WPS GHA Open Meeting – February 19, 2020

Moderator: Dr. Ella Noel
February 19, 2020
2:00 PM ET

Operator: This is Conference #2795326.

Operator: Ladies and gentlemen, thank you for standing by and welcome to the February Draft LCD Open Meeting.

At this time, all participants are in a listen-only mode. After the speakers' presentation, there will be a question-and-answer session. To ask a question during the session, you will need to press star one on your telephone. Please be advised that today's conference is being recorded. If you require any further assistance, please press star zero.

I would now like to hand the conference over to your speaker today, Dr. Bob Kettler, the facilitator of today's call. Thank you. Please go ahead.

Robert Kettler: Thank you, (Mariana), and welcome everyone to the Winter Draft LCD Open Meeting.

Before we begin, I just want to introduce my colleagues from WPS who are involved in this call today. On the phone, we have Dr. Ryan Holzmacher and Dr. Ella Noel. And in Madison, we have our policy coordinators, (Ann Everson), (Kathy Fischer), (Melissa Jacobs), (Melissa Lietz), and (Beth Scanlon).

The purpose of the meeting today is to provide an opportunity for public comment on the draft LCDs. And we have two LCDs up for comment today. This is the only business that we will be conducting during this meeting.

I'm going to just give a few ground rules for our procedure today. We will proceed by – I will introduce and summarize the LCD. Then I will take comment from each location, taking comment from Omaha first, then Madison, and then comment from those who have called in on the phone. And I will ask (Mariana) to release those lines for comment. If there is

comment, each speaker may speak for up to 10 minutes. And Ms. (Everson) will time the commenters and also provide a one- or two-minute warning.

I would ask that people realize that there is not a need to repeat comments that have already been made. We don't keep track of the number of comments for or against an LCD. What matters is the content that is presented, and that's what we would be paying attention to.

On completion of each commenter's period of comment, we will then move on to take up the next LCD and I'll repeat the process that I've just described. We do ask that people submit written comments to supplement any oral comments that they give today. There is an important aspect to providing public comment during this period. But also it does happen that occasionally we aren't able to adequately hear people on the line or the transcription doesn't convey the actual comment that was made. And so please submit your comments to policycomments@wpsic.com. On completion of today's meeting, the comment period is then open until March 15th of 2020 for both of the LCDs.

So, having provided that information, I'm going to proceed to the first LCD, which is DL38530, and it is titled, Molecular Diagnostics Circulating Tumor Cell Marker Assays. This is a non-coverage LCD that provides – that establishes non-coverage for all test related to circulating tumor cells or CTC assays. And the reason for this is that no data has been forthcoming to demonstrate improved patient outcomes, or that the assay changes physician management to demonstrate improvement in patient outcomes.

And there are no comments here in Omaha. Are there any comments in Madison?

Ann Everson: It looks like no comments in Madison.

Robert Kettler: OK, thank you. (Mariana), are there any comments on the phone line?

Operator: As a reminder, to ask a question, you will need to press star one on your telephone. To withdraw your question, press the pound or hash key. Please stand by while we compile the Q&A roster.

There are no telephone comments at this time.

Robert Kettler: OK, thank you. The next draft LCD is DL38528, Hypoglossal Nerve Stimulation for the Treatment of Obstructive Sleep Apnea. This LCD establishes coverage criteria for hypoglossal nerve stimulation in the treatment of obstructive sleep apnea.

And there are no comments here in Omaha. Are there any comments in Madison?

Melissa Lietz: Any comments?

Melissa Lietz No.

Melissa Lietz: No comments in Madison.

Ann Everson: Dr. Kettler, we do have the presentation here though as well as a reminder.

Robert Kettler: OK, this would be an appropriate time to do that.

(Inaudible)

Kathy Sherwood: Hello. I'm Kathy Sherwood. I am – you can go to the next slide. I am the Vice President of Market Access and Reimbursement for Inspire Medical Systems, and we manufacture the only FDA-approved hypoglossal nerve stimulator for treatment of obstructive sleep apnea.

So next slide. So, first of all, we would like to thank WPS. Seriously, thank you. This is a wonderful draft policy. We're very, very pleased with it. And more importantly, our physician societies, both (Sleep and ENT), really think that across the board, the MACs have done a phenomenal job at pulling together a relevant and appropriate policy. So to that end, I just have a couple of minor points that I'm basically going to tee up as potential minor modifications to the policy but really not about the coverage criteria, just some tweaks.

So, the first, all the other MACs have actually finalized with the exception, I believe, of Palmetto. Their final policies, I'm not going to make comments but

the other MACs have already said, no, thank you, too. So we're taking those off the table. For example, otolaryngologist implanting this only.

We do have three little areas that we'd like to propose. One is around the diagnostic for the appropriate patient for this therapy. It's really critical. And I think the MACs have recognized this that we do drug-induced sleep endoscopy, and that the ENT test basically for appropriate anatomy for implantation of this device. And the MACs have proposed the manufacturer performs this DISE training, and we actually certify and put it into our quality system, the certification for physicians before we would even sell them a product.

So all of the MACs have proposed an enhanced level of that certification, which we're fine with. So, actually, it's a great idea. Our proposal, though, is that for physicians that were prior – you know, trained prior to implementation of the policy, we're requesting that they'd be grandfathered in because some of these doctors have done 400 or 500 procedures. They've been doing these implants since the early, you know, 2000 – or actually, since the STAR trial begin in 2007. And I'll show one slide on that.

Then there's two minor things. One is the device interaction, exclusion clause, which we believe we have a good rationale for having eliminated. And then there is a lot of question on all of the policies of an active psychiatric disease. If someone is on a happy pill, does that mean they can't actually be treated, you know, for obstructive sleep apnea? And the other MACs have all clarified that language a little. So we're proposing the same thing.

So next slide. I think we can skip this. I already said we have a very rigorous and extensive drug-induced sleep endoscopy training that our implanters have to go through. When they passed that, they then go to cadaver lab training, and then they're proctored through like their first five to 10 cases, and we actually do certifications.

So, basically, this is sort of a background on that. Next slide. So, all we're really asking here is, again, if a physician was certified by the manufacturer to perform DISE in a way that has led to the outcomes that we currently have, and we do have very large publication of a registry where I think we've got

1,500 patient papers being submitted already. We ask that those people be grandfathered. And that is consistent. I believe five of the MACs have already agreed that that was the right thing to do. OK.

Next. OK. Implantable device interaction, this is an interesting one. When we originally did our STAR trial, which was the foundational trial for the FDA, we didn't have FDA approval. And at that point, testing had not been performed on whether defibrillators, pacemakers and other neurostimulators might have interaction.

We did spin out of Medtronic, so we had a very easy opportunity to go back to the implantable device industry and actually perform the testing, which was submitted to FDA. FDA agreed in 2014 after STAR was getting wrapped up, that in fact you have the adequate evidence. They did not contraindicate for device interaction, so we're requesting that that exclusion criteria be reconsidered, OK.

And then the next slide. This is – I call it my happy pill comment. So, basically, we got clarification from the other MACs. I think a lot of physicians have asked if we have well-managed anxiety disorder or other psychiatric issues, as long as that patient is well managed, you know, what's the justification for not allowing them to have treatment for their OSA. So the other MACs, I took this, I think, directly from the Noridian policy, where they're basically clarifying that what the MACs don't want is for someone who can't remember or isn't cognitive enough to turn the device on every night. That's the person that shouldn't get the device. But if they're being well managed through these psychiatric disorders, then that's OK.

And basically, I think last slide is probably a thank you. Yes, it is, thank you. So that's our feedback. And again, I hope you see these as we're really happy with this policy, just minor little tweaks as a suggestion, OK. Thanks.

Ann Everson: Thank you.

Melissa Lietz: Thank you.

Robert Kettler: This is Dr. Kettler. I just have a question. And you maybe said this and I missed it.

Kathy Sherwood: Yes.

Robert Kettler: Have the other MACs adopted that device interaction exclusion clause change that you'd like?

Kathy Sherwood: I believe that they have, Dr. Kettler. I can validate that for you. Yes, you know what, it was – to us, it was such a no-brainer that I didn't look at that when I was more concerned about the shared-decision making clauses and things like that. But I believe that they did.

Robert Kettler: OK.

Kathy Sherwood: Because again, FDA reviewed it, approved it, and these devices can be implanted with defibrillators or other neurostimulators or pacers.

Robert Kettler: OK.

Kathy Sherwood: OK.

Robert Kettler: Does anybody else have any questions?

OK. Thank you. Any other comment in Madison?

Kathy Sherwood: Thank you.

Ann Everson: Not at this time.

Robert Kettler: OK. (Mariana), is there any comment on the phone line?

Operator: There are no telephone comments at this time.

Robert Kettler: OK. That then completes the comment on the two LCDs. As I said, the comment period is open until March 15th of 2020. So people do have the opportunity to provide comments up to that point.

With that, then we are adjourned. Goodbye now.

Ann Everson: Thank you.

Female: Thank you.

Operator: Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.