WPS Government Health Administrators Combined J5-J8 Contractor Advisory Committee Meeting Transcript

Co-Chairs: Dr. Jill Sumfest & Dr. Shayan Sheybani

June 15, 2023

05:00 PM CT / 06:00 PM ET

Dr. Jill Sumfest: Welcome to the WPS GHA Contractor Advisory Committee meeting. Today's date is June 15th, 2023, and the time is 5:04 PM Central Time. My name is Dr Jill Sumfest, I am one of the Contractor Medical Directors with WPS and I will be moderating the meeting with the Co-Chair, Dr. Shayan Sheybani.

The purpose of the CAC is to present draft LCDs up for consideration and to take comments from the CAC. The public is welcome to attend in a listen-only capacity.

The meeting is being recorded and transcribed. Your attendance as a CAC member at this meeting implies that you consent to public disclosure of your opinion and agree. That it may be used and will be clearly identified as your opinion within the proposed or final draft LCDs discussed. If a CAC member does not consent, please disconnect now.

Individuals wishing to comment may click on the “raise hand” icon, press *3 if you are attending by phone. When Mr. Staley calls on you, please make sure that your microphone is on at your end, and that your speakers are silenced to prevent an echo.

To aid in transcription, please state your name and any conflicts of interest you may have, or state that there are none. CAC members should follow up any verbal comments in writing to policycomments@wpsic.com, and you can see that on the screen.

The open comment period for these LCD – these draft LCDs – is from June first, 2023, until July 15th 2023. Comments will not be addressed individually but will be compiled and addressed in a response to comments document posted with the final LCDs.

The first, draft LCD on the agenda is DL38682; Transurethral Waterjet Ablation of the Prostate. This is a reconsideration of an existing LCD. The lead CMD is Dr. Robert Kettler, and the policy coordinator is Michelle McCary. Transurethral waterjet ablation of the prostate is a minimally invasive alternative to regional resection of the prostate and open simple prostatectomy for the treatment of benign prostatic hyperplasia. The changes are in coverage indications, limitations and or medical necessity, and reflect eliminating the age limitation for individuals over 80 years of age.

Are there any comments? Richard, do you see anybody raising their hand?

Richard Staley: Not at this time. Panelists should be able to unmute their phone and speak up without raising their hand. if you are a CAC member and you have not been granted panelist status yet, you can just press *3 if you're calling from a phone or “raise hand” icon.

Dr. Sumfest: Okay, if there are no comments, we'll move on to the next Draft LCD on the agenda, which is DL34645, Urine Drug Testing. This is a reconsideration of an existing LCD. The lead CMD is Dr. Robert Kettler and the policy coordinator is Stephanie Richmond. This policy details the appropriate and allowed number of urine drug tests billed over time for safe medication management of prescribed substances in risk-stratified pain management patients and/or in identifying and treating substance use disorders; designates documentation by the clinician caring for the beneficiary in the beneficiaries medical record; of medical necessity for and testing ordered on an individual patient basis; and provides an overview of presumptive urine drug tests, and definitive urine drug testing by various methodologies. The changes are in CMS National Coverage Policy, Coverage Indications, Limitations and/or Medical Necessity and Sources of Information and Basis for a Decision, and are being made as part of a collaborative process for consistency and clarity of coverage across all MAC jurisdictions.

Are there any comments from CAC members?

Dr. Ramis Gheith: Dr. Gheith from St Louis, Missouri; Medical Director of Interventional Pain Institute. Can you hear me okay?

Dr. Sumfest: Yes, we can hear you.

Dr Gheith: Great. I just want to say that urine drug testing, in our field for interventional pain management, is absolutely crucial to identify early on patients who may be misusing abusing or have opioid use disorder. Issues that present to our offices. And we need to preserve access to urine drug testing in an adequate manner without, basically, tying our hands and limiting what we can test for on a patient's initial presentation to the office. I feel that the current policy, in which we can only bill for certain drugs that the patient is supposed to be taking is, unfortunately, not adequate enough for us to identify any medications of abuse, illicit medications or other opioids that they may be receiving from an outside physician. We feel that it really places our practice and the patient safety at risk.

Dr. Sumfest: Are there any other comments from members.

Dr. John Dooley: Yeah, I had my hand up, but I didn't hear anybody call on me, so I'll go ahead and speak.

My name is John Dooley. I'm also an interventional pain management physician and representing anesthesiologists from the state of Iowa. So, I made extensive written comments about this policy in the past, and it does look and appear to be better now. So, thank you for that, Dr. Kettler. There's still some issues with it though, that I have.

Although the frequencies are unchanged from before for substance abuse monitoring, they do seem to be a little limited for patients that are on chronic opioid therapies, unless some

circumstances are met, which require, what appears to me, very extensive documentation requirements that still are not entirely clear. And I'm not so much concerned that a diligent physician can't read through this and meet those documentation requirements, though despite the fact that they're onerous, In my opinion. I do have a lot of concern that your own reviewers, when looking at records to determine whether the documentation is adequate, will not be very informed about it and will consequently cause audits of a lot of physicians for who provide these services, unnecessarily. And I speak about that with some experience, because over the last several years, I've undergone several of those audits. And sad to say the competency in staff doing those audits is abysmal at best. And I think a lot of it, as opposed to any personal issue with those folks, is the fact that the policy was not clearly stated enough for them to understand, or their training was poor enough that they were never able to understand what was intended by the policy. And I can point to some specific examples that still exist in the policy and which still cause some problems for me.

One of the things that I find curious is, is that when you talk about testing, you actually reference – for patients with chronic opioid therapy – you reference the number one citation, the bibliography. And if you go down and look at it, It's a white paper by the American Society of Addiction Medicine. It's actually been supplanted by another guideline that was put out in 2017. But given the fact that you've referenced the one in there that you have, It applies only to patients in – that would be patients in an addiction medicine practice and has absolutely no applicability, that at least can be scientifically proven, or even supported for patients that are chronic opioid therapy for chronic pain. I think that's a mistake because it makes the policy appear dated, again, and also reliant on information that does not adequately apply to patients with chronic opioid therapy. I think a better job can be done.

By the same token, the reference number 14, which is used in the policy and cited for. The support for the frequency of testing, is a paper out of the Mayo Clinic Proceedings which absolutely has no evidence whatsoever in it for the frequency of testing. So, consequently, it appears to a reader that looks for the backup information for the contentions in the policy, that there is no support for that and it's simply a pure opinion about what frequency of testing should be.

Now, I will say that it is still an improvement over the past policy, because you left everybody an out when you said in a note that there's additional definitive that can be done above the recommendation, or beyond the recommendations but they have to have one of those five specific things. So again, it just adds layer and layer of documentation on top of other documentation. And it seems to want to reduce testing. Just by creating a hassle for justification of it.

And I'm not sure that this issue is all that complicated. Patients on chronic opioid therapy seldom tell their physician things that would cause alarm because they want to continue to have their opioids. It hijacks their judgement, their insight, their executive decision-making skills, just on the basis of the drugs effect on the brain. So trusting a patient on chronic opioid therapy across broad swaths of demography that I treat, there has to be another way to be able to monitor these patients effectively, to provide these medications safely. And there are definitely indications out there where medicine as it's currently practiced, has no solutions for these people to improve their quality of life to the point where they can accomplish their ADLs, and try to have a quality of life. So –

Dr. Sumfest: Dr. Dooley, excuse me, we appreciate your comments. If you have some medical literature or evidence that will help us improve the LCD, we'd love to have you submit it. And if you have some ideas on how to make the criteria clearer, that would be helpful as well if you could send that- submit that to us. We welcome your input.

Dr. Dooley: I will – I will do that.

Dr. Sumfest: Thank you. Appreciate that. Anyone else would like to comment on this draft LCD?

Dr. John Easa: I guess –

Dr. Sumfest: Also, Dr. Brad Orris –

Dr. John Easa: My name is John Easa, I'm an anesthesiologist, interventional pain management and I agree with both of the two previous speakers.

Dr. Sumfest: Okay

Dr. Easa: We need to be able to have urine drug testing available.

Dr. Sumfest: Rich, is Dr. Orris still available? That he wanted to speak to the first Draft LCD –

Dr. Brad Orris: Yeah, I'm available now.

Dr. Sumfest: Okay, please go ahead. I'm sorry we missed you the first round.

Dr. Orris: Yeah I'm sorry I'm new to the committee, so I don't want to speak beyond where I should. You said the only change in the LCD was the restriction on age, but there are several –

Dr. Sumfest: [Inaudible]. I'm sorry, go ahead.

Dr. Orris: Well, I mean, there are several other limitations listed that, to me as a clinical urologist, don't make a lot of sense. And should I outline those now or are we only speaking in reference to changing the age criteria?

Dr. Sumfest: The request to open the LCD was based off of a reconsideration request on removing the age limitation, and that was the only thing that we were addressing.

Dr. Orris: Okay.

Dr. Sumfest: If you have other concerns, please submit them in writing and then we can follow up with you afterwards.

Dr. Orris: Okay. Thank you.

Dr. Sumfest: Thank you, I appreciate that.

Dr. Sumfest: Anyone else, I'm sorry, on the LCD on urine drug testing before we move on?

Dr. Gheith: I just want to chime in one more time about the significant necessity of monitoring these patients more closely, given the CDC data. And we're seeing epidemic of the opioid crisis and that's - I'll leave it at that point. I know you wanted more data and I wanted to say that [inaudible] – publish that data for us so it's already available. It's widely available and accessible to everybody. That's all. Thank you.

Dr. Sumfest: Yes, and if you don't mind if you have that readily available and can submit it to us in writing. And if there's any literature, if you can send it in a PDF format, that would be very helpful. And I'm sure the group would – will take a look at that and take it into consideration.

Okay, we'll move forward. The next Draft LCD on the agenda is DL39624; Amniotic and placenta derived product injections and or applications for Musculoskeletal indications, non-wound. The lead CMD is Dr. Robert Kettler, and the policy coordinator is Melissa Lietz. This policy addresses, amniotic membrane, amniotic, fluid or other placenta derived product injections and or applications as a means of managing muscular. Excuse me managing musculoskeletal injuries joint conditions and other conditions. This policy does not include discussion on. Wounds or atomic conditions. Are there any, uh, do any of the CAC members wish to comment?

Rich, are you seeing anyone raise their hand?

Richard Staley: Yes, we do have some hand raises. We've got John Dooley and Susannah Friemel. As CAC members, you can unmute yourself and begin speaking. You do not have to use the raise hand icon.

Dr. Susannah Friemel: Can you hear me?

Richard Staley: Yes.

Dr. Friemel: So, sorry, I wanted to comment on the previous discussion. I've also had investigators looking into improper opiate prescribing and they were – I totally agree with Dr. Dooley. They were so – They did not understand the difference between milligram and a milliliter. You know, someone who has a – Anyway, I just, I would strongly recommend investigators be better trained, because they really make our lives a living hell. They don't know what they're doing, but they have all this power and I just want to make that comment. Thank you.

Dr. Sumfest: Thank you. Dr. Friemel.

[Inaudible] I'm Sorry?

Dr. Dooley: This is John Dooley. I'll speak a brief comment. I didn't have my hand up. I did it on the last one. It just must have kept stayed up, but I'll jump in anyway.

I would just point out to WPS that efficacy does not mean lack of effectiveness. And to the point that you limit your beneficiaries to therapies that can be helpful to them, I think that you eventually tie providers hands so badly that they shrug their shoulders and move on; the patient's leave dissatisfied, with no improvement of their life whatsoever. And I feel as a physician that we can do better sometimes than that. But unfortunately, the payment mechanisms don't seem to want to allow that. Maybe you folks do, but I don't think the payment mechanisms do. Which is too bad, because there's a lot of patients that can benefit from these therapies that are not candidates for steroid injections because they have side effects and complications from those, or limitations to using those. And there really are not a lot of other alternatives for some of them. And yet the therapy does work for some of them in my experiences as well as steroids do. Thank you.

Dr. Sumfest: Thank you Dr. Dooley.

Okay, anyone else before we move on?

Dr. Robert Kettler: Hello?

Dr. Sumfest: yes.

Dr. Kettler: Yeah, this is Bob Kettler and I just want to thank everybody for the comments that they have made. I think that this is a policy that we are struggling with, and this is not just WPS, but all the MACs are trying to develop a urine drug testing policy that meets a lot of needs. I did do pain management for a number of years before I joined WPS, and I know what a problem it is to balance the needs of these patients and also other considerations. And I do encourage you to submit the comments that you've made in writing, and I will be taking them back to the work group. So, thank you.

Dr. Sumfest: Thanks, Bob.

Okay, um, we'll move on to the next draft LCD, which is DL39620, Micro-Invasive Glaucoma Surgery, otherwise known as MIGS. I'm the lead and the policy coordinator is Stephanie Richmond.

This LCD addresses a group of new surgical procedures for glaucoma referred to as micro-invasive glaucoma surgery. A multi-jurisdictional contractor advisory committee meeting was held on January fifth of this year, hosted by Palmetto, CGS, NGS, Noridian and WPS, to discuss the evidence for the development of this policy. Transcripts are available on the Palmetto website. The LCD outlines limited coverage for this service with specific details under coverage indications, limitations and or medical necessity. And I understand from Rich that Dr. Di Lorenzo is interested in speaking and I see her on the - is online. If you can unmute yourself?

Rich, can you check with her? I see that she's –

Richard Staley: Okay, Dr. Di Lorenzo? Okay, I hear you.

I apologize, Dr. Di Lorenzo, I see your mic went off mute and I thought I heard you for a second there, but we're not hearing anything at this time.

Dr. Matthew Appenzeller: If Anna – this is Matthew Appenzeller – If Anna is having a lot of difficulty, I have the letter – she and I have collaborated on this letter – If she's having trouble, I can read it.

Dr. Sumfest: Can you let us know, Doctor, in the chat box?

I'm not sure – I'm seeing a comment about Dr. Friemel, is that on this LCD or on something else?

Dr. Friemel: No, I have not done. I've done nothing. Sorry.

Rich Staley: [inaudible]

Dr. Sumfest: Okay, so is that Dr. Appenzeller?

Dr. Appenzeller: Yes; Matthew Appenzeller, vitrio-retinal surgeon CAC for Nebraska.

Dr. Sumfest: Okay, well if we can get Dr. Di Lorenzo back, that's great. But if not, if you're familiar with what she wanted to say, why don't you go ahead and move forward?

Dr. Appenzeller: Sure. So just really quickly; This is a – I'm going to read directly from a document that she and I along with some other glaucoma specialists coordinated together to write. So this is exactly what she was going to read:

There is extensive published data and clinical experience over more than ten years using MIGS, including goniotomy and canaloplasty to treat glaucoma. These procedures reduce intraocular pressure and the need for medications, decreasing system cost, patient burden of drop administration, and occular surface toxicity. And while trabecular meshwork stents have an important role, there are significant limitations to their use.

Goniotomy and canaloplasty can be utilized across the glaucoma spectrum and are less limited by anatomy severity or diagnosis. By controlling intraocular pressure, these procedures provide a safe and cost-effective way to prevent irreversible loss of vision from glaucoma.

Laser cycle photo coagulation has played an important role in complex glaucoma management for decades. It is used across the treatment spectrum, often in patients who are not good candidates for incisional surgery. It has ample and long-standing evidence of its safety and efficacy in the surgical management of glaucoma.

Glaucoma Management, like that of any chronic condition, is complex and often challenging, requiring a high level of clinical expertise in close collaboration between physicians, patients and payers. Success in preventing visual disability is dependent on access to a range of safe and effective medical and surgical treatments, of which MIGS are a critically important part.

We urge you to ensure that Medicare beneficiaries with glaucoma have access to these transformative procedures by providing coverage for MIGS procedures. We thank you for providing coverage for trabecular stents and ask for continued coverage for adult goniotomy and canaloplasty. For many patients, treatment medications is inadequate, but their glaucoma is not

at a stage requiring more invasive procedures, such as trabeculectomy and tube shunts. For these patients, MIGS can preserve quality of life, Independent function and reduce total system cost. Thank you for your consideration of these comments and recommendations.

Dr. Sumfest: Thank you to both you and to Dr. Di Lorenzo. And so if you can submit that to us, so we have it in writing that would be helpful. And if there is additional literature that you feel we did not address in the body of the policy, please submit that as well. Many of the comments we heard yesterday in the open meeting are echoing what you just said.

Dr. Appenzeller: Yes, ma'am. May I make a further comment?

Dr. Sumfest: Yes, of course.

Dr. Appenzeller: The, uh, actually one is a quick question: is it, okay – should I submit through the policy comments page a letter that has been submitted by all – signed on by all of the fellowship trained glaucoma specialists in the state of Nebraska?

Dr. Sumfest: That would be perfectly appropriate.

Dr. Appenzeller: Okay. And just to echo upon what we as a group have put together, I just want to say from a personal perspective, I am a practicing ophthalmologist here in Nebraska. Mainly, as I had said, vitreo-retinal surgery and I've neglected to say, I actually have no financial conflicts with this. I actually do not even perform MIGS myself. But obviously a lot of my colleagues in the state do. I have personally seen many patients with, as a matter of fact, I had a conversation about this LCD with a patient who received a XEN in his eyes about four or five months ago.

The restrictions that are proposed in that, in this LCD are extremely onerous. For example, the XEN proposal suggests that approval would be there for if the patients. Have pressures of over 20 millimeters of mercury and are on maximum medical therapy of four drops or more. I would say that, for example, the patient that I had today, given that they have advanced glaucoma, their goals for pressure are well below those numbers. If we had waited until if this LCD were in effect, this patient would have lost vision and lost visual field before we were even allowed to use a XEN. And now this patient, and this patient's not a candidate for other procedures. And they have done incredibly well. And now, for example, no longer have to be on a medication called Rhopressa®, which is costing him as much as $300.00 per month. So these procedures have revolutionized glaucoma management and Ophthalmology over the last ten years. It's been absolutely incredible, with much better safety profiles, with great efficacy and greatly reducing costs because of these patients no longer requiring several medications.

So I, I strongly encourage that this LCD either be completely revamped, and us to go back and revisit this. This puts a very – echoing some comments about other – the prior LCDs, such as on Urine testing, et cetera – This puts a significant burden upon the ophthalmologists that make it much more difficult to treat our patients and will honestly, I believe, lead to further loss of vision.

Dr. Sumfest: Dr. Appenzeller, really appreciate your comments and we will take the – what we get in writing and any literature that you submit, anyone that's on the phone, and present that back to the collaborative committee, I will guarantee you that

We're having some issues, Rich is having some issues identifying CAC members from the general public. So if it's possible in the chat box, to let us know the first couple digits of your phone number or the last couple digits, so that Rich can identify you as a CAC member if you wish if you wish to speak or make a comment. Otherwise, we're probably going to miss you. There's that many people on the - that are attending right now.

Before – I'm Sorry.

Dr. David Vollman: Dr. Sumfest, this is Dave Vollman, I'm the ophthalmologist CAC representative from Missouri. I was wondering if I could have an opportunity to speak to this LCD as well?

Dr. Sumfest: Sure. Of course, Dr. Vollman.

Dr. Vollman: Thanks. Yeah, I'm a comprehensive ophthalmologist and appreciate everything that Dr. Appenzeller and Dr. Di Lorenzo laid out. I agree with all of their statements, and I did have the opportunity to attend the open meeting yesterday and just encourage you to really consider those multiple presentations that were made that really highlighted the efficacy, safety profile and quality outcomes for patients with all of these MIGS procedures.

I think one other thing that was highlighted well, yesterday, that really needs to be considered is that, glaucoma disease disproportionately affects African American and Hispanic populations and by limiting access to the whole armamentarium of treatment to these patients, we could unintentionally be developing health inequities for those populations and patients, because they would then be relegated to having more aggressive, incisional surgery and potentially not as good outcomes in the long run.

So, again, I just appreciate you listening to our concerns. Um, just encourage you to follow up on those presentations from the Open Meeting yesterday, and thanks for your time.

Dr. Sumfest: Thank you very much. Yeah, we certainly well, and I don't recall who it was mentioned the health inequities as well, last night. So I appreciate you repeating that. Are there any other CAC members who wish to speak to this Draft LCD?

Rich, can you see that?

Richard Staley: Dr. Janet Fett has her hand raised. You can unmute yourself.

Dr. Janet Fett: I'll try.

Dr. Sumfest: Okay, can you just announce, introduce yourself and if you – if there's a particular institution you represent, if you have any conflicts of interest?

Dr. Fett: I'm Janet Fett. Can you hear me.

Dr. Sumfest: Yes, we can. Thank you.

Dr. Fett: I'm Janet Fett, I'm an optometrist, and I have to echo my – the comments that my ophthalmological colleagues from Nebraska, Missouri also caught, mentioned. I've been in practice for over 35 years. We've, I've been treating glaucoma for over 20. MIGS are the best thing since sliced bread. And I also live in a community that has a high Hispanic community, and if we look at the overall costs, and not just look at the medical side, or the drug side, MIGS definitely improves the quality of life for our patients. So anything we can do to preserve their vision and improve their quality of life over the years is important. Thank you.

Dr. Sumfest: Thank you, Dr. Fett.

Again I just want to remind everyone; if you would like to follow up your verbal comments in writing, that would be helpful. And if you have any literature that you feel was not addressed in the policy itself, please send it to us in a PDF format so that we can share it with the collaborative work group. We want to hear your input as practicing physicians.

Anyone else before we move on?

Okay. The last draft LCD on the agenda is DL39614; MolDX: Molecular Biomarker Testing for Risk Stratification of Cutaneous Squamous Cell Carcinoma. The lead CMD is Dr Denise Nachodsky and the policy coordinator is Emily Zehner.

This LCD outlines non coverage for Decision Dx SCC, With specific details under coverage, indications, limitations and or medical necessity. Decision Dx SCC looks at changes in gene expression of 34 metastatic associated genes and six control genes to identify patients with high risk of metastasis of squamous cell carcinomas of the skin.

Do we have any members who wish to comment on this draft LCD?

Yes, I see Susannah Friemel?

Dr. Friemel: Can you hear me?

Dr. Sumfest: Yes, I can.

Dr. Friemel: Yes, so I agree. I have not seen the meta-type squamous cell carcinoma in a long time. That's very, very uncommon. They're easily treated locally. We never see [inaudible] melanomas. We never see basal cell and squamous cell – and I definitely have seen more basal cell further grow out of control or spread. So I don't see the utility of this test. But that's just me.

Dr. Sumfest: Thank you for your comment.

Anyone else?

Rich can you - I know It's difficult for you to see but do we have anybody else That is a CAC member who wishes to comment?

Richard Staley: At this point, there's I see no other CAC member's hands raised.

Dr. Sumfest: Okay, great. Well, again, I want to thank all of the CAC members who have made comments and will submit them in writing to us in follow up. We do appreciate your interest and certainly your dedication to caring for the Medicare beneficiaries.

I'm going to now turn the meeting over to Dr. Sheybani, the Co-Chair of the meeting. The meeting will continue in a members-only capacity. The members-only portion of the meeting will address MAC updates, projects and provider engagement.