WPS GHA Contractor Advisory Committee (CAC) Meeting

Moderator: Dr. Robert Kettler
October 15, 2020
4:00 pm CT (5:00 pm ET)

OPERATOR: This is Conference # 2349687.

Operator: Ladies and gentlemen, thank you for standing by and welcome to the J5 MAC Contract Advisory Committee Conference Call. At this time, all participants are in a listen-only mode.

After the speakers' presentation, the members will be able to ask a question by pressing star, then one on your touch-tone telephone. As a reminder, this conference call is being recorded.

I would now like to turn the conference over to your host, Dr. Kettler and Dr. Sheybani. Dr. Sheybani, you may begin.

Shayan Sheybani: Good afternoon, everyone. I would like to welcome you to J Section 5 Medicare administrative contractor advisory committee meeting.

My name is Shayan Sheybani. I am the co-chair for state of Iowa and I represent – as a representative chiropractic specialty. So, I'd like to welcome everyone to the meeting today and I'd like to call the meeting to order.

I believe the operator will be taking your attendance at this point. So, there's no need for going through the attendance process. That's going to happen automatically through the operator.

So, to begin, I would like to start discussing the draft local coverage determination, LCD, or evidence discussion for LCD development. In this case, the first item will be by our lead contractor medical director, Dr. Kettler. The first one is Colon Capsule Endoscopy, DL38837. Dr. Kettler?

Robert Kettler: Thank you, Dr. Sheybani. Just before I go through the description of this LCD, I just want to remind everyone that we'll take verbal comments on the LCDs as we go through them. And, also, please do submit your comments to

policycomments@wpsic.com. It is very helpful to have them in writing, as well as to have the verbal presentation just in case we have a misunderstanding about what was said due to audio quality or something like that. And with one exception, the comment period is open through November 14 and I will be noting that exception.

As Dr. Sheybani said, the first draft LCD is for Colon Capsule Endoscopy. This draft LCD would establish coverage criteria for colon capsule endoscopy or CCE. CCE involves the ingestion of a vitamin-sized wireless camera that provides a software constructed video of the GI tract with the intent of detecting GI tract anomalies.

It's important to note that this LCD supplements and does not replace, modify or supersede existing Medicare rules including, in particular, NCD 210.3 colorectal cancer screening tests. This is a collaborative LCD developed by multiple MACs and Dr. Kettler is responsible for this policy at WPS.

And as I mentioned, the comment period does run through November 14. Are there any comments on this first draft LCD? And, Valerie, you could let people know how they're able to comment.

Operator: Thank you. Ladies and gentlemen, in order to ask a question, please press star, then one on your touch-tone telephone. Again, to ask a question, please press star, then one. One moment please. I'm showing no questions at this time.

Robert Kettler: OK. Thank you.

Shayan Sheybani: Thank you. I'm going to go ahead and move to the next draft LCD. The next one is Non-invasive Fractional Flow Reserve for Stable Ischemic Heart Disease, DL38839. Dr. Kettler, I'm going to go ahead and turn this over to you.

Robert Kettler: Very good. Thank you. FFR-CT is a post-processing software for the analysis of CT angiography imaging to assess coronary blood flow in the face of coronary artery stenosis. Again, this is a collaborative draft LCD, which was to establish coverage criteria for FFR-CT. Again, Dr. Kettler is responsible for

this policy at WPS. And the comment period for this is open until November 14. And, so, with that, I would take any comments on this draft LCD.

Operator: Thank you. Again, ladies and gentlemen, to ask a question, you can press star, then one. One moment. I'm showing no questions at this time.

Robert Kettler: Thank you.

Shayan Sheybani: Thank you. The next draft LCD is Endoscopic Treatment of GERD, DL34659. I'm going to go ahead and instead of Dr. Noel, since she's not available today, Dr. Kettler will be making a comment on this (also).

Robert Kettler: Again, thank you. In the current version of this LCD, a hiatal hernia greater than 2 centimeters was a non-coverage criteria for trans-oral incisionless fundoplication or TIF. The literature that was submitted with the reconsideration request did support laparoscopic repair of the hiatal hernia to less than or equal to 2 centimeters, and then, performance of TIF.

So, the exclusion of a hiatal hernia greater than 2 centimeters has been removed as excluding coverage of TIF. Dr. Noel is responsible for this policy at WPS. And, again, the comment period for this LCD is open until November 14 and, with that, I'd take any comments on this LCD.

Operator: Thank you. One moment. If you do have a comment, please press star, then one. I'm showing no comments at this time.

Robert Kettler: OK. Thank you.

Shayan Sheybani: Thank you. The next draft LCD is MolDX: Minimal Residual Disease Testing for Cancer, DL38835 and in place of Dr. Noel, Dr. Kettler will be making comments.

Robert Kettler: Thank you. Again, this is a collaborative draft LCD. It would provide limited coverage for circulating tumor DNA tests to detect minimum residual disease in patients with a personal history of cancer and this LCD does establish the limited coverage criteria for that test.

Dr. Noel is responsible for this LCD at WPS and the comment period for this is open until November 14 and at this time, I'd take any comments on this LCD.

Operator: Thank you. For any comments, please press star, then one. I do have a comment or question from Samuel Caughron.

Robert Kettler: OK.

Operator: OK. Your line is open.

Samuel Caughron: Yes. So, this is Dr. Caughron, molecular pathologist. We – and I know that there are professional societies reviewing this LCD and will be providing written comments.

One thing I wanted to note in reviewing it myself, it actually says that, although the sample is taken – well, the process for this minimal residual disease testing potentially involves multiple points in time and it appears to lump what would typically be considered multiple lab tests into a single test.

And, I have concerns, I guess, about how that will be managed and administered and coverage – sort of what – how the coverage will be provided for something like that. Is it at the time of the initial test? Is it at subsequent tests? So, wanted to wanted to raise that concern.

Robert Kettler: OK. Is Dr. Noel on the line? What I can do – again, since this is a collaborative LCD, we do work with other MACs on any changes that we'd make, but also responding to questions. And so, that question will be passed on to the MolDX group and they should provide an answer for it at that time. So,will that work for you?

Samuel Caughron: How will that answer then come back?

Robert Kettler: There …

Ella Noel: Bob, this is Ella. I couldn't get to the phone quick enough to catch it before. If …

Robert Kettler: OK.

Ella Noel: If Dr. Caughron would send me the question, I will get an answer for him and respond to him personally.

Samuel Caughron: OK. Can maybe someone provide me with your direct e-mail?

Ella Noel: I can give it to you right now. It's E-L-L-A dot N-O-E-L @wpsic.com.

Samuel Caughron: Sorry. E-L-L-A dot N-O-E-L @wps…

Ella Noel: ic.com.

Samuel Caughron: ic.com. All right. Thank you.

Ella Noel: You're welcome.

Operator: Thank you. Our next question or comment comes from Joseph Muscato. Your line is open.

Joseph Muscato: Yes. I just got a question about the indications. I saw the colon cancer indication, and then – and I guess that was for stage – maybe for stage two and then other indications were active therapy and then follow-ups. So, I don't know about the intervals of testing plus the indications broadly for other cancers. I just needed to know how that was sort of going to work. Can you hear me?

Robert Kettler: Yes. Ella, do you want to take that a well?

Ella Noel: Sure. I don't have the copy of the LCD right in front of me, so I can't answer your questions right now. I'm actually in a car. So, I don't have access to anything. But same thing, sir. If you'd like to send me your questions, so I can look the answer up when I'm in front of my desk, instead, I'd be glad to give you any information that I can.

Joseph Muscato OK. I can do that.

Operator: Thank you. I'm showing no further questions or comments at this moment.

Robert Kettler: OK. Thank you.

Shayan Sheybani: Thank you, operator. The next draft LCD is Facet Joint Interventions for Pain Management, DL38841. Dr. Kettler is the CMD.

Robert Kettler: Thank you.

Shayan Sheybani: Go ahead, please. Yes.

Robert Kettler: Yes. Again, this is a collaborative draft LCD with established coverage criteria for facet joint interventions and facet joint interventions for purposes of this LCD are considered to be intra-articular facet joint injections, medial branch blocks, radiofrequency ablations and facet cyst aspirations or ruptures.

As Dr. Sheybani mentioned, I'm responsible for this LCD at WPS. And, this is the LCD whose comment period does differ from the rest. The comment period of this LCD runs through December 12 of 2020. And, so with that, I'd take any comments on this LCD.

Operator: Thank you. Again, if you have a question or comment, please press star, then one. Our first – our first comment comes from Thomas Brooks. Your line is open.

Thomas Brooks: Dr. Kettler, thank you for talking. I have a number of questions about this policy. We basically redid this policy four or five years ago. Is that correct?

Robert Kettler: I think it's a little longer than that. The history of the facet joint injection is, in terms of our current policy, right around the time I joined WPS, which would be about eight years ago now, there was a work group of CMDs who worked on developing a collaborative LCD for facet joint injections.

The collaborative process at that time was little looser than it is currently. And so, the LCDs did end up differing, in some cases, considerably among the MACs. More recently, we again had a collaborative effort to develop LCD for facet joint procedures and this current LCD is a result of that.

I think that the collaborative process is now a little more formalized. I think there is more of an emphasis on using evidence to develop the LCD. But, that's the basic history of the LCD, both the current one we have and this draft one.

Thomas Brooks: As an interventional pain physician, I have just a few concerns. It seems like the general processes become more restrictive specifically as it relates to therapeutic facet joint procedures. Previously, there has been some allowance for medical decision-making and, in this current policy, it seems to be less so.

I know that I have a number of patients who do very well with the therapeutic facet joint injection and will go for 6 months, 8 months, 12 months at a time. And for some of those people that may need two injections a year and it looks like the current criteria won't allow for that and we'll have to be forced into performing arguably a more risky procedure with RFA. Am I reading that correctly especially in Section B?

Robert Kettler: Let me go to the LCD. I'm not quite sure I'm following you there.

Thomas Brooks: OK.

Robert Kettler: Could you maybe just elaborate on that and I'll pull the LCD up?

Thomas Brooks: Yes, certainly.

Thomas Brooks: In therapeutic facet joint injections, it's considered medically reasonable for a patient to meet all of the following criteria. The first one is patient has had two diagnostic blocks with a minimum of 80 percent pain relief or 50 percent improvement in (active release) of daily living.

Subsequent therapeutic procedure at the same site results in at least a consistent 50 percent pain relief for at least three months. And, there has to be documentation why the patient cannot go on to radiofrequency ablation.

So, in order to perform a therapeutic block, you have to meet all these criteria and if the patient doesn't have an implanted pacemaker or bladder stimulator or whatever that the patient pretty much has to go through the radiofrequency arm. That's what I'm reading in Section B.

Robert Kettler: You know, I get your – I get your point. Just as a general comment – and this was something that I am going to discuss later, I think one of the things that

we have found with all of our LCDs is that the language can be interpreted differently by, for instance, practitioners who are doing this on a day-to-day basis and people who are writing the LCD.

What I would encourage you to do is to put that concern into an e-mail to policy comments. Those will be taken back to the work group. And what it is going to happen is we will be looking at all of those comments, developing a response to them and potentially modifying the LCD.

As I say, I get what you're – I get your point and I think it's a good thing to bring to the attention of the work group. There was a question earlier as to what is the way in which the comments are responded to. There will be a response to comments document that is appended to the LCD. So, that's how you can see what the results of your comment was. But, as I say, I would encourage you to send that into policy comments and we will take that up.

Thomas Brooks: Thank you.

Robert Kettler: You're welcome.

Operator: Thank you. Our next question comes from Justin Wikle. Your line is open.

Justin Wikle: Hello, thank you. Yes, Justin Wikle, one of the pain physicians here as well. I second some of the comments that the previous physicians spoke about.

The question I had was in regards to page four. One of the most important aspects of this new LCD is somewhat clearly to be a little bit more restrictive and I have some concern regarding the language. You know, it says 80 percent pain, but this is for the diagnostic medial branch block – 80 percent pain relief or at least 50 percent consistent objective improvement and ability to perform previously painful movements and ADLs.

I guess I'm just – I'm curious as to what they're going to want in regards to documentation of this. There's many different ADLs. Is this a yes/no? Was there 50 percent reduction, yes, or is it going to be more involved in that, it just seems a little bit vague from what I read?

Robert Kettler: Do you have suggestions for what might be a better terminology there?

Justin Wikle: I think I could perhaps come up with something.

Robert Kettler: OK. All right. That would be good.

Justin Wikle: OK. And then, in general, again, as the previous commenter spoke about, there's many reasons to decline a radiofrequency ablation in favor of doing the intra-articular facet injection.

Some of it is on chronic anti-coagulation, for example, holding that multiple times, so that you could then perform the radiofrequency ablation as opposed to just once or twice a year for a therapeutic facet injection. Is just another example of where I think that would be a poor choice in regards to denying the access to that particular care.

Robert Kettler: OK.

Justin Wikle: I think that's it. Thank you very much.

Robert Kettler: All right. Well, thank you.

Operator: Thank you. Our next question comes from John Dooley. Your line is open.

John Dooley: Good afternoon, gentlemen. I represent the Iowa Society of Anesthesiologist sand I am an interventional pain physician. Several comments.

First of all, I would reiterate the therapeutic nature of intra-articular facet injections being useful for some patients and would actually suggest that the criteria that are in the last statement in parenthesis simply be prefaced by "e.g.".

So, for example, these are listed, meaning that – or implying that there are other circumstances where medical necessity earlier documented in the charts would then be allowed for payment of therapeutic intra-articular injections. So, a simple change in that terminology or the written word as articulated in those current parentheses could be made to solve my concern about that.

Another thing that I've noticed is that, in the preface, on the covered indications for facet injections, it basically mentions severe chronic neck or low back pain, that really leaves thoracic spine pain up the air unmentioned.

Now, on down later in the LCD, it does mention the evidence for thoracic facet joints diagnostic injections and, in particular, the fact that there is very little in the literature about them. I think it might be useful in order to clear any confusion about the fact that the listed criteria for chronic neck and low back either be expanded to mid-back pain, axial pain, and that actual mentioned or you leave it out lower in the LCD, so people aren't really confused about this.

I know, personally, I don't do thoracic facet joints workups with medial branch blocks because it's unclear to me because of controversy in the literature about where the medial branch arises and whether or not is could even be accessed safely with a radiofrequency probe, you know, at least as I understand it right now. So, I think it would be useful to clear that up some because it just leads to less confusion later on.

My remaining two comments actually are made because there is no comment in the analysis of evidence about this – about these two topics. And so, I wanted to address them. One of them has been mentioned by Dr. Wikle is the fact that how do we measure ADL improvement in the timeframe of the local anesthetic duration done in the case of a diagnostic block.

You know, ADLs are not defined in the policy here. There is two comments or two descriptions of standing and walking made, but other than that, nothing else is there. Most of my patients are – have rural residences that are sometimes located 100 miles away from my office. I'm not even sure that they can back home in time in the duration of the local anesthetic to even test ADLs at least as I conceive of them, which are things like housework, yardwork, cooking, shopping, those sorts of things.

So, I think reliance on ADLs is too vague to actually allow measurement. And the fact that it requires, in that statement, a proof of the effectiveness of the block to be either improvement in provoked pain by movement and ADL improvement really is going to create heartburn for a lot of people trying to

interpret what they actually have to document in order to move on in the treatment of these diseases in the facet.

So, I would suggest that you simply correct that by, instead of saying “and”, just put “or”. And, then if we have documentation of improvement of provoked pain “or” improvement of ADLs, which some people definitely meet that criteria because they’ll come in and you try to provoke the pain and you can’t always provoke the pain reliably with extension or lateral flexion or rotation, which we commonly think of as loading facet joints, but they can go out and walk for five minutes or they can go sit in their car for five minutes and tell you whether or not the block has been effective.

So, I would correct that with “or”. I would point out again that – as I preface this, there’s no comment in the analysis of evidence. So, perhaps this could be considered without offending anyone who has gone to the trouble of writing this product.

It also is noted that the tools of function are not going to be accurately assessed as they rely on experiences that are unlikely to be encountered in the duration of the local anesthetic for the diagnostic block. And, it’s noted by myself in reading through the evidence and the guidelines there listed in the LCD that there was no agreement as to the cutoffs in those tools, which would distinguish an effective block versus non-effective block. So, I still think that there’s room to improve the LCD on that basis.

My last comment is the fact that the treating requirements for this are simply left up to the state. And, you know in the state of Iowa that includes, I guess, CRNAs that can do this. However, I would caution the Medicare contractor that, simply because the state determines what practitioners can do what, doesn’t necessarily protect Medicare beneficiaries from poor care.

CRNAs are not trained to do these procedures in their training programs as far as I know. And, I would point out that the structures underlying the needle when placed deep in the cervical spine and thoracic spine include not only vascular structures, but solid spinal cord structures.

And, in the lumbar spine, it's different. Most of the underlying structures at most of the levels that facet joint diseases encounter are not solid cord structures that needles are going to damage if they hit them in the usual circumstance.

However, in the cervical cord, or in the cervical region or in the thoracic region, if you have a practitioner who is not well trained in the anatomy, and especially the fluoroscopic anatomy, and the process by which a practitioner guides safety in the placement, the final placement of that needle fit before injecting it, disasters have been known to happen, are documented to have happened, and the litigation world is filled with them because I've been included in a number of them for analysis of cases.

And those are treacherous areas that if Medicare is going to say, "OK, this is fine to have a CRNA degree and put these needles in there," and actually destruct a deeper tissue structures, which in no other specialty of medicine do I see nursing practitioners do, then I think you should aware that some of your beneficiaries may come to harm potentially.

It's a different thing taking off a mole on the skin as opposed to excising a tumor well under the skin, or putting a needle into the skin versus putting a needle down next to the spinal cord where, if you don't know where that needle tip is, when you inject that local anesthetic or a steroid or you sent down a (heating) amount of current to destruct tissue, treacherous results can occur. And, I make this comment again because no comments are made in the analysis evidence about this or about training criteria. Thank you very much.

Robert Kettler: Thank you. And, just one thing, when you submit your comments in writing, going back to the example you mentioned about people having a ways to be transported from your clinic, I think that's a good practical consideration that does need to be brought to the attention of the workgroup. So, I'd encourage you to include that example.

Operator: Thank you. Our next question comes from Alison Weisheipl. Your line is open.

Alison Weisheipl: Hi, yes. Alison Weisheipl, pain physician in Iowa. And, first, I want to just kind of reiterate that the RFAs and MBBs, facets are the special procedures for our world for patients, they really provide a lot of relief for patients, long-term relief and can minimize use of steroids, minimize use of opioids and really increased functionality.

And then, just really to keep my comment brief, I'm kind of piggybacking on what Justin and John just mentioned. One of the things is that in the therapeutic facet injections in the wording of the document here, it kind of implies that you have to have had two diagnostic procedures before considering the therapeutic.

And like, I believe, Justin said, there are considerations or times when a therapeutic facet injection or (MBB) injection is indicated and it seems – and then, document why the patient is not a candidate for RFA. It seems like a lot of extra steps to go through when it may be more appropriate to consider a facet injection. The other thing – I agree with John as he mentioned is having a criteria placed for training requirements for people doing these procedures, so I largely agree with that. And that's it.

Robert Kettler: OK. Thank you.

Operator: Thank you. I'm showing no further questions at this time.

Robert Kettler: OK. You know, I want to thank everybody. I think that this has been a really good discussion. I just would summarize by saying that 4 of the LCDs that were presented, the comment period ends November 14. For this last one, the comment period is open until December 12. And, please do submit your comments.

This does end the public portion of our CAC meeting. And, so Valerie, would you please disconnect the observer line so that our observers may get on with the rest of their evening?

Operator: Thank you. One moment please.