National Government Services

P.O. Box 7108
Indianapolis, IN 46207-7108

www.NGSMedicare.com

National Government Services, Inc.

Moderator: Paulette D'Elia

February 25, 2019

12:00 PM ET

OPERATOR: This is Conference # 5298580

Female Speaker (Paulette): So, this meeting is to give you an opportunity to provide input into the development of proposed Local coverage determinations. Today's meeting will be conducted in accordance with the guidelines established by the centers for Medicare and Medicaid services. Based on the CMS guidance and CR 10901, the analysis of evidence and the summary of evidence are presented and discussed within the proposed LCD itself and have been available on our website for the past two weeks.

We have Dr. McKinney, who is our Vice President and Chief Medical Officer and Dr. Clark, who is our Medical Director with us today and Dr. McKinney will open the meeting with a few words. Thank you.

Dr. Greg McKinney: Good afternoon everyone. Thank you for coming out on such a blustery day. Greg McKinney, if I haven't met many of you. Thank you Paulette for the introduction. I am the Chief Medical Officer for NGS and this is our first attempt at the open LCD meeting and I wanted to spend a few minutes to talk about that process, not in a lot of detail, not to review the entire material that is in the change request, but as most of you know through the 21st Century Cures Act.

CMS revised the way that LCDs are presented and drafted and that is all outlined in the Medicare Program Integrity Manual online Chapter 13. So, if you need some leisure reading and your Ambien prescription is out, now go ahead and take on that. It's a lot of -- lot to absorb and we've spent probably, I would say good year in discussions with CMS about these changes that became final last fall. So want to kind of go over that, we did present as summary article on our website. So I will refer you to that. They came out the first of the year, which is a kind of overview of the process at a very, very high level and about what essential parts of the process are different and so I would refer you to that article just a sort of our reference there, but the sequencing of an LCD is kind of changed and the evidence with which we present an LCD has changed.

Now the sequencing is this that before we even created draft LCD that we're going to present today, our job is to go out and gather information through medical literature, medical experts and this is a change in our CAC. Therefore, we do not have a formal or nor is it mandated that we have a CAC meeting to present the draft LCD. Now the order is that we go to the CAC for input on the topic much like you did a research paper. They are source of information for us to present information that we bring back along with experts, medical literature, all those various inputs then we create a draft and we bring into this meeting.

So that sort of at a very high level how the order will be. CACs again are not mandatory. We can make them a specialty CAC. If we will -- if we are having a CAC, an LCD are on the specific topic, we can tailor our CAC to just those members. CACs members are invited to this meeting. It is open, anyone can attend. So, the lines are open. So we probably have various entities on the phone as well. So that's the order in which the process will happen. We will present policies today and the sole purpose of this meeting is to present the draft LCD. It's not for random com -- random topics or any other discussion is to discuss the LCD that was posted on the website.

I understand that there may be some that are present from entities that have submitted a consideration for an LCD and I do want to touch on that just for a second. A consideration of LCD, first of all, this is a new process for us.

It's a new process for CMS. So, we openly admit that this is a learning process that we're learning how to best navigate. So we ask for your patience, but the sole purpose of this process is to provide transparency.

To be open and communicate, not necessarily give you the answer that you want, but to give you transparency where we are. So for those of you have submitted considerations, those are in queue and because we're trying to sort of put in motion this process, those are in motion to be considered for an LCD. But we can't tell you the status of that.

CMS prohibits that because that would be privileged information. So if you're an entity that is questioning or says when can I write a policy on XYZ, we won't be able to the respond to you today. So we appreciate you not asking, okay. To be blunt because we can't tell you, but you'll know when the public knows because that CMS's direction, is that it's all transparent. Everyone knows at the same time. So, we'll publish something on the website soon as it's public, we will probably give you a courtesy, hey by-the-way check on the website, but it has to be transparent and public to all and noted to all. We're going to put it in the docket for queue for creating and gathering information for that.

So, that's pretty much kind of that is going on and that's sort of a chapter 13 condensed into just a few comments. It is a change for us that the CAC is kind of taking on a new role and new face, the order of our LCD development has taken on a new face the transparency of the literature that we're looking at and our critique of that literature and then handling any other comments about the literature that is taking kind of ramped up a little bit. Again for transparency, so what we know is what was in the article.

Again per CMS is the ultimate decision relies on the contractor. So, we have the ultimate authority in the decision. But the process should be transparent and outlined as I mentioned just now. So again we appreciate everyone coming. I'm going to turn it over to Dr. Clark to discuss our one draft that we have for today and we'll go from there. Thank you for your attendance.

Dr. Larry Clark: I'm Larry Clark. I'm one of the three JK Medical Directors along with Dr. Craig Haug and Dr. Steve Boren who are working on other projects today, so you're stuck with me. Some of you have heard me speak to industry when

Dr. McKinney and CMS let me out once a year and I always assign homework. So to really make this trip worthy in terms of your hardiness in getting here. I like to recommend and this is not an endorsement, but I do think you're going to hear us talk about levels of evidence. So something like the grading of recommendations, assessment, development and evaluation grade is a good thing for you to take back to your respective companies. Another thing is one of our J6 resources Winona State University in Minnesota in J6 jurisdiction put out an evidence based tool kit. It talks about levels of evidence and you're going to hear me talk about that in just a brief synopsis of the policy that's in front of you.

I only can add one thing to Dr. McKinney's summary and that is that sequence of the meetings have changed a little bit. In the Open meeting now, we're a little further along in the process. This is actually the draft becoming a proposed LCD. And we are bringing it to the public in a much more developed form for your comments. So, again as we go on, our CAC coming up in the future is going to be a specialty oriented CAC and it is going to also involve collaboration with other contractors. So we're stretching out into the new world as well.

I'm here today to give a brief presentation on DL38014. The proposed local coverage determination for Corneal Hysteresis. Hysteresis is a term from physics. It’s a measure of resistance to deformation by an applied force. The concept in terms of ophthalmology is basically two structures. The posterior sclera and lamina cribrosa, where the nerve fibers exit the eye, provide a resistance to deformation by pressure in the eyes. That being the process usually describes glaucoma, although it may be associated with other processes. And the concept is that using a thing called ocular response analyzer, you measure this resistance to deformation of the structure of the eye and as such it is a monitoring and therapeutic guide to glaucoma and other corneal diseases.

The substance and rationale for our determination after reviewing 24 pieces of literature and 6 other policies, three Medicare and three Commercial was that we did not find significant evidence in support of this when measured against other similar glaucoma predictors like Central Corneal Thickness. There was no predictive relationship.

There was clear evidence in the literature and I will conclude with the concluding sentence. The lack of level one evidence, which is why I suggest understanding this absence of proven clinical utility, no clinical practice guideline endorsement that includes the AAL and the Canadian counterpart as well as neither Medicare nor Commercial coverage, strongly argues against Corneal Hysteresis coverage, as medically necessary for treatment of Medicare patients. And that is basically the policy that is here and we did invite some folks in industry to participate and unfortunately nobody chose to participate.

So anyway thank you very much.

Female Speaker: (Paulette) Thank you Dr. Clark. So all the meeting is an open forum again for receipt of your information for your comments regarding only the proposed policy. Please be assured that all comments provided will be addressed during that and considered during the development of the policy. The official comment period extends from February 27th, 2019 to April 13th, 2019. So, there's plenty of time to submit your written comments. Are there any comments in the room? Are there any comments from anyone who is called in? As there are no further comments being offered today, comments related to Corneal Hysteresis are now closed.

Thank you to our observers for participation in the LCD open meeting and the meeting is now closed. Thank you.

Operator: And this does conclude today's conference call. You may now disconnect.