WPS Government Health Administrators J5 Contractor Advisory Committee Meeting Transcript

Chair: Dr. Robert Kettler

October 20, 2022, 6:00 PM CT (7:00 PM ET)

Dr. Robert Kettler: Okay, thank you.

And good evening, everybody, this is the jurisdiction 5 Medicare Administrative Contractor Advisory Committee meeting. And we are going to, as our first order of business, take comment on the draft LCDs. I'm just going to run through a little bit of a procedure to orient everyone. This is a public portion of our CAC meeting. Its purpose is for taking comment on the draft LCDs that have been posted, and there's no other business that we will conduct during this portion of the meeting. The public had the opportunity to comment at the open meeting yesterday, and this time is reserved for the CAC members to be able to provide comment. I do encourage those CAC members who provide comments to also submit them in writing as well, in case there are audio problems. Comments may be submitted in writing to policycomments@wpsic.com, and the comment period is open until November 12th for all of the draft LCDs.

During this portion of the meeting, WPS personnel will probably not provide a comment or response to the comments that we get. We typically research the comments that we have been given and will respond in writing in the response to comments form that is attached to the LCD when the LCD is finalized. Also, these LCDs are collaborative LCDs developed with other MACs. We tried to act consistently across jurisdictions, so there may well be some discussion amongst the MACs in terms of the comments that we receive. So, that's why we don't always respond during the comment period here. If somebody has a question of clarification, that's probably something that we'd be able to handle, but as I say, a response to comment is something we typically don't do.

I'm going to run through the draft LCDs one at a time. I'll identify them by number, title and the CMD who is responsible for the LCD. WPS will then take comment on the LCD from any members of the CAC who wish to provide comment. If any CAC member would prefer to comment in writing, rather than this evening, written comment, as I said, maybe submitted to policycomments@wpsic.com. Comments that are intended to recommend a substantive change in the LCD should be accompanied by published medical literature to support the recommended change. And it's important that you submit the document as a whole and not just an abstract or a link to an article. We do need to have the entire article for review.

And with that, I will proceed to the first LCD, which is DL39477, Allogeneic Hematopoietic Cell Transplantation for Primary Refractory or Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-Cell or T-Cell Origin. This LCD supplements NCD 110.23 by clarifying that the aforementioned lymphomas are covered for the diagnosis

indicated when refractory to standard of care treatment, or relapsing and without alternative potentially curative options. This is consistent with a statement in the NCD that diagnoses not listed in the NCD are coverable or non-coverable at Contractor discretion. Dr Barry Whites is the responsible CMD for this LCD, and I will take any comments.

Dr. Joseph Muscato: Just a comment from me, I reviewed this and it looks very reasonable. And certainly, I think it's well written. So no other comments from me. Thanks.

Dr. Kettler: Thank you Joe.

Any other comments?

Hearing none I will proceed to the next LCD.

This is DL39479 MolDX: Molecular Assays for the Diagnosis of Cutaneous Melanoma. This is a limited coverage LCD, providing criteria for the coverage of molecular DNA or RNA assays to assist in the diagnosis or exclusion of melanoma in biopsy specimens. Dr. Whites is the responsible CMD for this draft LCD. And with that, we will take any comments.

Dr. Muscato: Hey Bob, I just have a question or clarification; so the way it reads, and I guess it's true, is that the pathologists would read the biopsy and only if the pathologist is then struggling with this indeterminate question of melanoma then they can request the molecular testing. Is that the way I read that? Is that the implication of this? I was reading that, right?

Dr. Kettler: Yeah. Yeah, I'm going to ask Dr. Whites to take that question. Barry, are you on the line?

Dr. Barry Whites: That that is the intent of the policy. Yes.

Dr. Muscato: So, how do you how do you write that into a policy? So that the pathologist should be able to request it, and then you just have to say the problem is that I can't make a definitive diagnosis and that's how you justify it by the pathologist. Is that right?

Dr. Whites: Yes, it is not something that we can put a specific edit in, but we do get the records, if we happen to get a record, and we'll be looking for that documentation. If it's not there, it would be most likely be denied or ask for additional information to be submitted.

Dr. Muscato: Sounds reasonable. Yeah thanks.

Dr. Kettler: Any other comments or questions?

Dr. Joshua Mammen: This is Josh Mammen from Nebraska. Can I make a comment as well?

Dr. Kettler: Yes, go ahead. Please.

Dr. Mammen: And just, this is a little bit about more of context; at most treating cancer centers, melanoma pathology is routinely reviewed as a second opinion as a standard of care, not only for melanoma, but for breast cancer as well because there's a tremendous inter-pathologist variability in the diagnosis.

Dr. Kettler: Okay, thank you. Other comments or questions?

Okay, hearing none, the next draft LCD is DL39481: MolDX: Molecular Biomarker Testing to Guide Targeted Therapy Selection in Rheumatoid Arthritis. This is a non-coverage LCD that on review of the available evidence, concludes that the tests measuring genetic and gene expression factors do not provide value above the available clinical, laboratory and demographic data in terms of treating rheumatoid arthritis. Again, Dr. Barry Whites is the CMD responsible for this draft LCD. And with that, we will take any comments or questions.

Okay, hearing none the next draft LCD is DL39475, Sacroiliac Joint Injections and Procedures. This is a limited coverage LCD, providing the indications for coverage of sacroiliac joint injections, both diagnostic and therapeutic, and it does state that radio frequency ablations of the sacroiliac joint are not covered. I, Dr. Kettler, am responsible for this draft LCD, and I will take any questions or comments.

Dr. Ben Northrup: This is Ben Northrup from Missouri, radiologist. I have a comment on this one. So, I have in front of me a document from colleagues at the Society of Interventional Radiology as well, as the North American Spine Society and the ASNR, which is the Society for Neuro-Radiology. They have comments on two separate portions of this. The first one, being the sacroiliac joint – the therapeutic sacroiliac joint injection portion of it – on that, and I'll use their words here to make sure I get it exactly. correct here, what their concern was, they say "the proposed LCD states under limitations, that sacroiliac joint injections to treat axial spine pain are investigational, and therefore not considered medically reasonable and necessary. As written, the language could possibly be construed as excluding pain over the sacrum. Therefore, we recommend that the language be revised to axial spine pain, primarily above the level of L5." And they will be submitting, the society, as I mentioned, will be submitting this written comment via the ACR to you in the next few days, I believe. So, that was their comment on that portion.

Their other comment was on the RFA portion of it, and again, I'll use their exact words there to make sure I'm fully clear on what they're saying. So, on this portion, they explain that "the sacroiliac joint has both anterior and posterior innervation. The joint itself is innervated anteriorly by the lumbo-sacral trunks, obturator nerve and gluteal nerves. The posterior sacroiliac joint complex is innervated by the posterior sacral network, which consists of primarily the S1 through S3 dorsal rami, and in some cases fibers of the L5 dorsal ramus. It is important to note that the intra-articular joint and the posterior sacroiliac joint complex are two different pain generators with different innervations. It logically follows that they should require different treatments to appropriately target the structures responsible for the respective generation of pain. Intra-articular injections target anterior innervation. If pain is originating from the posterior sacroiliac joint complex, intra-articular injections will not result in significant improvements in pain or function. As currently proposed, patients with pain originating from the posterior sacroiliac joint complex have no interventional treatment options. Intra-articular SI joint injections do not diagnose or treat pain originating from the posterior sacroiliac joint complex." So, their concern is the two different sites essentially, and the potential coverage gap, the lack of access patients who specifically have pain arising from that posterior joint complex, for which in our literature, there's no other treatment beyond RFA.

Dr. Kettler: Okay, thank you Ben. And you said they are planning to submit those comments in writing then to us?

Dr. Northrup: Yes, yes, I have a copy of the letter here, and this has references, articles, societal statements from at least two of the societies that I mentioned. And they've sent it to the ACR and plan to- once the CAC network of the ACR looks over it

and gives our stamp of approval, they have said they will send on a letter or a very close version of this to you.

Dr. Kettler: Okay, thank you, and then just for your information and the rest of the people in attendance, this is a collaborative LCD. It was developed by a work group consisting of multiple MACs, and so that would be something that the work group would discuss. But thank you for the comment.

Are there any other comments or questions on this LCD?

Dr. Justin Wikle: This is Justin Wikle, one of the pain docs from University of Iowa. And I'd actually just like to thank Dr Northrup, because he's somewhat clarified, and essentially said, what I was about to. So thank you.

Dr. Kettler: Other comments?

Okay. Moving on, the next LCD is. DL38684, MolDX: Prognostic and Predictive Molecular Classifiers for Bladder Cancer. This is a limited coverage LCD that provides the indications for coverage of tests allowing for an individualized risk to benefit assessment in order to guide therapy in patients with bladder cancer. Dr Barry Whites is the CMD responsible for this draft LCD.

Are there any comments or questions?

Dr. Muscato: This is Joe. I guess I'm – I read through it, and I'm trying to decide what they're actually recommending, because I can't exactly tell. And they talk about a lot of tests, and certainly for stage four disease, many of these are appropriate looking for molecular treatments. But, is this just an outline of how this would be approached? Because I can't find justification for doing the tests in terms of stage two or three disease. I'm trying to figure this out. What was the – what's the actual recommendation here?

Dr. Kettler: Barry, do you have any comments on that?

Dr. Whites: All the unmutes here… As mentioned before, these are multijurisdictional. This was from MolDX, a group from Palmetto. It was primarily to predict response to specific therapy among accepted therapy options, based on nationally recognized societal consensus. And so these, these predictive, elected are classifiers, are

mentioned in national guidelines to help predict which medications the patients will respond to when multiple therapies or an option. And that's how they're to be used, according to this policy.

Dr. Muscato: Okay, so, yeah. So, it's not really for earlier stage disease, unless it's neuroendocrine. For later stages, these, I certainly agree. So, it's generally for the bladder, so it wasn't – it mentions – it talks a lot about options for earlier stage of muscle invasive like cystectomy and stuff, but it's really a general statement about bladder cancer and how you'd approach the problem.

Dr. Whites: Yes, sir.

Dr. Muscato: Okay.

Dr. Kettler: Other comments or questions?

Okay, and then I have the last draft LCD. I almost feel like I'm in a Karnak routine for those who remember Johnny Carson from back then. This is for DL34645, Urine Drug Testing. This draft LCD is a collaborative revision of a current LCD with the goal of establishing consistency and clarity of coverage across MAC jurisdictions. And again, Dr Barry Whites is the CMD responsible for this LCD.

Are there any comments or questions?

Dr. John Dooley: Hi, Dr. Kettler, my name is John Dooley, I'm a pain physician in Iowa, representing anesthesiology. And I have quite a few about this LCD, so, bear with me a little bit. I'm just going to go through it by the page.

It seems that there are some areas that are redundant in the policy that may lead to misinterpretation. If you read one and consider that, what it says, or you read another part of it and consider that the guiding standard.

And I'm not so certain that I'm worried that the doctors won't understand what they should do in regards to urine drug testing, but the reviewers for both WPS and the, and various other Medicare **r**eviewers for post claims reviews, historically, have not done a very good job of paying attention to the LCDs, let alone understanding them, in my experience. And I have several specifics of that, that I can share with you offline.

One of the problems is, is that it seems that it's a little confusing about when definitive UDTs are considered reasonable and necessary. And on page 7, it lists quite a few

things there that would lead one to believe that UDT reasonableness and necessity covers quite a bit of things; if you look at that paragraph, it's about the fourth one down from the top of the page. But yet, when you go back further in the document, It becomes less clear that all of those things are reasons that are put forward later on in the document, when it specifically talks about the frequency of definitive UDT testing. And I think that needs to be clarified so that people aren't confused about how often and what the true indications are in Medicare's eyes for doing a definitive UDT. If you look at page seven, it covers quite a bit of stuff. But if you go further back, it's not quite as clear.

Furthermore, down, when you talk about on page seven, in drug testing panels, under definitive UDT panels, you have in there that based upon historical use, clinical findings and community trends. But yet, back in the table that talks about risk and frequency of testing, it says historical use, clinical findings and/or community trends. And I think that's important, because some of the clinical findings and historical use are not going to reveal some of the indications that doctors would consider important to do definitive UDTs, if only, if all three of those components had to be necessary. So, again, a little bit of inconsistency between that and the tables.

Going further into it, it seems to me like it's very unclear to me what the risk assessment plan actually is for. I'm not sure what risk Medicare is trying to hinge urine drug testing on; is it the risk of developing an opioid use disorder, or now known as the substance use disorder? Pseudo- Versus OUD, which seems to be the old terminology, and which is used throughout this document, which may need to be updated. Or is it actually aberrant behaviors that are sometimes associated with patients on chronic opioid therapy. Because ORT was first developed to predict aberrant behaviors, not development of opioid use disorders, and it's the old original ORT which you've listed as an example. So I'm assuming by the fact that that was developed to detect aberrant behavior risk, that that's what Medicare is indeed concerned about. Because I would simply point out that behaviors, aberrant risk behaviors, can be related to a lot of other things besides abuse or misuse of opioids. And I'm not sure that it's clear-cut here exactly if that's what the risk is you want assessed in determining frequency of UDT, or if it's a different risk, that may need to be updated some, and actually propensity for these patients to go on and develop an opioid use disorder. I understand there's some satility to this, but I do think it's worth teasing out so that the doctors understand truly why UDT can be- when it can be done - under this LCD, cause it's not entirely clear what risk you're trying for us to quantify here.

I realize that you preface that with, this is yet but just one example as opposed to many other examples that are out there and which could also be used, but I would challenge any of those other metrics done with testing and screening testing to actually produce an accurate and predictable risk assessment. As opposed to clinical judgment, of a physician, who's going to prescribe a controlled substance and talking to the patient about the currency of some of these things in their historical background, which under the testing – under the screening test - would put them at risk, but which a physician

exhibiting judgment might say “Yes, I realized that's a historical fact of your history, but it's been 25 years ago and when you were a young person, and is not an operative concern at this point in time.” Because I think we can all say that people do evolve in their maturity levels, and particularly from younger people to older people in adulthood. And so, I think that clinical judgment here also needs to be elevated, at least to the level that Medicare seems to want to ascribe to screening studies, which have really not good predictability for what is yet not totally a defined risk that you're trying to assign to a patient to determine frequency.

So, I think there's some concerns there that need to be worked out. The actual citation that you talk about first in COT monitoring testing on page 11, number one, is actually outdated information, that has actually been removed from the website of the Society of Addiction Medicine, because a more current recommendation now exists, and which has been up there actually for quite a long time.

So, I think that even though there may have been an effort here to try to come into agreement with all the other MACs, I'm not sure that that's the best you can do. I think you can do a better job and sort out more clearly for us when UDTs are a reasonable thing and a necessary thing for doctors to do.

The other thing that that I noticed when talking about other covered services on page 13 - I had to go back a little bit because I missed that - It also seems in this part that you talk about reflex testing, but you qualify it by reference Labs. I mean, is it really different reflex testing by a reference lab versus a physician lab, If that capability is present, and what would be the discerning difference there? It makes an allusion to that there's no access to patient specific data, but kind of goes on to suggest that if there's a prescribed list of medications that may or may not predict the result, that that could be used by the reference lab. But there's a whole lot of other reason to do definitive testing as denoted way up previously, when I first started to speak about this on page seven, that covers a wide variety of definitive testing.

I'm happy to put all of this into writing. It'll probably be a fairly long document, so I apologize to you about that. But I think there's some work yet to be done on this. Even though it may have to occur across multiple MACs. If you really, truly, want this to be a clarifying document for physicians out here, trying to decide how to do the right thing by the payer policy, because this is less than clear. And to me, almost muddies the water a little bit more because of the inconsistencies in the document.

Dr. Kettler: Okay, thank you, John. I think that those are all some really good comments and we look forward to receiving them, so thank you. And then also, I'll get in touch about those other issues you wanted to talk about. We can talk in a few days.

Dr. Dooley: Okay.

Dr. Kettler: Are there other comments or questions?

Hearing none, Rich, we can let the public listeners go on about their business for the evening and I am going to turn things over to Dr. Brady to conduct the rest of the meeting. And Mark, I think we could give Rich a minute or two to release the public, and then we can begin the closed portion of the meeting.