April 8, 2021

Dear DME Medical Directors:

On behalf of our members, the Oley Foundation Board of Trustees is writing to request a revision to the Proposed Enteral Nutrition Local Coverage Determination and Policy Article DL 38955 to prevent undue suffering and make it consistent with current medical practice.

The Oley Foundation was founded in 1983 by Dr. Lyn Howard and her patient, Clarence “Oley” Oldenburg to enrich the lives of those living with home parenteral and enteral nutrition through education, advocacy, and networking. The Oley Foundation is a national, independent, non-profit organization representing over 24,000 members. On behalf of our members, we would request re-evaluation and revision of the following language for coverage of specialty nutrient formulas:

Proposed EN LCD (DL38955)

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

This language would require a failed trial of standard formula prior to specialty formula being considered for coverage. In many cases, such as patients with history of malabsorptive disorders, pancreatitis, partial or complete pancreatectomy, or chyle leak, this would result in significant complications, such as diarrhea, gas/bloating, or worsening of chyle leak.
Additionally, recent literature has demonstrated that use of specialty formulas such as peptide-based enteral feeding (PBD) can be cost effective. Mundi et al recently published review of PBD use in adult home enteral patients. In patients who were transitioned from standard formulas to PBD, there was significant reduction in nausea/vomiting (42% to 22%), diarrhea (46% to 25%), and abdominal pain/cramps (22% to 5%), and individuals with no symptoms increased from 21% to 49%. Healthcare utilization also declined significantly, including mean number of phone calls (1.8 ± 1.6 to 1.1 ± 0.9, P = 0.006), mean number of emergency room visits (0.3 ± 0.6 to 0.09 ± 0.3, P = 0.015), and mean number of provider visits (1.3 ± 1.3 to 0.3 ± 0.5, P < 0.0001). Similarly, LaVallee et al evaluated the use of PBD using medical claims data and found that adults experiencing no GI intolerance increased from 41% to 59% after transition to PBD. They also noted a reduction in healthcare utilization with the proportion of patients with at least one hospital inpatient visit decreasing from 100% (1022/1022) to 72% (737/1022) and the mean number of inpatient visits per patient decreasing from 15.6 to 13.0.

References:

Given these considerations, we would request the addition of language that allows documentation of medical necessity of specialty formula along with why a trial of standard formula would not be medically appropriate to suffice for coverage.

Sincerely,

Beth Gore, President
Joy McVey Hugick, Vice President
James Senese, Treasurer
Lillian Harvey Banchik, Secretary

On behalf of the Oley Foundation Board of Trustees

Submitted by email, 4-9-2021
ENTLCDComments@cgsadmin.com