OPEN MEETING: Oral Appliances for Obstructive Sleep Apnea, Positive Airway Pressure (PAP) Devices for the Treatment of Obstructive Sleep Apnea, and Respiratory Assist Devices

Meeting Date & Time:	March 30, 2021, 10:00 a.m. ET
Facilitator:	Jody Whitten
Location:	Virtual Meeting

Jody Whitten: Thank you everyone for taking the time to join us today in our open meeting for the following Local Coverage Determinations, known as LCDs. The first one is Oral Appliance for OSA, then we have Positive Airway Pressure Devices for the Treatment of OSA, and then Respiratory Assist Devices. For those of you scheduled to present your comments today, you should have received a webinar invitation with instructions. Also, the follow up e-mail was sent with the order the speakers will present their comments, and a few important reminders, including first, making sure you log onto your webinar. And we have already checked to make sure everybody's audio is synced up and working without any background noises. So that's really good. So, with that said, I would like to now turn the call over to Dr. Hoover for his opening remarks.

Dr. Robert Hoover: Thank you, Jody, and first happy doctor's day to the physicians on the call. Good morning and welcome, members of the public and interested stakeholders, to this virtual public meeting.

I'm Dr. Robert Hoover, DME MAC Medical Director for CGS, the Jurisdiction C DME MAC, and one of the four DME MAC Medical Directors responsible for the proposed Local Coverage Determinations that we'll be discussing today, the Positive Airway Pressure Devices for the Treatment of Obstructive Sleep Apnea or PAP LCD, the Respiratory Assist Device LCD, and Oral Appliances for the Treatment of Obstructive Sleep Apnea. We've allotted almost two hours for comments on these proposed LCDs since all 3 have similar proposed language. Obviously, we don't have to take the full two hours, but we have that allotted for this meeting. Following a break, the Medical Directors will be hosting another open meeting to solicit comments on the new Enteral and Parenteral Nutrition LCDs. So, if you've joined for that call, you may want to check back in in a couple of hours. Some housekeeping details, we'll be recording the meeting today, audio only, and we'll have the recording posted on the DME MAC websites in a short period of time after the conclusion of the meeting. By signing in today you're giving your consent to the use of your recorded voice and comments. Please be mindful of sharing any personal health information in your verbal comment.

And we also ask that any comments made today also be submitted in writing and you'll have the e-mail addresses at the end of this presentation. The comment period closes on Saturday April the 10 at 5 PM and details for submitting comments, in addition, as I said, at the end of this meeting will also, they're also available on the DME MAC websites. We have several commenters presenting today, Jody Whitten, who you heard just a moment ago, one of the Noridian Policy Coordinators, will be moderating the meeting and queuing up the speakers. Only registered commenters will be allowed to comment at today's meeting, but anyone can submit written comments to the addresses that you'll see shortly.

For those commenting we'll strictly enforce the time limits to stay as close as possible since we do have a follow-on meeting. Probably the most important of anything that I've just said is take a moment to locate your mute button. We ask that you mute your line if you're not speaking. Do not, please do not place it on hold or will all be subjected to whatever hold music or hold message that

you have on your phone. Speakers should be prepared to present your comments immediately when they're called upon. So, we'll go to the next slide.

I'll introduce the DME Medical Directors now. Dr. Smitha Ballyamanda is the jurisdiction A Medical Director at Noridian Healthcare Solutions. Jurisdiction A is 11 Northeastern states and the District of Columbia. She's a family physician with a specialty certification in Sports Medicine and has been a DME Medical Director for 3 years. Dr. Stacey Brennan is the Jurisdiction B Medical Director at CGS Administrators. Jurisdiction B encompasses 7 mid-western states and she's a family physician. She's been a DME Medical Director for 12 years. Dr. Peter Gurk is the Jurisdiction D Medical Director at Noridian. Jurisdiction D is 17 western U.S. states and 3 territories. He's a family physician and has been a DME Medical Director for 6 years. And as I mentioned, I'm Dr. Robert Hoover the Jurisdiction C Medical Director. Jurisdiction C is in the south-east, encompassing 15 states, Puerto Rico, and the U.S. Virgin Islands. I'm an internist by training and have been a DME Medical Director for over 20 years.

So now I'll go over the highlights of the proposed LCD. You may have noted that the PAP and RAD and Oral Appliances proposed LCDs have a common proposed change involving revising this section on sleep testing. The DME MACs proposed to modify the sleep test section to defer to the Coverage and Payment Rules for Diagnostic Sleep Tests in the CMS NCD manual at 240.4.1, and in addition, also to the A/B MAC LCDs, and their Coding and Billing Articles for sleep testing.

As a reminder, for those who will be commenting today, it would be helpful to the Medical Directors if you state if your comments apply to all 3 LCDs, or if it's just one or more, and also, be clear if your comment only applies to a specific LCD. Finally, we ask that you address your oral comments to the proposed changes to the LCD.

The Medical Directors appreciate that you may have comments about other criteria in the LCD and you're welcome to submit those in your written comments. However, in today's open meeting, we're really looking to solicit public feedback on the proposed LCD changes.

So, Jody, we'll now open things up for our public commenters.

Jody Whitten: Thank you, Dr. Hoover. We had previously informed speakers of the time limitation that, as a reminder, you will have 11 minutes for your presentation. I will give you a one-minute warning and then we'll let you know when your 11 minutes have expired. So, first up, today, we have Diana Guth. Diana, your line is now open. Are you there? Diana, you may have muted your own line. You need to unmute your line. We have unmuted it.

Diana Guth: Yeah, ok. Can you hear me now?

Jody Whitten: I can. Great, thank you Diana. Your time will go ahead and start now.

Diana Guth: Yes, hi, I want to thank you for the opportunity to voice my opinion. I'm, my name is Diana Guth, and I am a registered Respiratory Therapist. I'm the owner of Home Respiratory Care, located in Los Angeles, California, and I've been treating patients with sleep disorders for about 35 years. I ju, I thought I was going to be able to comment on more than just the proposed changes. And I, just from Dr. Hoover, says, I should limit myself to that. I did have some comments about other other problems that I've encountered in treating patients. So, I don't know if I should go forward with that.

Jody Whitten: Well, you have 11 minutes so.

Diana Guth: OK, all right, so I'll go, I'll put this out. OK. So, with the home sleep studies have been proliferated. And with, with, with that, the problems that I am seeing now are there, there are people who never had had titration studies in an attended study, and as a result, when they are treated with, with positive airway pressure, usually CPAP, or auto CPAP, it becomes really evident that they actually have complex sleep apnea. The, the central apneas emerge. But these, in order for these patients to get treated for that condition and then have to go back and have an attendant study. This is a problem, especially, right now during COVID because many of the sleep labs are not, not having attended studies. So that's one, one problem that I want to bring forth.

The other one is it in there there's a problem with patients, who especially have hypoventilation syndrome and severe COPD. These patients need, first need to have a trial on a, an E0470, which is the bi-level device without a backup rate. in order to then qualify for one that does have a backup rate. This has become problematic, I have seen patients that are in the hospital

hypoventilation syndrome who have never been on a bi-level device at all and they immediately need to be on, on a, on a RAD with a backup rate, but because of this problem, they go directly to a ventilator, which, you know, under normal circumstances, if they were, they just, they could not tolerate being on a machine without a backup rate So, they go directly to a ventilator, which is much more expensive, when, in fact, they would probably do fine with a, I guess it's a E0466, a RAD with a backup rate. And so these are the two big problems that I have observed, and I would encourage, changes be done to better treat the patients. Thank you so very much.

Jody Whitten: Thank you, Diana. Our next commenter is Michael. Are you there, Michael?

Dr. Michael Pagano: Hello, yes. Hi, this is—

Jody Whitten: [inaudible] unmute your line.

Dr. Michael Pagano: Hi, this is Dr. Michael Pagano. Thank you for having me on.
My background—

Jody Whitten: Oh great, go ahead.

Dr. Michael Pagano: Excellent. My background—

Jody Whitten: I'm sorry, go ahead.

Dr. Michael Pagano: I'm a, I'm a Dentist, I am a Diplomate of the American Board of Dental Sleep Medicine. I got started treating dental sleep medicine while I was on active duty with the Army. And, along some of the comments I want to make today, I just kind of want to bring in some of my military experience as far as what I've seen happening there versus what I'm seeing on a civilian side. As it pertains to this LCD specifically, one of the changes that I saw was under the coverage guidance in the Coverage Indications, Limitations, and/or Medical Necessity, it lists A through D, what must be covered for E0486, in the first line, A, it says "the beneficiary has an in-person clinical evaluation." Previously, that has said face-to-face. I would like to point out, especially as the world has changed with COVID how much more telehealth has come into the practice of medicine, and recommend that in-person remain documented as face-to-face clinical evaluation, which includes telehealth services.

Next, at line D, it says the device is provided and billed by a licensed dentist. My recommendation is to add, provided in-person, by a billed, and billed by a licensed dentist. Within dentistry we are starting to see kind of what's referred to direct-to-consumer, where patients are being sent impression kits, and they are really left almost treating themselves, and the care is being done remotely. By changing the language to say the device is provided in-person, it would help make this a more safe process for patients and reduce the chance of harm due to any side effects. Then I would also consider the Medical Directors to change, underneath there, they have definitions, and they have the definition of a treating practitioner. They specifically outline the term treating practitioner does not include a dentist, DDS, or DMD. I would encourage that, to, to include a dentist for the following reasons: The American Dental Association has recently recognized oral facial pain as a specialty. It is a residency program that includes sleep training, and dentists do regularly sedate patients where we are monitoring patient's airway, and making decisions based on that as well. Based on the number of patients that we see, approximately 50% of the American public will visit a dentist once a year. And we have an incredible opportunity to screen and get more patients diagnosed and treated and lower the overall cost of health care by preventing some of the comorbidities that go along with sleep apnea. That is all of the comments that I have for the proposed LCD. Thank you for taking the time.

Jody Whitten: Thank you. Thank you very much. Our next up for comments is Jan Palmer. Jan, are you on? Jan? You may be muted.

Jan Palmer: Yes. Good morning. Can you hear me?

Jody Whitten: We can. Thank you very much. Your time will start now.

Jan Palmer: Thank you, thank you for having me. I'm talking about the Oral Appliance for Sleep Apnea. A lot of my comments go along with Dr. Pagano's comments here. The first part is, on the draft LCD that the beneficiary has an in person clinical evaluation by the treating practitioner. Since the pandemic has happened we're seeing more and more telemedicine. And, perhaps we could add in there that the face-to-face could also be included in that with the telemedicine and

telehealth, when applicable, just so that it is in writing. That's the only comment on that slide. Next slide.

OK, so, this also goes along somewhat with what Dr. Pagano was talking about. So, some of the dentists that I work with, I do consulting with dentists all over the country on oral appliance therapy. I'm in the POEAGs and everything like that. So, one of the big questions is about the evaluation and management. And I know, I'm so, sorry doctors, I have bothered you all about this before, and I hate to keep harping on it. But, in the dental community, we don't know what we can and cannot charge because we're being told by Part B that it's OK to charge evaluation and management services under Part B for the dentists, as long as they have billing privileges. However, DME is telling us no, you can't do that. Everything from the initial evaluation and consultation through 5years is included in the coverage. So, we just need some clarification, yes or no, because one of the other LCDs that is out there, is stating that it's OK for the oral appliances to be, the evaluation to be billed. But, that article is not connected to this LCD, so we just need some clarification on that. Maybe if part B and DME could get together and just make a decision so that the whole community is understanding what we should do. That's that for that slide.

Oh, one of the things it's not mentioned in the LCD anyplace or any of the articles is the age of the PSG. Now, we all know that verbally, it's all stated, you know 12 months, we have 12 months for the PSG until it's no longer considered a viable PSG to use for Medicare beneficiary submittals for the claims. Could we put this in there someplace so that it's actually written, because everything else is pretty black and white, written down, except for this, and I know, I get challenged a lot from different providers and suppliers stating that it's not written down, so it doesn't matter. But, because of continuation of care, we want to make sure that everybody's on the same page there. So, that is my opinion that one. I think, do I have one more slide, or, it was at the end of that? Aah the RUL, ah, OK. I know this is a federal thing but is there anything to, any way to go about looking at this and having it reviewed because, unlike, you know, a cane or a crutch that is very durable, these oral appliances though they are durable, they are metal and acrylic.

And when you put this in your mouth for 6 to 8 hours a night for 5 years, that's a lot of hours and a lot of wear and tear, let alone if you have somebody that is a bruxer. So, most of the commercial insurances do allow after 3 years, to replace the appliance, if it's medically justified. And I was just wondering if there was any way we could get this reviewed to, to maybe have it moved to the 3-year mark. I know that they say that they will replace the oral appliance, but it's not due to wear and tear, it is only due to the natural cause– you know, natural events, hurricanes, stuff like that, if it gets lost or damaged. So, these are my thoughts on it. I think that's about it, and I thank you so much for your time.

Jody Whitten: Thank you. Our next commenter is Dr. Vohra. Dr. Vohra, your line is open.

Dr. Kunwar Praveen Vohra: Good morning, everyone. Yes. Can everyone hear me?

Jody Whitten: Yep. We sure can. Thank you. Go ahead. You have 11 minutes.

Dr. Kunwar Praveen Vohra: Thank you. I thank you for the opportunity to present today our comments on the proposed LCDs. I am Praveen Vohra, and I chair the payer policy review committee at the American Academy of Sleep Medicine and will be commenting on their behalf. I am also a pulmonary specialist, and I do sleep medicine. My comments today are going to be on the proposed LCDs DL33611, DL33718, and DL33800. I do not have any financial disclosures, at this time.

So, the first comment is about the removal of the home sleep apnea details. Currently, there is very specific information in the Local Coverage Determinations, which is not included in the NCD 240.4.1 specifically looking at patient education, physician training and credentialing, and sleep facility accreditation. So, the first being, patient education, the present LCDs include details regarding patient education on proper application of portable sleep devices, either via a face-to-face demonstration of the application and use, or video, or telephonic instruction with 24 hour availability of personnel for questions and troubleshooting. And that's important because if you remove this criteria, then it will lead to improper use of these devices, technical failure rates go up, diagnoses will get missed, and then there will be increased multiple night studies, potentially increasing cost of care too. So, we feel that it's important to continue to include the patient education portion, and not to remove it.

The next comment is on the training and credentialing for the readers of people, physicians, who interprets sleep medicine studies. So, the Academy emphasizes the importance that the raw

data from a home sleep apnea testing device being reviewed and interpreted by people with the following qualifications, either they should be board certified in sleep medicine, they may be in board eligible, that is, they have completed their training and are eligible to sit for the boards, they may be overseen by a Board-Certified Physician, and they could be an active staff member of a Sleep Center or lab that is accredited by the American Academy of Sleep Medicine Accreditation Commission for Health Care or The Joint Commission.

The next comment is about the sleep facility itself that sets up these, the sleep study, the accreditation of the sleep facility. So, the accreditation is a standard by which the entire medical community can evaluate the sleep studies– sleep medicine facilities. And it demonstrates the provider's commitment to high quality, patient centered care so that the standards are being adhered to. Data demonstrates that accreditation certification status actually is associated with better treatment adherence, better patient education, better patient satisfaction, and greater timeliness. So, I think these criteria should continue to be included in the, in the NCD or in the LCD, depending upon what the final determination would be. So, the issue here is there are no details currently in the NCD 240.4.1 regarding education, training credentialing, or facility accreditation. And the solution that we would recommend is that the current language either remains in the LCDs or it gets added to the NCD 240.4.1 simultaneously. The advantage of doing this would be that this would standardize the steps needed to do and interpret home sleep apnea testing and will make it more efficacious. It will also help to potentially prevent fraud and abuse in the conduct of home sleep apnea tests. There are some references that we have included in our comments and these are available to you. And that is the end of my comments.

Jody Whitten: All right, well thank you. Our next commenter is Jim Hogg. Jim, your line is now open. Are you there?

Jim Hogg: I am and—

Jody Whitten: Ok, your 11 minutes starts now.

Jim Hogg: Thanks. I just wanted to thank the CMS for inviting us to comment on changes that you have proposed. I am a board member for the American Academy of Dental Sleep Medicine, so I'm commenting on their behalf. I've been a general dentist for 40 years, although in the last 14 years my practice has been limited to dental sleep medicine for patients suffering from sleep related breathing disorders.

I practiced in Chicago for most of those years, but currently am in Asheville, North Carolina and I practice in Brevard. And, so, as the Academy, we've looked at these changes and we did think that we were supportive of changing these policies in order to make it easier to navigate the system. And, certainly, since it's already been covered in the language of the National Coverage Determination, we felt that it was rather redundant to have it in the, in the initial proposal. Commenting on Dr. Pagano and Jan Palmer's, we also do agree with many of their different comments, especially, I know, telehealth is all already an accepted face-to-face. But we are concerned about these mail-in ordering of appliances, where patients take a putty impression of their teeth, and some far away dentist is determining what they should do with it once it's made. And so, you know, our academy is really trying to have standardization in the field, and to have specific policies that not only have guidelines for how to treat the patients, but also, especially at collaborative care with our sleep physician partners. And we certainly embrace the fact that they are going to be the ones that are going to diagnose the obstructive sleep apnea that we'll be treating and will follow up with the efficacy of it. So, I want to thank you again for having us give some comments and appreciate your time.

Jody Whitten: Alrighty. Thank you. And we'd like to thank all of our commenters today. And this does conclude our verbal comments for the sleep study related LCDs. I will now turn the call back over to Dr. Hoover for some closing remarks. Dr. Hoover?

Dr. Robert Hoover: Thank you, Jody, and and also to Rachel for moderating the call today and, and certainly, thanks to the commenters. we appreciate your thoughtful comments on the proposed LCD and we look forward to seeing your full written comments being submitted.

I'd like to now discuss the LCD reconsideration process and the next steps that will be taken.

On your screen now, you'll see the information for how to submit comments on the proposed LCD. As I mentioned earlier, you're welcome to submit separate comments for each of the 3 LCDs to the separate mailboxes. Or, since we're proposing the same change to all 3 LCDs, you can

submit one set of consolidated comments to a single mailbox. Once the comment period closes on April 10th, the DME MACs will consider today's comments and the information presented. We'll also be considering other comments that we received in writing from stakeholders. Once we go through those and collate them, we'll review the proposed LCD language and make any changes necessary as a result of the comments received. And we'll do any necessary additional research and then post a final LCD along with a Response to Comments document. So, we will be responding to both the written and the verbal comments today. The DME MACs will post our final LCDs on our websites and distribute links to the information via our listservs. The final LCD would take effect a minimum of 45 days following the posting of that final LCD.

So again, thank you, thank you everyone who took time out of their day today to attend this public meeting and provide your thoughtful comments. This portion of the meeting is adjourned. For those registered to provide public comments on the Enteral and Parenteral Nutrition proposed LCDs, we'll begin that one as scheduled. Thank you very much. That ends the meeting.