WPS Government Health Administrators Draft Local Coverage Determination (LCD) Open Meeting Transcript

Moderator: Dr. Robert Kettler

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2:00 PM ET / 1:00 PM CT

Richard Staley: Welcome to the WPS draft LCD open meeting. My name is Richard Staley, I'm the policy administrative assistant. I've placed all attendees on mute at this time, but I will open the lines for communication when we are ready to take comments. I would like to turn things over to our facilitator now, Dr Denise Nachodsky.

Dr. Denise Nachodsky: Good afternoon, everyone. Can you hear me, Rich?

Mr. Staley: Yes. Oh, sorry. When we come out of the practice session…

Dr. Nachodsky: I'd like to say good afternoon and welcome everyone to the June 15, 2022, Draft LCD Open Meeting. As Rich said, I'm Denise Nachodsky. I'm one of the Contractor Medical Directors for J5 and J8, and I will be your moderator for this meeting.

What we're going to do today, in this meeting, is you have the agenda, I hope you all have of the LCD Drafts that we will be [discussing]. The purpose of this Open Meeting is really an opportunity for interested parties to discuss the rationale, to review the evidence and to provide feedback on proposed LCDs. Interested parties, generally, include those who are affected by the proposed LCDs, including physicians, providers, beneficiaries, caregivers, vendors and manufacturers. We do invite members of the public and the stakeholders to attend and to provide verbal comments or statements to our proposed LCDs. Anyone attending the call can offer their comments after each one of the LCDs are presented, and prior approval to participate is not necessary. As Rich stated. I just want you to all know that this meeting is being recorded.

Some of the ground rules for today's open meeting: number one: anyone can make comments on policy being presented today, if you choose to, after each one of the draft LCDs are presented. Please identify yourself before you speak, and that is just for our documentation for the minutes. If you are a presenter with a documented presentation, please inform those on the call of any conflicts of interest. You will be stopped after 10 minutes, to allocate equal time for other presenters. Rich will get- will have a timer and will let you know as your time is approaching the 10-minute mark. WPS will not answer any of the questions today.

We do have one outside presenter; a stakeholder who is presenting. It is going to be Mr. Scott Blackman. But today there's a presentation of eight drafts for this open meeting. All were

published already to the Proposed/Draft Local Coverage on the WPS website. It was posted on May 26th, 2022, which was the start of the open comment period. So, the open comment period looks stand from May 26th through July 9th, 2022, for all of these drafts. They said, there's eight of them today. Two of them have already been presented to a multi-jurisdictional CAC or an evidentiary committee. So Draft DL39356, The Molecular Testing for Detection of upper GI Metaplasia, Dysplasia and Neoplasia was presented at a multi-jurisdictional CAC on October 21st, 2021. And the other DL34641, Transcranial Magnetic Stimulation, was presented at a multi-jurisdictional evidentiary committee on September 29th, 2021. This is the one that Mr. Scott Blackman will be, He is the director of market access for BrainsWay. He will be providing a presentation.

There are six other drafts that you see on the agenda there. These are all for retirement, and due to the changes with the 21st century CURES act, that these retirement LCDs - they need to be presented at Open Meetings before moving forward with the retirement process.

At this time, I'd like to introduce Dr. Barry Whites, he is the lead for all eight drafts today that will be presented. So, he will present a short synopsis and a summary for each draft. Afterwards which, Rich will open the lines for anyone who has any comments. Dr. Barry Whites - his medical education and specialty training includes that he received his MD degree, residency and pulmonary fellowship at the University of Mississippi. Subsequently he received a master's degree in health administration from the University of Alabama – Birmingham. His clinical experience includes private practice in pulmonary critical care, and sleep consultation for nearly 37 years with 11 years being concurrent as a CMD for a Part A contractor. His health care industry experience is approximately 20 years, which includes a CMD for a part A contractor, an A/B MAC CMD, and currently WPS GHA J5 and J8 CMD since 2020. He is currently the chair-person of numerous multi-jurisdictional LCD work groups, which includes such as pricing committee, category T and 3 codes, drugs of abuse, et cetera.

As part of our, our process over here, as I said, after Dr. Whites gives his synopsis of the draft LCDs, we will then take a time for oral comments about this. Written comments: please note, please feel free to send in written comments. These again are due by July 9th, 2022. Please send your written comments to policycomments@wpsic.com, and include the topic of the LCD on the email subject line. We ask you include published scientific studies and/or literature to support your additional coverage with your message. We won't – not send individual responses to the comments, but we will make sure that responses are available in a comment and a response document that will be posted with the final LCD. So, at this time, I'd like to turn over the presentation to Dr. Barry Whites, which is my pleasure to present him today.

Dr. Barry Whites: Thank you, can you hear me?

Dr. Nachodsky: Yes, we can. Dr. Whites.

Dr. Whites: Good, good, thank you so much.

Well, today, most of these, as you see are Molecular Diagnostic policies, and both there, the draft LCD as well as their articles that accompanies them, to, in the interest of not having to have someone sit through this for our only presenter today, I think it would be prudent of us to ask Mr. Blackman if he would go ahead and initiate his presentation.

A few brief words about Transcranial Magnetic Stimulation: It is an existing policy, that, under that policy with limitations, there's coverage for treatment-resistant depression. The request for reconsideration was brought to us by Mr. Blackman and his company, for expanding this coverage to obsessive-compulsive disorder. He presented information to us. We, since everyone has a policy on this, I am talking in terms of all the MACs, we reconvened or convened a multi-jurisdictional CAC where we could all have the opportunity to review the literature submitted by Mr. Blackman. He did submit it to several, If not all, of the MACs. And we reviewed this literature. It was determined at that time, because of, what we felt to be insignificant amount of literature to provide coverage, we didn't expand our coverage to additional items past what Mr. Blackman had sent us. We had an evidentiary CAC that was well attended, and experts were there. The bottom line on this meeting, and the results of that meeting were, we felt that there was insignificant, uh, or not significant enough data to provide coverage. We felt that it does show promise, but it's yet to be determined how to best optimize the approach of using TMS to achieve clinically relevant results. And so non coverage was – for obsessive compulsive disorder – was elected on this draft. And now, Mr. Blackman, if you go ahead with your presentation, we should note that limitation, time limitation is ten minutes on each presentation. Thank you.

Scott Blackman: But the, uh, share screen is not enabling me to share my screen right now.

Mr. Staley: I'm just - I just wanted to check with you that you had your PowerPoint presentation up and ready. Are you ready to receive the screen share?

Mr. Blackman: Yes, I am.

Mr. Staley: And here we, thank you, sir.

Mr. Blackman: Can you see my screen.

Mr. Staley: Not at this time, I do show that you are this, that I have rendered control to you.

Mr. Blackman: pressing share content. Let's try it again.

Okay, see now - you can see it? You can?

Dr. Nachodsky: yes, we can. Thank you.

Mr. Blackman: Okay, thank you. Thank you for the opportunity today to present our comments regarding this draft LCD. My name is Scott Blackman, and I'm the director of market access for BrainsWay. As far as the conflict of interest, I am an employee of BrainsWay, the manufacturer of deep TMS, and I'm a paid employee. I'm also a member of the clinical TMS Insurance committee.

Our agenda is going to briefly just mention major depression, but focus more on the analysis that was made with the evidence on OCD by WPS and point out some of the evidence which you have already seen, but I'd like to make a point about deep TMS verses all TMS. For major depression, the reason why we're here and for OCD, is to really request a less restrictive major depression selection criteria, and for a re-evaluation of deep TMS evidence. Currently WPS policy has very limited references of Deep TMS for OCD, and most of the summaries combined all TMS for OCD treatments, both traditional figure 8 quote TMS studies and deep TMS, in order to reach their conclusion of mixed results. Those studies had mixed protocols, parameters, different shams, different brain regions and different frequencies, the small numbers of patients. This was from the figure 8 trials, the deep TMS evidence should really be evaluated separately and not combined with those because deep TMS has the protocol that was actually approved by the FDA, and that's what's been used in all the trials for deep TMS and not in any of the figure 8 trials. We're just going to request that instead of severe major depression, we would request that your policy include moderate-to-severe. All the studies that have been done with TMS in major depression have had moderate to severe, not severe.

Your request an evidence-based psychotherapy trial, all three pivotal trials for TMS…

Dr. Whites: Mr. Blackman, Mr. Blackman, this is Barry Whites. This is, this is not open – the whole policy is not open. This is a reconsideration on obsessive compulsive disorder, which is what you requested.

Mr. Blackman: Oh, very good.

Dr. Whites: Please Stick to that subject.

Mr. Blackman: Okay, sure Thank you. I sure will. Uh, Dr. Whites, and everyone else. The analysis by the contractor advisory committee, as I was mentioning earlier, talked about small sample size of the studies, low quality design, risk of bias, short-term follow up, lack of long-term data, real world application – whether it's low or high frequency – different brain regions that were stimulated and what's clinically meaningful. And the analysis, as you mentioned earlier, was there is still some questions that remain regarding the brain regions, the

frequencies, the actual protocol, long term data and what would be appropriate for OCD and for the treatment, and right now only deep TMS has the demonstrated evidence to answer all those questions. So, I would ask WPS, is, the real question is: is deep TMS, not all TMS, with the H7 coil, should it be covered? And is the evidence sufficient? Has it been proven safe, effective and durable? has the brain region been identified? The frequency of the sessions, the actual protocol, and the duration, and are the effectiveness outcomes in the clinical trials also seen in the real world? Is it FDA cleared and is it – I know you don't care about cost – but is it cost effective? Your analysis that was done by WPS, I understand, and we understand the confusion when looking at the multiple trials that have been looked at between 1980 to 2019. If you look at just the RCTs in general, they look at different brain regions, like 4 or 5 different brain regions, SMA, prefrontal cortex, orbital frontal cortex; they also look at small numbers of patients from 33 to 45, usually about 10 to 60, or now, were analyzed. But those small trials were done in figure 8 trials with these different brain regions, the frequencies ran from 120 hertz. They ran from 2 to 6 weeks with low follow up. So, you're looking at a lot of small trials that had mixed results. Some, some moderately effective. Most were not effective. And then, you're looking at these meta-analysis, but if you look at my read and logistic, there wasn't even any deep TMS involved in these trials or meta-analysis. So, they're looking at only figure 8 trials, which were very small, and didn't gain clearance from the FDA from those trials.

Same thing with the other [inaudible] or reference trials all from 2016 and ‘17 had no deep TMS, and another one in 2021, looking at figure 8, and only our pilot in our pivotal trials in their network medical analysis, actually states that the analysis requires caution due to invalid conclusions. So, I can understand that. It's very confusing to look at what protocols and whether or not it's effective. Generally, as we briefed before, the protocol that's been approved and proven effective stimulates the ACC, which is deeper into the brain and the, and the medial prefrontal cortex. OCD Is not like major depression. Rather than being episodic, It's chronic and unfortunately, there's very limited treatments. In fact, when you look at psychotherapy, and only five SRIs in the last 20 years that have been approved, there's been nothing else. And, in fact, 50% of the patients that have been treated for OCD with these drugs fail; they don't get a response. And so, they usually go to more expensive inpatient or outpatient treatment or residential facilities, doing more intense of the same here. The coil that was produced by deep TMS, the red stimulates the electric field distribution stimulates deeper and broader into the brain and, in fact, deeper and broader in order to hit the areas that we associate with OCD, as I mentioned earlier. Deep TMS actually goes four times deeper than a figure 8 coil – three centimeters subdural. And a head-to-head study that was done by Tzirini, actually showed that when you compare the MagVenture coil, which got an FDA clearance based upon substantial clinical equivalence, actually has no clinical studies using this protocol. In fact, they have safety, but they don't have any clinical evidence, other than a very small trial that was done in 2016, but that that's it. They don't have any clinical evidence to demonstrate the efficacy.

So, again, I would ask that for clinical. Evidence for anything, other than deep TMS, they should have clinical studies to demonstrate their effectiveness for OCD with the protocol that's been approved by the FDA. There's been a number of trials, 14 in particular. The ones that we haven't shared was a cost effectiveness trial, the long-term durability from the long-term outcomes from the registry and just recently an unbiased no conflict of interest network medical analysis was conducted, and actually looked at 19 different treatment strategies and showed that deep TMS was the best treatment choice to be used when SRI treatments fail. The low frequency study - excuse me – the pilot study, actually show that low frequency was not

effective, and that high frequency was. That led us to go to the pivotal trial, where we looked at the moderate – excuse me – the modified intent to treat, which was predetermined to look at efficacy. Intent to treat was to look at all the patients, and any safety outcomes. And in fact. We wanted to make sure there was no bias so if a patient increased their medication, we didn't want that to occur and say that “oh, they got better because of medication change.” So, anybody with a medication change that started the protocol was left out of the modified intent to treat. And ultimately, 38% of the patients actually demonstrated that they responded. 58% responded in the real-world outcomes. And in fact, they did even better with ten additional treatments: they went from 33% response to 50% response. Our response is a 30% improvement in YBOCS. Durability just came out that showed 87% of patients had equal to or greater than a year of durability with the average of two years. An improvement of functional disability, 67% of patients improved in their productive work-days, and they basically went from two lost days a week to no lost days. Ultimately, this is a study that I stated, that showed that deep TMS was the treatment of choice. Other treatments included zofran, which is a nausea drugs for cancer, and Abilify® or aripriprazole, which both are non-indicated, by the FDA, for OCD.

The same problems with meta-analysis and reviews, combined all the TMS and not deep TMS. CTMS Society has a published recommendation, and right now Highmark just approved eight million members, also approved OCD. So, you've got Palmetto, Tricare, Health Care Services in five States, almost 70 million patients are covered. Ten million dollars is spent a year with a third of the treatments being ineffective for OCD. Deep TMS was shown to be cost effective and in incremental cost effectiveness, was actually demonstrated to be very cost effective after the anti-depressants and cognitive behavioral fails before they go to even adding an anti-psychotic, or going to the partial hospitalization and residential. Deep TMS is cost effective.

So, in summary you can see 38% to 58% response with deep TMS, rather than going from psychopharm – excuse me – psychotherapy and meds, to more of the same at an intense partial hospitalization or residential, you can get a very good response with deep TMS in these patients. And in closing, I would ask that based upon the deep TMS evidence, the research, the large evidence trials, the protocols, the FDA clearance, the real-world evidence, the long term effectiveness, the improvement in patient's functional disability and the durability of two years, and the cost effectiveness, solely deep TMS and BrainsWay has done the evidence. And even without the BrainsWay evidence, the recent network meta-analysis of all the 19 different treatments for OCD, it was shown that after they fail SRIs, deep TMS would be appropriate, and medically appropriate. So that would be my, my close.

I thank you very much for the opportunity to briefly present and recommend that WPS looks solely at the evidence to support deep TMS for this underserved population, which is a very chronic disease and there's not much to help these patients once they fail their first line treatments. Thank you very much.

Dr. Whites: Thank you, Mr. Blackman. The, you brought up several studies that were not included in your initial request, and you may need to submit another reconsideration if you would like all those studies. We, we cannot, during the process of reconsideration, we're obliged and which we, we do, we follow that protocol with the exception of, we can do more if we want to, and we did more, but we, this this process has been now going on for well over a year. So, we do not have late ’21-‘22 information in that, and cannot be expected to that the time for

comment, et cetera has gone through. So, I would encourage you, if you're – We will look at your information there. This is the time for notice and comment, and we will make comments on this, and we certainly appreciate your bringing all of this to our attention. Thank you.

Mr. Blackman: Thank you very much, and I'll follow up with written information as well as documentation and inclusion of all those studies for your review. Thank you very much.

Dr. Whites: Right that that would be great and say all of that in writing, if you could, and you got the information on where to do that, and you're familiar with it.

Dr. Nachodsky, would you like me to go on and give a summary of the other items are, I will just see whether anybody else has a comment on the Transcranial Magnetic Stimulation and treatment.

Dr. Nachodsky: Lets, um, thank you Mr. Blackman, much appreciated your presentation. And Dr. Whites, I think for the rest of the protocol here is if there, if anyone has comments in regards to this draft LCD, Rich will open the line for them. Please know, he will unmute you, but if your phone is, your own phone is muted, please unmute it and then Dr. Whites, I think just after each one of your drafts we'll briefly do that. I believe that the other six are up for retirement. It may not have comments, but that'll be the protocol that we follow today.

Dr. Whites: Thank you very much. We'll do it.

Mr. Staley: At this time, I will open lines for comments. Please make sure you have unmuted yourself on your end. If you would like to make a comment and to ease transcription please state your name before speaking.

The lines Have been unmuted.

[Unknown]: [inaudible]

Mr. Staley: All right yes. Do we have someone who would like to make a comment?

All right, I will place the lines back on mute and you can move forward with the next draft LCD. All right, Dr. Nachodsky and Dr Whites, if you would like to present the next LCD, you can go ahead.

Dr. Nachodsky: Dr. Whites, take it away for us. You may be on mute.

Dr. Whites: Now, can you hear me?

Dr. Nachodsky: Yes, we can.

Dr. Whites: Okay, good. I'm sorry. The first molecular diagnostic policy – and we'll go through these in order, and we'll ask for comments as Dr Nachodsky noted, after each one of them to make an overall statement.

I'll give a brief summary, but just all of these policies, without exception, are policies that have been in existence. They now have, by the molecular diagnostic program, of which we are partners with them, a decision has been made instead of having so many different policies, those molecular diagnostic tests that can be grouped under a common commonality of procedures, types of diagnosis, have been now put into a foundational policy, and this is what these are. These are singular policies that now have been moved over to a foundational policy. There's been no change in coverage. There's been no change in the requirements of any of them; the diagnosis tests that are – diagnostic tests that are necessary for coverage – none of the coverage items have changed. And there just can be found in another foundational policy.

The - My first test for upper GI metaplasia, dysplasia neoplasia is one of those tests. The title really does explain what it's all about; it's detecting upper GI cancers and trying to decide whether there is there's an indication for endoscopy or for seeing things further. That has now been moved over – Let me see what that's - that's been moved over to L38966, which is - has to do with cancer. The transcran- the next one, are there any questions about this transfer overall, to a foundational policy for all of these and or, is there a question in particular about this one test?

Mr. Staley: All right, at this time I am, I'm unmuting. Yes. At this time I am unmuting you again.

[Unknown Attendee]: Oh, I'm sorry, I'm your first, again, this is for 2024. so, is there anything you want me to change in terms of what I've already prepared for 2023.

[Unknown Attendee]: Then if I have exit. Alright. Alright,

Mr. Staley: I apologize. We have, I believe, people speaking at once. I'm going to go with doctor - or go with Jeff Salzman first. Jeff, Good. Speak.

[Unknown Attendee]: [inaudible] Filter and then the VCO settings.

Mr. Staley: All right? I'm sorry, I'm hearing multiple people speak. I'm going to mute everyone. All right, if you would like to make a comment, please note in the chat window. And send it directly to me, and I can unlock you for speaking, but we had three or four different Inputs coming in.

Alright. I'm not seeing anything in the chat window. Um, I can unmute the lines once again, but please, if, if you do not plan on putting a comment, please mute your own lines.

[Unknown Attendee]: Quarters so, um, I mean, unless you want me to leave it as it is, I can combine the quarter. So for 2023 and 2024 will. We'll be in the same format or leave it as it is, but we're

Mr. Staley: Who is speaking right now?

[Unknown Attendee]: Andrew or anybody's looking at this will make more sense.

Dr. Nachodsky: If you are speaking on another line, please mute yourself. Thank You

Mr. Staley: I, I've just muted everyone. Um, I believe there's someone having a different meeting and just speaking. So I, so I do see, there are people commenting in the chat. I don't see if anyone has would like to make a comment on this specific policy. Please, let me know through the chat and I will unmute you individually.

All right, I do not see any chats coming through at this time.

Um, I'm going to open up Dr. Whites line again.

Dr. Whites: …6793, I gather you are, can you hear me. And that again is another test that's been transferred over to inherited cancer for patients, L38966. no change in the coverage. No change the diagnosis, no change in the edits will be forthcoming. Everything is staying the same. We'll entertain any comments about this policy. Being retired.

Mr. Staley: All right, if you have any comments, please indicate in the chat.

And, which was this, what was the name of this draft LCD, Dr. Whites?

Dr. Whites: This one was for Lynch syndrome and it's DL36793

Mr. Staley: Thank you. If anyone has any comments they would like to place on the draft LCD, please indicate in the chat and I will open up your line.

All right, I do not see any comments on the draft LCD.

There is a question from Delana Williams asking for a more fundamental understanding of the call that's up to you and Dr. Nachodsky how to address that.

Dr. Whites: Fundamental understanding of the purpose of this call. Is that the question?

Mr. Staley: Yes, that was the question.

Dr. Whites: Okay. The purpose of this call is: any changes now by regulations that are made to a policy, whether it be retiring it, whether it be an addition or a deletion of certain parts of it, or reconsideration, because of transparency, must go to an open format before retiring. This is a requirement that has been in place now for approximately three years, and even though it is, we have, we requested to CMS that tests such as these that are being incorporated into a foundational policy should not need to go because there's no change, I think that will be – The last call that we had with them, they said that they did not see why it should either, but they would have to change the language. So, we're hoping that we'll not have to bore you with these items in an open call in the near future. But for right now, all of these tests again, is saying that we are mandated since we're being – they're being retired, even though they're being put in a new LCD, a foundational LCD that offers no change at all to any of the coverage or any item that would affect our providers, We have to bring them up.

And what I'm, what I will do right now, with, with take some liberty is I will go ahead and just give the summary on the last three to four of these tests and entertain at one time, in the incident – in the interest of a little bit more brevity – going through these items, which I really agree with the question. I asked the same thing on another call that we had with CMS.

So, the next, the next one is genetic testing for BRCA1, BRCA2 Breast Cancer Genes, and that is DL36813. that is another test that is being moved over with for the LCD L38966, which is for inherited cancers. So that one is being moved over.

The next one is 375- excuse me – 37005 and that one, likewise is going to another molecular assay policy.

4KScore itself is being retired because it is no longer in our – it's a test that the MolDX group said it was no longer – It was not covered under the MolDX policy. This task is only performed in one jurisdiction and it is not ours. So, we have, by regulation, no reason to have this policy and should not have the policy.

The policy for APC and MUTYH, again gene testing, they're going to a foundational policy. And DL37770 Corus Coronary Artery Disease assay is going to – is now being removed from the MolDX process all together, and is being retired.

So, I'll be happy to entertain any questions about any of these tests that we have. I hope that explanation, although not accomplishing a whole lot is the reason that we're here: it is by regulation.

Mr. Staley: All right, so all right, so any comments please note in the chat, and I will open you up individually to provide your comments.

All right, I see no comments at this time.

Dr. Whites: Dr. Nachodsky, back to you.

Dr. Nachodsky: Thank you, I'm coming up from mute Thank you all. At this point, these are all the draft LCDs that needed to be presented.

I want to thank the one attendee who asked this question, and was forthright to say what the reason why these drafts presented. Dr Whites, thank you for your explanation with the mandate of the 21st Century CURES act and why these drafts have to be presented to all of you.

I want to state that if anyone, just in summary, if anyone has any comments that they would like - any written comments – please note that they're due by July 9th, 2022. Please again, send them to the Medicare policycomments@wpsic.com. Include the topic of the LCD and then on the email subject line. I went to thank Mr. Scott Blackman for his informative presentation. Dr. Whites, again, thank you. I want to thank all the attendees. And lastly, of course, I'd like to think Mr. Rich Staley here, for without him, we would not be able to have this Webex run as smoothly as it does. Again, at this point, if there's no comments, the meeting will be adjourned.

Mr. Staley: Thank you, I will open for comments one more time. If you would like to make a comment on any of the draft LCDs please send a chat and I will open your line.

All right, I am receiving no request for comments at this time.

Dr. Nachodsky: Thank you everyone again so, at this point, I would say that the meeting is adjourned.

Dr. Whites: Thank you, Denise, appreciate it.

Dr. Nachodsky: Thank you all have a good day now.