WPS Government Health Administrators J8 Contractor Advisory Committee Meeting Transcript

Chair: Dr. Denise Nachodsky

October 25, 2022, 5:00 PM Central (6:00 PM Eastern)

Dr. Denise Nachodsky: All right Thank you so much Rich.

Well, good evening, everyone, all of our CAC members and WPS Staff. My name is Denise Nachodsky and I'm one of the J8 Contractor Medical Directors at WPS, along with my fellow colleagues, Dr Barry Whites: he represents J5-J8; Dr. Robert Kettler, J5, and one of our new CMD's, Dr. Joelle Vlahakis.

I want to welcome you to this J8 Medicare Administrator Contractor Advisory Committee meeting tonight, which is Monday, October 24th, 2022. I will be your moderator tonight. And at this point, I'll say that the meeting has been called to order. We will be providing this meeting through virtual Webex teleconference due to continued social distancing concerns related to COVID-19. For transcript and recording purposes, an audio-video will be available through the Webex, and audio-only by call in. Again, I appreciate your attendance and participation tonight. We will begin this evening with the open CAC meeting and the presentation of six proposed draft LCDs followed by a closed educational meeting with the WPS staffing CAC members. As a reminder this meeting is being recorded. Continued participation indicates your consent for identification in any discussions regarding the draft policies presented during this meeting tonight.

So just a few logistics with this meeting: it says, noted as the slide here, that people who have called in by phone and don't have the Webex, I'll reiterate some of the logistics here. All the callers will we placed on mute upon the log-in or upon their call-in. When it is time to speak, please click the raised hand icon. It's in your lower right-hand screen, or press *3 if using a dial in phone. When the facilitator calls on you to speak, make sure your telephone and headset is not on mute. This meeting, as I stated, is being recorded and transcribed. To aid in transcription, please introduce yourself before you speak. Follow up all verbal comments on the draft by sending them in writing to medicarepolicycomments@wpsic.com.

So, the beginning part of this meeting, as I said, we are going to present six LCD drafts. Our presenter or facilitator will be Dr. Barry Whites. Open comment period for all of these six drafts is- it opened on September 29th, 2022, and the comment period will close on November 12th, 2022. The following drafts we will accept comments from up until November 12. Please send all of your comments to policycomments@wpsic.com. Please include the topic of the LCD on the email subject. We also ask that you please include published scientific studies and/or literature to support any additional coverage that you may wish to with this support. We will not respond directly to each comment

submission. Rather we will compile all the comments and publish a comment and response document with the final LCD.

Now, the purpose of this open portion of the CAC meeting is really an opportunity for all the interested parties here today to have reviewed the evidence and to provide feedback on the proposed LCDs. The interested parties here today, which for those who may be affected by these proposed LCDs, and these interested parties certainly include our physicians, our clinical physicians, beneficiaries, caregivers, vendors and manufacturers, we do invite the members in attendance tonight to provide verbal comments or any 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.

So at this time, I would like to introduce Dr Barry Whites. He is the presenter and facilitator, as I said, who actually is the lead for five of these six drafts today, that will be presented, but he will present all six drafts; at least a brief synopsis and a summary for each draft. Afterwards, Rich will open the lines for anyone who has comments.

Briefly, 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 is quite extensive and 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 B contractor. His healthcare industry experience is approximately 20 years, which includes a CMD for Part A contractor and an A/B MAC CMD, and currently a WPS GHA J5 and J8 CMD since 2020. He's currently the chair-person of numerous multijurisdictional LCD work groups, which includes such committees, such as the pricing committee, Category T and III codes, drugs of abuse, et cetera.

As part of our process, Dr. Whites will give a synopsis of the draft LCDs, and then we'll take oral comments afterwards. Again, just to reiterate, I may say this a few times tonight so please bear with me, but any written comments, please note, please send them again by November, 12th, 2022 and if you could send in your written comments to policycomments@wpsic.com. And at this time, it's my pleasure to have Dr. Barry Whites begin his presentation. Thank you and take it away Dr. Whites.

Dr. Barry Whites: Okay, thank you very much, Denise. We have some interesting items to bring up; four of the six are molecular diagnostic codes, and those were primarily developed by Palmetto, who handles the MolDx Contract, and we are participants with them, along with two other MACs who make up the MolDX Contractors.

The first one I'd like to present is not a MolDX practice, but is a LCD number 39477. It is Allogeneic Hematopoietic Cell Transplantation for Primarily Refractory and Relapsed Hodgkin's and Non-Hodgkin's Lymphoma with B-Cell or T-Cell Origin. This policy was an adoption of a policy from Palmetto in response to a request by ASH and other societies for adoption. There has not really been a problem with coverage, but- it should not have been, but the hospitals were liking some guarantee of coverage if certain criteria were met. This policy addresses the local coverage indication for allogeneic stem cell transplantation. It is consistent with the NCD 110.23 for primary refractory or relapsed Hodgkin's and non-Hodgkin's lymphoma with B-cell or T-cell origin. And the important point, is for whom there is no other curative intent options. This meets the statutory and CMS requirement for medically reasonable and necessary coverage and reimbursement. The overall review of the evidence is consistently supportive of the potential benefit. Patients who suffer from such disease may have no other available therapeutic options for curative intent. The effectiveness of Allo-HSCT in such patients has been identified, and accounts for its inclusion in many national oncologic hematologic clinical practice guidelines that are evidence graded. The development of reduced intensity conditioning, the adoption of maximum age increases for transplant programs, and the improved screening and treatment of comorbid conditions in older persons had led to the conclusion that age should not be a contraindication. At this point, I'll be happy to entertain any comments or questions that you may have.

Dr. Nachodsky: Thank you so very much Dr. Whites, for this draft DL39477. Are there any comments or concerns from the audience regarding this draft? Please remember to utilize your hand icon If you're on Webex or *3 from your phone. Rich will open the lines and unmute if there are any comments at this.

Richard Staley: Dr Nachodsky, one quick correction. This is the "Events" version of Webex, which means that the panelists, the CAC member panelists, simply have to unmute themselves by clicking the unmute icon. They don't have to raise their hand.

Dr. Nachodsky: Oh, thank you so much my dear friend. One less step you all have to do, so just unmute if you'd like to speak.

Okay, seeing that there's no comments from this, Dr. Whites, if you could proceed with our second draft.

Dr. Whites, you might be speaking to yourself. You might have to unmute.

Dr Whites: Well, does this sound a little better?

Dr. Nachodsky: Sounds so much more better. Thank you.

Dr. Whites: Yeah. Okay. All right. This is LCD- the proposed LCD 39479, Molecular Diagnosis of Cutaneous Melanoma, another MolDX policy. The purpose of this test is to aid the dermatopathologist to arrive at a correct diagnosis of melanoma versus non-melanoma when examining skin biopsies. The contractor will provide limited coverage for molecular DNA and RNA assays that aid in the diagnosis or exclusion of melanoma from a biopsy when all of the seven listed conditions are met as listed in the policy. They must demonstrate that Medicare beneficiaries with diagnostically challenging results, which may have improved outcomes as defined by an increase in accurate diagnosis, appropriate clinical management and interventions and a reduction in the burdens of unnecessary treatments.

I'll now take any comments from the audience.

Dr. Aleodor Andea: This is Dr. Andea. I'm a Michigan alternate representative for pathology. Can you guys- can you hear me?

Dr. Nachodsky: Yes, we can.

Dr. Andea: Yeah, I have a few comments related to this policy, so the first is related to the criteria. They said the test is ordered by a board certified or board eligible dermatopathologist. This test is used by pathologists to make a diagnosis of melanoma in histologically ambiguous cases, so any pathologist should be able to order the test, not just dermatopathologists. I happen to be a dermatopathologist, but I think any pathologist should be able to order the test, and they should do so. There are a lot of places that don't have a dermatopathologist, but they're still required to make a diagnosis.

The second comment I have relates to- they said the patient has not been tested with the same or similar assays for the same clinical indication. There are several assays that do the same thing, DNA or RNA based: there's the gene expression profile that this assay refers to, but they also talk about CGH or DNA arrays, and also PRAME immunohistochemistry, and fluorescence in situ hybridization. Most of these tests will issue an indeterminate result, like, the gene expression profile up to- some publications quote up to 20% indeterminate results. So, in in an instance like this, it would be appropriate for the patient to seek an alternative, or for the pathologist to seek an

alternate test. So this is not unusual. I happen to be doing this assay, so that's why I speak informed.

And then I have more general comments regarding the write up. It seems like the proposal is skewed heavily towards the gene expression profile testing, whereas they mentioned there are other tests available. There are four or five of these tests available. The coverage is made for DNA and RNA testing, which covers some of the other, like the SNP arrays and FISH, but they talk, for example, about PRAME Immunohistochemistry, which is not the DNA assay, but it's a similar test. So, I assume, is that covered or not? I don't know.

So I think the evidence presented lacks in presenting evidence for fluorescence in situ and SNP array, and some of the evidence is not up to date. So, I'll be happy to provide- I don't think we need to spend a lot of time on this - I'll have to provide comments, written comments on this LCD.

Dr. Nachodsky: Thank you so very much for your comments. Go ahead, Dr. Whites.

Dr. Whites: Yes, Thank you so much for the comments.

These policies are primarily written by the molecular diagnosis physician at Palmetto. The issue is that recently they had decided that they would only be covering or writing about policies for DNA and RNA assays and I'll [inaudible] would be up to the individual MACs. So, this is their policy concerning only DNA and RNA assays, not any other items outside that realm. We certainly realize that there are other tests outside the DNA and RNA realm, but what would be extremely helpful, if you would submit to us your comments in writing with the documentation, where we may bring this, which is one of the things that we've been trying to get established, is that molecular diagnosis is not just about DNA and RNA assays, that certainly are the proteins that are generated by those same items, so it would be very helpful to us to have your comments and the literature to support that. And I do appreciate your comments.

Dr. Andea: So, I'll be happy to do that in the next few days.

Dr. Nachodsky: Thank you very much.

Dr. Whites: Thank you, thank you.

The next item is- Any other comments?

Dr. Nachodsky: Any other comments? Yeah.

Dr. Don Selzer: Yeah, I would like, if I – I'm Don Selzer, from- I'm a general surgeon and representing the American College of Surgeons chapter in Indiana. And I would have to add on specifically in regard to the need for it to be a board certified, a board eligible, dermatopathologist. I think when you look at Indiana, my expectations, based upon the distribution of the population centers in Indiana and the medical schools, the likelihood of a board certified, board eligible dermatopathologist throughout the state is probably pretty low. And I don't think that that will be best, with regard to our rural population, at managing access to care for melanoma. This is something that should be able to be diagnosed in population centers as small as 10,000 or 15,000, that have a hospital that's 50 beds or less. I don't think that it needs to necessarily be at a medical center, like in Indianapolis, or presumably in Detroit or Ann Arbor. It should be something that should be accessible to the wide population that CMS represents.

Dr. Nachodsky: Thank you so much for your comments, much appreciated, you know, so, if it'd be greatly appreciated, if you could put this in writing these comments and email them to the policycomments@wpsic.com.

Are there any other comments regarding this draft 39481.

Richard Staley: This is Rich, the administrative assistant. I just want to remind; there are several CAC members I see that are on telephone only. You can press *3 if you would like to make a comment and that way, you can contribute to the meeting even though you are not on your computer at this time. Thank you.

Dr. Andea: I have a quick question coming back; we've discussed an LCD similar to this a couple of months ago. Is that a different contractor? Or where is this coming from?

Can you hear me?

Dr. Whites: Yes, it is the same contractor who seems to have changed their responsibility areas. That's our issue.

Dr. Andea: Because I think that what Dr. Selzer said, which is, I mean, I think we said at the time that we wanted not just dermatopathologists to be able to order the test, and that has not been changed.

Dr. Whites: We certainly agree with that recommendation and we just need it in writing to present it back to the MolDX, if you would, for them.

Dr. Andea: Okay, Okay, sure.

Dr. Whites: Thank you. Appreciate it.

Dr. Nachodsky: Okay, Dr. Whites, if you'd like to proceed with the third draft.

Dr. Whites: Yes, the third draft is another molecular diagnostic panel. It is Limited Biomarker Testing for Targeted Therapy in Selected Patients with Rheumatoid Arthritis. This is a non-covered test by this contractor and all molecular diagnostic contractors. Despite the availability of multiple treatment options, there is no certain way to predict which patients will respond to various available therapies.

An evidentiary CAC was held using subject matter experts across the United States by the MolDX contractor. The findings and conclusions of the panelists were they were not aware that any such tests had rigorously been validated for routine clinical use at the present time. The- also, the international national and societal guidelines have not endorsed predictive, correspond to therapy, biomarker testing to date, and members of this committee, while agreeing with the value of such tests, did not think that such tests had demonstrated enough evidence to warrant routine clinical use. Therefore, the concept of clinical validity and utility was not yet established according to these experts. They established that molecular biomarker tests that guide therapies in the current. practice milieu, the contractor will continue to monitor the evidence. It may modify coverage as more information becomes available.

Any comments on this, please?

Dr. Amar Majjhoo: Yeah. Hi, this is Amar Majjhoo, I'm a rheumatologist in Michigan. You know, I believe there was a meeting last December and several specialists did jump on the meeting and present the available data. And I believe you're referring to the PRISM RA study; this is the test that's predictive of non-response to a anti-TNF agent. And, admittedly, from what I know, there's not a ton of data out there. But the data that

has been made available seems promising, and the value of this test is to be able to predict or not if someone's going to respond to that particular agent, a TNF agent, and the data they had presented some of the meetings was that if in two groups of patients, patients that had received care with using the test, versus those that got the usual care, that it saved them, like, something like, in the order of six months of time. If these patients are predicted not to respond to a TNF, they ended up being on a TNF inhibitor. And so it would save a considerable amount of time. So I think, you know, the position that many of the Rheumatology groups have taken is to support use of this test, and obviously, keep an eye on to look at the more data that comes up. But it does seem promising to be able to predict and fine tune the therapies that we have.

Dr. Whites: If you have new data, certainly as mentioned, please present that to us. It was I felt about the panelists and the subject matter experts that it was very promising, but just not quite there yet, but that soon would be. So, any new data that you might have that's not listed on the publication having been considered would certainly appreciate your, including that in your comments. Thank you.

Dr. Majjhoo: Okay. I will, I will do that. I think, you know, we have our big national meeting coming up soon in the next couple weeks. So I'm sure they'll do some follow up there.

Dr. Whites: That would be great.

Dr. Majjhoo: All right. Thank you.

Dr. Nachodsky: Thank you so much for your comments. Please note though – you said you had a conference coming up – note that the open period closes on November 12th. Okay.

Dr. Majjhoo: All right, thank you.

Dr. Nachodsky: Thank you.

If there are no other comments for this LCD, Dr. Whites, if you'd like to proceed with our fourth draft?

Dr. Whites: …hit all my correct mute buttons. The next one is, believe it or not, not a MolDX. It is Sacroiliac Joint Injections and Procedures. This is a terribly long policy; it's 37 pages long. It has significant number of covered indications; six that are listed. It has diagnostic injection criteria, and they must meet all of the criteria listed in the policy. There are both definition for diagnostic as well as therapeutic. The diagnostic has five criteria as mentioned, therapeutic have four criteria listed. Limitations, as far as the number of tests can be done over a rolling 12-month period, and the performer of these tests should certainly be familiar with this. In addition, radiofrequency ablation, or RFA, is considered investigational and not reasonable and necessary. The requirements is listing are nine criteria that are listed in the policy for coverage requirements, and all of them have to be met. There are 11 limitations in this policy. And again, this 37-page document has specific criteria and limitations is to diagnose physical findings, limitations to the tests that are done, the diagnostic interject- injections, therapeutic injection criteria as well as ablation criteria. That's a very brief summary of a very long LCD. Comments? Questions?

Dr. Josh Suderman: Hello, this is Josh Suderman, I'm a pain management physician from Michigan. I appreciate your time tonight and effort. This was a big policy and it's taken a lot of experts and input on this. And it's a big deal, because it's a very important procedure that a lot of people will get benefit from. So really appreciate your time and effort putting this together.

Specifically, looking at the SI joint ablations, I've talked with people from multiple specialty societies. A lot of concern about the non-coverage for the SI ablation technique. Multiple national societies do not agree with this, and there were some studies that some experts I talked to, that were not included, in multiple societies do believe there's actually level one evidence for SI joint ablation techniques. One request, or one thought, because it is such a big policy and there's a lot of ground to cover: would it be possible to exclude the SI ablation from this LCD, carve it out and put it into a future LCD, so that there can be more time for discussion of this, because it is such a big topic already.

Dr. Nachodsky: Thank you for your time.

Dr. Whites: I am not the primary author of this one, Dr Kettler is. And he is on the call and can certainly answer that question better than I can answer it. But if you would put your request, the reasons, and the documentation that you have and address that to the policy comments email, that certainly would be helpful and it will be given due consideration.

Dr. Suderman: Okay, one, I had one clarifying part or question for the policy unless Dr Kettler had any other response on that.

Dr. Robert Kettler: Josh, why don't you go ahead with your next, and then I'll just take them both at the same time.

Dr. Suderman: Okay, the requirement for the 75% benefit with a diagnostic joint injection, is that going to apply to people who already are getting the therapeutic SI joint injections?

Dr. Kettler: Just so I understand what you're saying is that somebody is getting therapeutic injections, and then the question is, do they have to undergo a diagnostic block?

Dr. Suderman: Yeah, like, when the LCD takes effect, if someone historically has been getting therapeutic SI injections, and they meet the inclusion criteria - the exam maneuvers and documented benefit – when this LCD takes effect, do we need to kind of retroactively do a diagnostic injection, show 75%, in order to keep moving forward, or is this just for newly diagnosed from there on?

Dr. Kettler: You know, I think it would be good to submit a recommendation that we clarify that.

Dr. Suderman: Okay.

Dr. Kettler: And just by way of background, I think Barry did mention this is a collaborative LCD. And it was developed by multiple MACs to try to achieve some consistency across jurisdictions.

Dr. Suderman: Mm Hmm.

Dr. Kettler: And so, the reason why I'm suggesting that you submit that recommendation is that would be something that I think is open to interpretation and it would be good to make it explicit to have consistency. I understand what you're saying. I think what you're saying makes a lot of sense, but I do think it's important that we make it explicit in the LCD

Dr. Suderman: Okay.

Dr. Kettler: And then, your other comment or suggestion was that we carve out the ablation part, give it some time for us to gather further evidence. Again, I would recommend that you submit that suggestion. The one thing that I would say is – even if the ablation part stayed in and was unchanged, there is always the option to provide, or to have a reconsideration request with the submission of evidence to support a change.

Dr. Suderman: Yeah

Dr. Kettler: and I think that the thinking, in having it in this was that we would have one policy that would address most of the modalities, if not all of them. And so, I think it was an attempt to try and tie everything together. But again, I'd encourage you to submit that suggestion, provide as good a rationale as you feel you can, and the collaborative group will discuss it.

Dr. Suderman: Okay, great. And as you said earlier, it's that email and I saw it in the chat there, but the policy email.

Dr. Kettler: Yes

Dr. Suderman: Great. Okay.

Dr. Kettler: And then November 12th, as has been mentioned is the end of the comment period.

Dr. Suderman: Yes, November 12, appreciate that.

Dr. Kettler: You're welcome.

Dr. Nachodsky: Thank you Dr. Kettler, for your discussing this LCD and answering some of the questions. Much appreciated.

Dr. Whites: If no other questions we'll go to the next one. This is another molecular diagnostic LCD L38684; it is the Prognostic and Predictive Molecular Classifier for Bladder Cancer.

The molecular diagnostics, or the MolDX, program has assumed the posture of trying to have as many foundational tests, or policies, as they can, and grouping like tests together so that they can add a test to a policy, instead of having to go through all of this every time, that we're going through today.

The contractor will cover molecular diagnostic tests, these, in a beneficiary with bladder cancer when all of the following conditions are met: you must be actively managed about- managed for bladder cancer, within the population that is indicated for which the test was developed, and have at least two, the two criteria; being a candidate for multiple potential treatments, which would be considered to have varied or increasing levels of intensity and a patient test is about to show that it predicts response to specific therapy among accepted therapy options, based on nationally recognized societal consensus guidelines. So, this is part of a bladder cancer panel. This is one of the tests that's out for it, and it is now being added to this found- proposed to being added to this foundational policy.

Any comments on this one?

Dr. Nachodsky: Just remember if you are dialing in only on a phone press *3, and you can speak. Otherwise if there are no other comments, let's proceed with our, our last draft. Thank you. Dr. Whites.

Dr. Whites: Thank you. The moment everybody's been waiting on, and you wonder why didn't get to it first, is number six. This is a proposed LCD that is a redo of various. Urine Drug Testing LCDs that were present from all the MACs. They – I don't think any of them had exactly the same verbiage in them, and this was an attempt, after the Department of Justice and OIG found several inconsistencies in our coverage across MACs, and what we would consider and not consider for coverage. This LCD is part of a collaborative process. All of the MACs worked with us on this policy – I was the chair – for consistency and clarity of coverage.

The policy contains several definitions; proposed testing methods for both presumptive the definitive tests; limitations; already in criteria and the limitation of the urine drug test, only 14 classes of drugs to be the maximum number of classes considered for definitive testing, based on references listed in the policy. There are three groups of patients that are well-defined with testing criteria for each one. Some including risk assessment, others with a frequency of testing depending upon the grouping of each of these patients. The changes to the policy, as stated, has been made to be consistent with other MACs and help resolve issues, noted by the OIG determination, a potential overpayment for definitive tests in particular.

I'd be happy to entertain any questions or comments on this one.

Okay, thank you so much appreciate you -

Dr. Suderman: I had one clarification. Sorry, on the- Under the non-covered services, it would be page 13. Point number 2: Reflex- Sorry, Josh Suderman, pain physician in Michigan – Reflex definitive urine drug screens is not reasonable and necessary. They may have- it says when presumptive testing is performed, because the clinician may have sufficient information to manage the patient, If they're not satisfied, they must determine the appropriateness of sending out that definitive testing. And some of the examples where a patient admits to using a particular drug, and the reference for that was a white paper from the American Society of Addiction Medicine, and it says for pain management, it says, in a pain practice it is sometimes, but not always important to identify the specific drug, not just the class of the drug.

I guess I'm just thinking back to my clinical practice. If I'm testing someone because they've admitted to taking medicine and I would want to confirm that, I see that I would always want that confirmation of not just an opioid, but, oh yeah, it's not heroin; It's actually the hydrocodone that they, you know, or something, you know, it's not OXY, it's the NorCo that they admitted to. Is that, if I put that in my plan: "Hey, it's for compliance to insure, Hey, we're matching up what they said they took." just given between that reference and the LCD, a little bit of a different statement there, is what I've said in my clinical scenario, sufficient in this LCD spirit or context?

Dr. Whites: Absolutely. All I can give you is an absolutely.

Dr. Suderman: Okay.

Dr. Whites: It must be documented in the record. That's all we ask for. What we've seen from reflex testing is: there's no information, but a list of tests performed without

that information. So, if you want to define the reason, certainly, that's very reasonable. Nobody's going to question you on that. They shouldn't at least. Give me a call if they do. We'll discuss.

Dr. Suderman: got you in my corner, I suppose

Dr. Whites: You got me, Yes, sir.

Dr. Suderman: Okay, okay, because I, I think, I mean, day to day, now, I'm just thinking in the pain world, if we get a negative qualitative at the first, like, addiction medicine and, like, other literature says "no, we're not going to just send that out for automatic definitive."

So, the other thing too is, you know, physicians are ultimately responsible, but we let, for instance, we let Quest do all the work. We purposely don't have our lab. We purposely don't get involved with it. Probably everyone who's been involved with this LCD knows the treacherous waters you can get into when you're running your own lab and all the kickbacks and stuff. So, is there – is there a standard of care that Quest and a lab also has to follow, or is this all on the physician here? I mean, which I assume it is, but just kind of wanting some background on how Medicare would do that.

Dr. Whites: We- it's on the lab, I mean, whoever is performing the test if they don't have the documentation, the test is not covered. If they don't have information from you, and they sometimes try to tell us that "Hey, we couldn't get the information." The regulations clearly state that the lab is responsible for establishing the reasonableness and necessity of this. So, if they don't get it from you, we don't pay them. So that's the way it is. It's not your responsibility; it is indirectly, because you won't get them paid, where the lab says "I'm not doing any more of your tests if you don't supply it." But it is their responsibility to have that information.

Your order should state the reason for a test. You want to confirm the- confirm the positives, confirm the negatives, and patient, if they are – or are not – taking it, that's good. We don't need every little thing written out, but it does need- we do need some information that makes sense of why you're ordering the test, and it may be a reflex. You say that you got a screening test that says they're negative for X, Y, Z drug, it may very well be that the screen test is too high sensitivity and it's not detectable as you know, so you weren't a definitive drug, you want to know they're not shaving it so you want to make sure the metabolites in there; all of this is very, very necessary, and I don't think you're going to find us, if you provide that information, denying unnecessary tests. Yes.

Dr. Suderman: Perfect. Thank you so much.

Dr. Whites: Yes, sir.

Dr. Nachodsky: Are there any other questions for this last LCD draft?

None being heard, I see. At this point, all six draft LCDs have been presented with allocated time for public comments.

Again, just to reiterate please put in writing any of the comments that you made tonight, or any other additional comments that you may think of, regarding these proposed draft LCDs and send it to medicarepolicycomments@wpsic.com. Please include the topic of the LCD on the email subject line, we ask that you to include any published scientific studies and/or literature, not abstracts, to support your additional coverage with your message. Again, we will not send out individual responses to the comments, but we will make sure that the responses to your concerns are available in a comment and response section document that will be posted with the final LCD.

Dr. Andea: A quick, quick question for the references do you need the actual papers or just a reference like a note, reference note? Because I wasn't-

Dr. Nachodsky: yeah, if you could please provide us with the paper.

Dr. Andea: Okay, thank you.

Dr. Nachodsky: Thank you so much.

At this point, we're going to end the open portion of the J8 CAC meeting and proceed with the educational portion of the J8 CAC for tonight. So, at this point, Rich, if you could close the lines to the public, and we can then proceed with our educational meeting.