

OPEN MEETING: Enteral Nutrition

Meeting Date & Time:	March 30, 2021, 12:00 p.m. ET
Facilitator:	Jody Whitten
Location:	Virtual Meeting

Jody Whitten: Good morning or afternoon, everyone, and welcome to the Open Meeting for Enteral Nutrition Local Coverage Determination, known as LCDs. For those of you scheduled to present your comments today you should have received a webinar invitation with instructions, and we have verified that our speakers are able to speak, and we can hear them loud and clear. So, I will now turn the call over to Dr. Brennan for her opening remarks. Dr. Brennan?

Dr. Stacey Brennan: Thank you, Jody. It's now noon Eastern Time so we will begin. Welcome everyone to our Virtual Open Meeting covering first the new Enteral Nutrition Local Coverage Determination, followed by the new Parenteral Nutrition Local Coverage Determination. My name is Dr. Stacey Brennan, the Jurisdiction B DME MAC Medical Director from CGS Administrators, LLC (CGS). Joining me today, are Dr. Robert Hoover from Jurisdiction C also from CGS, Dr. Smitha Ballyamanda from Jurisdiction A, and Dr. Peter Gurk from Jurisdiction D, both of whom are with Noridian Healthcare Solutions. The four of us work together to write these policies.

We are looking forward to hearing your comments regarding the new Enteral Nutrition LCD. Please be sure to write down all comments that are given verbally and send them to us via e-mail at ENTLDCOMMENTS@cgsadmin.com. These details are also available on the DME MAC websites. And please remember that we may only respond to written comments. The comments are due by the close of business on Saturday April 10, 2021. Also, today's meeting is being recorded and the proceedings will be posted on the DME website shortly. Your consent to the usage of your recorded voice and comments is given by signing into this meeting. Please also be careful about sharing any personal health information in your verbal comments. We have two commenters who have pre-registered to speak about the new Enteral Nutrition LCD. We are only permitting registered commenters to speak at today's meeting, but anyone may submit written comments to the e-mail address I mentioned before. For those pre-registered commenters, each of you will have 25 minutes to speak. To everyone on the phone who is listening in, please remember to mute your phone line and computer. And please do not place the call on hold because we will all be forced to listen to background music. Also, we ask that speakers are prepared to begin their comments immediately after being called upon.

Now, let me briefly summarize the proposed Enteral Nutrition LCD. Due to the evolution of enteral nutrition clinical paradigms, the DME MACs retired the existing LCD on November 12, 2020. Subsequently, the DME MACs have created this new proposed Enteral Nutrition LCD based upon current supporting literature and guidelines which are included in the Summary of Evidence. This proposed LCD was posted on February 25, 2021. Now, back to Jody to introduce our first of two speakers. Thank you.

Jody Whitten: Thank you, Dr. Brennan. We have previously informed speakers of the time limitation, but just as a reminder, you have 25 minutes for your presentation. I will give you a one-minute warning and then a thank you once your 25-minute limit has expired. So, our first commenter today is Connie Sullivan. Connie, your line is open. Are you there?

Connie Sullivan: I am here. Thank you very much.

Jody Whitten: You're welcome.

Connie Sullivan: So, thank you very much to the DME MACs for allowing this opportunity for public comment during this meeting and I just will start by introducing myself. I am Connie Sullivan. I'm the President and CEO of the National Home Infusion Association. We are a trade association that represents providers of enteral and parenteral nutrition products, as well as manufacturers and distributors of these products and supplies and equipment. I won't need 25 minutes for my



comments, but I appreciate the generous amount of time to speak today. My comment is focused on specialty formulas for enteral products.

Under the proposed EN LCD, specialty formulas 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. The proposed EN Policy Article goes on to state that 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 diagnosis, the formulas tried, and unfavorable events associated with the standard formula.

Our recommendation on this particular part of the proposed EN LCD pertains to the language around medical necessity for specialty enteral formulas. In this particular case, we would recommend that you all consider reverting back to the language in the prior retired EN LCD. While we feel that these new proposed LCDs are a much-improved set of LCDs for these product lines they're in, in this particular case, we think the language in the prior LCD is clearer and offers more direction for the clinicians and also for the providers. An alternative to the previous language could be to add language that states something along the lines of in the case that 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. And that concludes my comments. Thank you very much.

Jody Whitten: Thank you. Our next commenter is Penny Allen. Penny, your line is open. Penny, you might have put yourself on mute, so if you could take yourself off mute, that would be helpful.

Penny Allen: I'm all set, thank you, I was clicking much too fast. Good afternoon and thank you so much for allowing us to present, and it's nice to speak to the physicians on the DME MACs once again. My name is Penny Allen. I'm a Registered Dietitian. I'm certified in nutrition support and I'm a Fellow within ASPEN. My role is Chair of the Public Policy and Advocacy Committee. So, on behalf of myself, Dr. Patty Byers and Jay Mirtallo, I'm representing the American Society for Parenteral and Enteral Nutrition.

So just a quick summation and like Connie, I will not require 25 minutes. But to give you just a little bit of background for those in the audience, ASPEN is a national interdisciplinary organization that is dedicated to improving patient care by advancing the science and practice of clinical nutrition and metabolism. ASPEN was founded in 1976 and members are involved in the provision of clinical nutrition therapies, including parenteral and enteral nutrition.

ASPEN is made up of more than 6000 members from around the world, and this is a community of dietitians, nurses, pharmacists, physicians, scientists, and researchers, students, and health professionals from every facet of nutrition support clinical practice, research, and education. We set the standards on a national level for what is appropriate practice including the appropriate use of parenteral and enteral nutrition.

Again, like the National Home Infusion Association, we are very optimistic regarding the changes that have been taken with the proposed new PN and EN LCDs. One caution is the limits of the prosthetic device benefit. So, in the future, we welcome and are grateful for the ongoing engagement with the DME MACs. since the prosthetic device benefits still remains a little bit of an access issue for those patients who may not require long term parenteral and enteral nutrition, but that's a topic for the future. And again, we thank you for the opportunity to provide comment.

Much like the National Home Infusion Association, our issue really is along exactly the same lines, to eliminate the mandated trial of a standard formula, where appropriate, based on the prescribers documentation of medical necessity, due to possible contraindications of utilizing a standard formula for a beneficiary's given disease state and diagnosis.

Again, not to repeat this same thing, this is really just with the proposed EN LCD states, that a standard formula should be trialed initially and then, if documented the beneficiary's diagnosis, what formulas were trialed and any unfavorable events that might be associated with the standard formula.

The example quoted in the proposed EN LCD is if a treating practitioner orders a diabetes specific formula first, without having trialed a standard formula, then, potentially, that would not be covered.

On the next slide, we outline some suggested disease states where, a little bit more intense, perhaps, than than diabetes, but, for those patients who have severe GI malabsorptive disorders, potential allergies to ingredients that may be in standard formula such as soy oil, corn oil, or any

other components of that standard formula, diseases like pancreatitis, or renal disease where a patient may be limited by the amount of protein or certain types of electrolytes that may be found in a standard formula.

Basically, ASPEN is recommending looks similar to NHIA that you know, the medical necessity for a special enteral formula must be justified for each beneficiary. And if that, if a special enteral nutrition formula is provided, without the trial of the standard formula first, and the medical record does not document why that item was medically necessary, it will be denied as not reasonable and necessary. So perhaps, the addition of language that might state, in those cases where the trial of standard formula is either contradicted, could potentially cause harm to the patient, could incite more complications from a GI perspective for that patient, the medical record must document the medical necessity in detail of the rationale for the use of the specialty formula and why the standard formula trial could not be performed. So that is all we had. Otherwise, we are grateful for the opportunity and are in line with the rest of the recommendations in the proposed EN LCD.

Jody Whitten: Well, thank you both for your comments. This concludes the verbal comments for the Enteral proposed LCD. I will now turn the call back over to Dr. Brennan for closing remarks.

Dr. Stacey Brennan: Thanks, Jody, and thank you, too, Connie and Penny for your comments today. We really appreciate them. Please remember to send these in writing and any further full text or peer-reviewed articles, to help support any comments, which may not already be included. Again, the comment period will end on Saturday, April 10, 2021. And, following our collection and consideration of all comments received during the entire open comment period, we, Medical Directors will discuss any potential modifications to the proposed LCD and then, post a final LCD along with the Response to Comments document. The Enteral Nutrition LCD will become effective at least 45 days following the posting of the final LCD. Please refer to our DME MAC websites for any updates.

And now, back to Jody, who will hand the program over to Dr. Ballyamanda. Thank you so much.