments submitted by the clinical community who are better suited to provide evidence-based recommendations on EN therapy coverage. AAHomecare also supports Healthcare Nutrition Council's (HNC's) comments and National Home Infusion Association's (NHIA's) comments.

For the reasons stated above, AAHomecare recommends that CMS not remove the NCD 180.2 but instead update the NCD with more comprehensive stakeholder feedback. It is critical for beneficiaries and suppliers for CMS to provide objective criteria that will reduce subjective interpretation by the DME MACs and other contractors.

We appreciate the opportunity to provide comments on the proposal. Please contact me at kimb@aahomecare.org with any questions, or if you would like additional information.

Sincerely,

Kimberley S. Brummett
VP, Regulatory Affairs

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[1] Niihara M, et al. Supplemental enteral tube feeding nutrition after hospital discharge of esophageal cancer patients who have undergone esophagectomy. Esophagus 2021;18:504-512.
[2] Ojo O, Brooke J. The use of enteral nutrition in the management of stroke. Nutrients 2016;8(12):827.
[3] Committee on Nutrition Services for Medicare Beneficiaries, Food and Nutrition Board. The Role of Nutrition in Maintaining Health in the Nation's Elderly: Evaluating Coverage of Nutrition Services for the Medicare Population. 2000. ISBN : 0-309-51551-3. Pg 319-320.
[4] Barazzoni, R., et al. ESPEN expert statements and practical guidance for nutritional management of individuals with SARS-CoV-2 infection, 2020. Clin Nutr. 2020 Jun; 39(6): 1631–1638.
[5] *Id.*
[6] ASPEN Board of Directors. Clinical Guidelines for the Use of Parenteral and Enteral Nutrition in Adult and Pediatric Patients J Parenter Enteral Nutr. 2009;33 (3):255-259.