OPEN MEETING: Parenteral Nutrition

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

Jody Whitten: OK, well, good morning or afternoon everyone, depending on where you're located. This is Jody again with Noridian and welcome to our Open Meeting for Parenteral Nutrition Local Coverage Determination, as scheduled at 1:10 PM Eastern Time. For those of you scheduled to present your comments today you should have received a webinar invitation as well as special instructions and we have just confirmed that everybody can speak and unmute their line, so, we should be good to go in that field.

Um, let's see. If I am, I would like now to turn the call over to Dr. Ballyamanda for her opening remarks. Dr. Ballyamanda?

Dr. Smitha Ballyamanda: Thank you, Jody.

Jody Whitten: OK, good.

Dr. Smitha Ballyamanda: Is everyone able to hear me?

Jody Whitten: Yep, we can hear you loud and clear.

Dr. Smitha Ballyamanda: Alright. Great.

Good afternoon, everyone, and welcome to our virtual meeting. This meeting is regarding the new Parenteral Nutrition Local Coverage Determination. My name is Dr. Smitha Ballyamanda the Jurisdiction A DME Medical Director, DME MAC Medical Director. I work for Noridian Healthcare Solutions and with me today also from Noridian Healthcare Solutions is Dr. Peter Gurk from Jurisdiction D, and from CGS, is Dr. Stacey Brennan with Jurisdiction B, and Dr. Robert Hoover with Jurisdiction C. We're looking forward to hearing your comments regarding the new Parenteral LCD. And, while we value your comments today, please remember that we may only respond to written comments. So, please put these comments in writing, and send them to us via e-mail, at PENRECON@noridian.com. Again, that's PENRecon@noridian.com. Details for submitting comments are also available on the DME MAC websites. Please remember that we can only respond to written comments. These comments are due by the close of business on Saturday, April 10, 2021.

Also, we will be recording the meeting today which will be posted on the DME MAC websites. You are giving your consent to use your recorded voice and comments by signing into this meeting. So, please be careful about sharing any personal health information in your verbal comments.

We have five commenters who are pre-registered to speak. We are only permitting registered commenters to speak at today's meeting, but anyone can submit written comments to the e-mail address I mentioned earlier. For those who pre-registered, those commenters, each of you will have 11 minutes to speak. And for those on the phone who are listening, please mute your phone line and the computer.

We ask that you do not place this call on hold, because we will all be forced to listen to background music as a result. So, please, if you need to get off the call, just hang up. But by all means, by no means, please do not put us on hold.

Speakers should be prepared to begin their comments immediately after being called upon.

Now, a little bit about this new proposed Parenteral Nutrition LCD. Due to the evolution of clinical indications and management of the parenteral nutrition over time, the DME MACs had decided to retire the previous LCDs and have created new Parenteral Nutrition LCD based on current supporting literature and available guidelines. The new proposed parenteral nutrition policy language was posted on February 25, 2021.

And and that's about it in a nutshell. So, I will turn this back over to our moderator, Jody, from Noridian. Thank you, Jody.

Jody Whitten: Oh, thank you, Dr. Ballyamanda. We have previously informed speakers of the time limitation, but just as a reminder, we actually have 12 minutes for each of your speaking presentations. I'll give you a one-minute warning and then I'll thank you at 12 minutes to let you know the time has expired. So, our first commenter comes from Connie Sullivan. Connie? Your line is open.

Connie Sullivan: Thank you very much and I'll introduce myself again for those who might be new to this session. I'm Connie Sullivan. I'm the president and CEO of the National Home Infusion Association. We are a trade association that represents home infusion providers, who are primarily pharmacies that offer parenteral and enteral nutrition products, and we also have members who are manufacturers and distributors of products and supplies and equipment that serve this population. I would like to start by saying that NHIA is very pleased with the direction of the DME MACs, with regard to the proposed Parenteral Nutrition LCD. We view these changes as a significant improvement over the recently retired PN LCD and believe the proposed changes will improve beneficiary access to this important therapy. So, thank you for the opportunity to provide comments in the public meeting and we will submit our written comments for your consideration, as well, as you move forward with developing the final LCDs.

For this slide I just wanted to offer a summary of our recommendations, but I'm going to go through them one by one, so, you can go to the next slide. Thank you.

So, our first recommendation has to do with the home mix codes that are associated with the PN LCD. As I'm sure you're aware that preparing parenteral nutrition products requires combining up to as many 40, as 40, or more different drugs and ingredients. And this is done in pharmacies that are licensed and compliant with standards for sterile compounding practice. Our primary standard for sterile compounding comes from the United States Pharmacopeia, Chapter 797, which governs practices around facilities and processes associated with preparation of sterile products, which, of which parenteral nutrition is one of those primary products that are made by our pharmacy members. As you can see, the text from the currently effective chapter of USP 797 is provided here, which classifies parenteral nutrition as a medium risk type of compound. So, essentially, providers are mixing commercially manufactured, sterile ingredients, into a final container for patients to use, and these are customized for individual patients. These standards have been well developed over the last couple of decades and have now become the standard of care, as far as preparation for home parenteral nutrition.

Home mixing, as it's described in the LCD, is no longer a common practice. And as you can see on this slide here, that with the utilization data from 2014 to 2018, these kit codes reflect how parenteral nutrition is billed, and almost exclusively it's being billed as a premixed kit. The home mix codes that are represented here are probably coding errors and anomalies, and so the the point we want to make here is that by eliminating these codes, which is our recommendation, this would have no negative impacts on patients or providers.

On the next slide, we've provided you with a few photos of what the inside of a typical clean room pharmacy looks like, where these products are made. And these, again, are, these facilities are built to USP 797 specifications, as compared to what a typical patient kitchen might look like, where that that home mixing would occur. The process that we use for preparing these products involves automation as well. It's not a manual process anymore and that automation allows us to ensure greater accuracy of the ingredients of the parenteral nutrition and also, that the ingredients are prepared in a manner that avoids things like precipitation of the individual ingredients.

So, our final recommendation for home mix codes related to the proposed LCD is that these be removed. And, they are obsolete and no longer compliant with our standards and would create a less safe product for patients.

Our next recommendation has to do with lipid dosage. The proposed LCD requires the ordering practitioner to document the medical necessity for lipid use greater than 1500 grams per month. Lipid injectable emulsions are an essential component of parental nutrition, and dosing recommendations for lipids with PN are generally provided in grams per kilogram per day and can vary based on the type of product that is used. So, our recommendation, regarding the lipid limit that's in the proposed LCD, is that either be removed altogether or changed to be a weight-based dosage formula which is generally in the format of grams per kilogram per body weight per day. So, this would be the standard way that lipids are ordered and a limit that is consistent, is written

consistent with that format would be more useful to providers. And, we do feel like if you wanted to include a limit, the two grams per kilogram body weight per day would probably [inaudible].

Our next recommendation is related to the timing evaluation requirements. Sorry, I'll let you get back to the slide. There you go, thank you. The proposed PN LCD states that the treating practitioner is required to evaluate the beneficiary within 30 days prior to the completion of the DME information form or DIF. The DIF is created by the supplier based on the standard written order, which may be obtained after the start of care. So, the supplier will have the standard written order and the completed DIF on file prior to billing for services, but the timing of the practitioner's evaluation, we don't believe should be tied to the DIF. The recommendation for, for this component is that the treating practitioner is required to evaluate the beneficiary within 30 days prior to the initiation of parenteral nutrition. You can go to the next slide.

Our next recommendation actually has to do with documentation, and there's actually two places where this documentation is used. It's here on the enteral nutrition requirement. But it also comes up in the section around the documentation of medical necessity for protein orders outside of range, dextrose, and lipids, as well. And our point here is that parenteral nutrition patients are managed by teams of clinicians, not necessarily one practitioner, and orders frequently change for these patients. And so our recommended change in the language here is that we change the "ordering practitioner must document" to "the medical record, must reflect these changes", and the reason for this proposed change is to ensure that patient care is not delayed and that nutritional component changes can be made timely. And, you know, we don't disagree that it should be documented, that there's a need for these out of range requirements or when certain requirements can't be met, but we would just recommend that it be part of the medical record to allow different clinicians to satisfy that requirement. You can go to the next slide.

So, the next slide is about caloric range. And our recommendation here is with regard to the parenthetical. We support the recommendation to either remove the parenthetical altogether or refer in this case back to the retired PN LCD, which included parental, enteral. and oral components to be considered as part of that daily intake. The current proposed language, we are concerned, could be interpreted to mean that patients cannot take any food by mouth, for fear of losing coverage for their parenteral nutrition, even if that oral intake, excuse me, minimally contributes to their caloric requirements. And for some patients, that small amount of oral intake can be very important to their emotional needs. You can go to the next slide.

The next recommendation is related to the kit codes daily allowance. This recommendation is more of a clarification that would clarify the PN LCD in a similar manner as to the proposed EN LCD. There can sometimes be confusion during audits about whether these have to be specified and meet the refill requirements and so this is just recommending to use similar language to the EN LCD where it's very, very clear that the refill requirements are not applicable to these HCPCS codes. We feel this recommendation would reduce administrative burden associated with the PN audit process, for all involved. You can go to the next slide.

This one here is simply just pointing out that we believe there was a typo in the proposed LCD around the code B4186. It was not listed in the table of Group 1 HCPCS codes and we believe it was meant to reference B4187 for OMEGAVEN.

And then I have one more recommendation. I feel like that one of our slides might have been missing here. So, I think that recommendation around, excuse me one second. I'm sure I covered everything. Nope, I think I do have it covered. I'm sorry, there, two of our slides got combined. So, I think that concludes our comments for the proposed PN LCD and very much thank you again for this opportunity and for the, the, the direction that the PN LCDs or are moving in. Thank you very much.

Jody Whitten: Thank you, and our next commenter is Penny Allen. Penny, your line is open, are you there?

Penny Allen: Yes, I'm here. Thank you so much and good afternoon everyone. My name is Penny Allen and I'm a Registered Dietitian, certified in nutrition support and today I am representing as Chair of ASPEN's Public Policy and Advocacy Committee. For those who weren't on the previous session, a quick summary of who ASPEN is, the American Society for Parenteral and Enteral Nutrition is dedicated to improving patient care by advancing the science and practice of clinical nutrition and metabolism. This is an interdisciplinary organization of subject matter experts whose members, whether they be dietitians, nurses, pharmacists, physicians, scientists, and researchers and students, are involved in the provision of clinical nutrition therapies, with over 6000 members

from around the world. ASPEN is a diverse community and in the United States sets the standards for care and determination of when the use of PN and EN is appropriate.

Again, as Connie Sullivan stated, we are thrilled regarding the changes and the direction that the DME MACs are taking, have taken and are incredibly grateful that they are open and receptive to the paradigm shifts that have taken place within nutrition support in the last couple of decades. We, we also, view the proposed PN LCD as it is a tremendous improvement in beneficiary access to lifesaving home parenteral nutrition therapy as compared to the somewhat restrictive retired PN LCD. There are some limitations of concern with the prosthetic device benefit that, as long as we remain open and receptive to discussions moving forward in the future, I think that this will open up the door for many patients and beneficiaries who had not had been able to have access to home PN and EN, and moving forward, those that perhaps may not need it for the long, long term, or indefinite term may be able to benefit in the future. But overall, we are grateful for the opportunity to provide comment. You will notice in the next few slides that the position of ASPEN is right in the same direction as the National Home Infusion Association. So, what I hope to do is comment on some of the clinical pieces of the LCD and provide a little bit of color and background to support that.

Summary of recommendations. Again, we'll go through these slide by slide, So, I won't spend time on this, but this is basically a summary of exactly what we would recommend to change as well.

If we jump to the home mix codes, and, again, this is pretty much the same exact recommendation coming from the National Home Infusion Association. When the National Coverage Determination was created in 1984, during that time period, there were patients, and I, having been in the field of home nutrition support for greater than three decades, I recall specific patients saying that they, they used to mix their own TPN. They were shipped individual, you know, containers of dextrose, amino acid, lipid, and they really put it all together themselves, in the home setting, as you saw in some of the previous slides. Today, that that just isn't what takes place and it hasn't for decades. So, combining with the notion that this is an obsolete practice, non-compliant with compounding standards in the US today, and unsafe, based on what we know about sterility and safety. So, ASPEN also strongly recommends removing all home mix codes from the PN LCD and policy article. Next slide, please.

Again, not to reiterate, you know the exact same data, but if you look, you'll note that there are very few home mix kits being billed in the last, you know, the 4 or 5 years, between 2014- 2018. So, we definitely feel that these are probably done in error since in the field of home infusion today there are no patients that we've been aware of, within the ASPEN organization, that are doing home mix. Next slide, please.

The next few slides will deal with the documentation of PN nutrient ranges related to the proposed PN LCD, specifically this paragraph that states: the ordering practitioner must document the medical necessity for protein orders outside of the range of 0.8 to 1.5, dextrose concentration less than 10%, or lipid use greater than 1500 grams. We'll examine a couple of pieces of this, but first and foremost, we are in line with NHIA's recommendation that due to the number of clinicians in the hospital setting who are involved in the management of a parenteral nutrition patient, it may be that a hospitalist is involved, there could be residents and fellows, there could be a nurse practitioner, and so on and so forth, depending on the state. so, we would agree with the recommendation to change, "the ordering practitioner must" to "the medical team must document" or "the medical record must reflect" whatever, whichever is appropriate. Next slide.

When we speak about fat restriction, the previous retired LCD had a restriction of 1500 grams per month. To put that into perspective unless you're a nutrition support clinician, this would equate given there's 30 days in the month, that would be about 50 grams per day for a patient. Above and beyond that, there is always the need for additional documentation on behalf of the practitioner and the submission to CMS. Usually lipid is dosed at a ballpark of one gram per kilogram a day. So, if you think about the 50 grams per day as a limit, that means any patient, over 110 pounds we would consistently have to ask the physician to document why that patient needed lipid above and beyond that. So, again, we support the suggestion to either remove the lipid limit or change it to a weight, weight-based dosage formula, like other ingredients within the prescription, to a max of 2 grams per kilogram per day. The majority of patients are in that ballpark of 1 to 1.5 grams per day and if you flip to the next slide, it's a bit busy, but when we submit written comment, we'll provide the references here that, you know, I'd have to put my reading glasses on, but if you look at the box on the left-hand side, the majority of recommendations are anywhere between that 1 to 2 grams per kilogram of body weight per day for an appropriate dose of fat or lipid per day. Next slide.

When we, when we speak about the protein range, being between 0.8, which would be for many of us on this call, a normal, healthy protein dose for a patient or beneficiary with absolutely no clinical needs going on, to a max of 1.5 grams per kilo, in the interest of minimizing the amount of additional documentation the practitioner must provide, and then on the audit process as well, we're recommending that the protein range be increased to 2 grams per kilo from 1.5 in the, in the, in the spirit of current paradigm shifts, and practice patterns, to better meet patient needs. So, again, if we look to the next slide, somewhat of a busy chart. But we'll submit this with our written documentation along with peer-reviewed articles showing that in the top left, where you see protein slash amino acids, you know a stable patient is in that range of 0.8 to 1.5. But many patients, most patients at home on parenteral nutrition today are not necessarily stable, particularly when they come out of the hospital. So, most often, the range could be anywhere between 1 to 2 grams per kilogram of protein per day. Hence our suggestion that possibly the protein range be extended to 2 grams per kilo, to be in line with current practice patterns. Next slide.

We are in support of NHIA's recommendation that the treating practitioner should be required to evaluate the beneficiary within 30 days prior to the initiation of parenteral nutrition, understanding that the evaluation of the patient's nutritional status, their nutritional needs, making the recommendations for the appropriate amount of calories, protein, lipid, etc., should take place before PN is started. Not necessarily before, you know, completion of the DME information form, which may not take place for 30, 45 days after the initiation. It shouldn't, but there are times when that is definitely extended beyond the initiation of PN. Next slide please.

The Enteral Nutrition Consideration Clause. In the proposed PN LCD it states, "For parenteral nutrition to be considered reasonable and necessary, the ordering practitioner must document that enteral nutrition has been considered but deemed impractical, inadequate, or it might exacerbate GI tract dysfunction." So, again, this is a language recommendation, changing that phraseology of ordering practitioner "must" to either "the medical team must" or "the medical records must reflect that enteral nutrition is, is impractical, inappropriate" and so, forth. Next slide.

When we look at the caloric range interpretation, again, we support the notion that there there does appear to be confusion amongst home infusion providers, or home PN providers, in terms of what that means. You know, meaning the proposed PN LCD states, a total caloric daily intake with the parenthetical, meaning parenteral of 20 to 35 calories per kilogram per day is considered reasonable and necessary. There's a difference of opinions of does that mean that the PN, is, is supposed to be 20 to 35 cals per kilogram per day? And if the PN prescription falls outside of that, is the additional documentation necessary? Or, is it just that, in general speaking, in the previously retired LCD, when we, when it stated, you know that, oral enteral/parenteral, that's just a general terminology that most people in the world need 20 to 35 Kcals per kilogram of body weight per day. So, in order to minimize the burden of administrative documentation and so forth, ASPEN is just recommending clarification of the intent that, if this is meant to be that the parenteral nutrition itself provides that 20 to 35 cals per kilogram per day, or is there additional documentation required. Next slide. Kit codes.

Jody Whitten: You have one-minute remaining.

Penny Allen: Yep, OK, kit code, pretty much the same thing. Recommend doing away with a request for refill, because this is a given that this is allowed within within the daily allowances. And I believe that might be my last slide, in the nick of time. The typo regarding the lipids as well, same as NHIA, that we believe that there's a typo. So, just asking for clarification if this is meant to reference B4187.

And I believe that is the last side. So, thank you, thank you for all of your time and consideration. And I look forward to hearing the results of the new LCD.

Jody Whitten: Great. Thank you. And our next commenter is Robert Coston. Robert, your line is open.

Robert Coston: Good afternoon, everyone. Well, to be honest with you, our comments were addressed by the previous two speakers. So, I'm happy to yield my time to the next commenter.

Jody Whitten: Alright. Thank you.

Robert Coston: Certainly.

Jody Whitten: And our last commenter for today is Amanda Scippa. Are you there, Amanda?

Amanda Scippa: Yes I'm here, thank you.

Jody Whitten: Go ahead. Thank you.

Amanda Scippa: My name is Amanda Scippa. I'm the Registered Dietitian Supervisor at KabaFusion, a national specialty home infusion company that provides enteral and parenteral nutrition to over 5000 patients. This was touched on during, by the last two speakers, but I am speaking today against the need for medical necessity documentation of lipid use greater than 1500 grams per month. ASPEN recommends 10 to 35% of total calories derived from fat. Calories are calculated using a weight-based calculation, therefore, restricting lipid dose using a weight-based model would be more clinically appropriate than using a total gram per month restriction. To give you an example, if we calculate the needs of an 80 kilogram person, which is approximately 175 pounds requiring 30 Kcals per kilogram per day, which is fairly common caloric requirement, it would require 2400 calories per day. Even if we only provide 25% of their total calorie needs from lipid, this would equate to 1800 grams per month or 60 grams per day, exceeding the amount allotted in the proposed LCD.

So, as previously mentioned, patients are the larger sizes would require additional documentation, and therefore we're recommending a weight based lipid intake of at least 1 gram per kilogram per day be reasonable and necessary, as outlined by ASPEN, rather than the medical necessity documentation for the total grams per month.

Additionally, I'm seeking clarification on if the Medicare patients are required to initiate parenteral nutrition in a hospital setting. The LCDs states: "the treating practitioner is required to evaluate the beneficiary within 30 days prior to the completion of the DME information form," with no other mention of hospitalization requirements. This is in comparison to the NCD that states that "following a period of hospitalization, which is required to initiate PN and to train the patient on catheter care, solution preparation and infusion technique, the parenteral nutrition can be provided safely and effectively in the patient's home." Therefore, we are requesting clarification on if hospitalization is required for the initiation of PN, or if it is something that can be started in a home setting.

These are just the references and I appreciate the opportunity to comment today.

Jody Whitten: OK, thank you. And this concludes our verbal comments for the Parenteral Nutrition LCD, the proposed LCD. I'll now turn it back over to Dr. Ballyamanda for her closing comments.

Dr. Smitha Ballyamanda: Thank you, Jody. And just wanted to confirm everyone can hear me, correct?

Jody Whitten: Yes, we can.

Dr. Smitha Ballyamanda: Thank you. So, again, we would like to thank all the members of the public and stakeholders for your thoughtful comments today. Once again, please remember to send your comments in writing. If you have any full text or peer-reviewed articles to help support your comments, that were not included in the bibliography, please send them along as well. As another reminder, the comment period will end on Saturday, April 10, 2021. Once we have considered and collated all of the comments received during the open comment period, we will consider any changes necessary, as a result of the comments received and then post a final LCD, along with a Response to Comments document.

The final LCD will take effect a minimum of 45 days following the posting of the final LCD.

So, for any updates, please refer to the DME MAC websites and I want to thank everyone for your participation today. And we will formally adjourn this meeting at this time. Thank you.