Jurisdiction J Open Meeting Transcript November 2, 2020

Dr. Shane Mull:

I have just started the recording and in compliance with CMS for the record prior to doing so, I announced that Palmetto GBA would make an audio recording of the Open Meeting and consented on behalf of Palmetto GBA. So now we will get started. Again, welcome to the Jurisdiction J Open Meeting. We had a Jurisdiction M Open Meeting earlier today. Everyone just take a minute and look at their phones and make sure that mute button is on. Please stay on mute unless you're speaking. We have a number of presenters today, so we're trying to keep it moving and on time.

Dr. Shane Mull:

But again, I want to thank everyone for taking time out of their day. I want to thank all the presenters for forwarding their materials ahead of time. I want to make sure everyone understands that we truly appreciate their input and is part of the process that makes for a good coverage decision. We will now start with our first presenter. Each one of our presenters will have 15 minutes today. The first one is Dr. Jason Levy. Dr. Levy, are you on the line?

Dr. Jason Levy:

I am.

Dr. Shane Mull:

All right, sir. I'll let you go ahead and introduce yourself and begin with your presentation. Thank you, sir.

Dr. Jason Levy:

Thank you. Okay.

Dr. Jason Levy:

Thank you very much Dr. Mull. I am Dr. Jason Levy. I am an Interventional Radiologist in Atlanta, Georgia. I am presenting on behalf of the Society of Interventional Radiology for the Vertebral Augmentation LCD. It is my understanding that the physicians and people from Palmetto do have my slides. I think it is a little bit of a shame that we are still discussing any LCD for a procedure such as vertebral augmentation that has clear proven mortality benefit, and unfortunately, an LCD assumes that a procedure is overutilized and creates excessive costs, but that is not the case here. Unfortunately, these restrictive policies are going to lead to higher costs and worse overall outcomes, which has been shown in the literature from what happened in 2009 with healthcare outcomes.

So, what do we already know? We know that it takes from a number needed to treat, to save a single life. This comes from Josh Hirsch in 2019, he published that it takes 15 vertebral augmentation procedures to save one life if you're following patients for a year and only 12 if you follow them out for five years. To assume that this is not founded, is inaccurate. In fact, the United Kingdom recognizes the mortality benefit in a statement, and I have listed there a link to their statement, suggesting that there is a mortality benefit. There were plenty of literature for that, that are deep embedded in the slides that I will not be going over today. In addition, Dr. Schneider is going to be following me down; I think

two or three speakers later, this was his registry was on your patients.

These were on Medicare patients. It was a different Medicare carrier, but these are American Medicare payments and his results showed significant improvement in this patient population. Next slide. So unfortunately, we are still talking about an LCD. So how is this current LCD restrictive? I'm going to go over six things. Number one, the age of the fracture and excluding patients who have older fractures with still having edema. Number two, it is unclear whether cancer fracture and cancer is still involved in this LCD. Number three, there is an exclusion based on the location of the fracture this LCD should simply be for the thoracic and lumbosacral spine or the thoracic and lumbar spine, but it excludes fractures from C1 through C4. Number four, it excludes patients who have more than three fractures. Number five, the inclusion criteria on the outpatients is insufficient. Number six, we are treating in this LCD relative contraindication, the exact same from a coverage standpoint as absolute.

And that can't happen. That's certainly not how medicine works. Next slide please. So, let's start with limiting access due to the timing and age of the fracture. As it stands now, the current LCD will allow for fracture treatment up to 12 weeks. So, this is problematic in two ways. Number one, it is essentially unclear and unrealistic to ask a physician to date and time a fracture. It is problematic in a number of ways. So, it is almost impossible to define the date of a fracture. There's no real definitive method of determining that, whether it's an MRI or any kind of study like that. And there is not always a historical event in some of these patients who are elderly. We cannot always define an event. More importantly than that is, this is not supported in the literature. But to ask this from a physician is, again, unrealistic and unclear.

So, what is supported in the literature? What is clearly supported in the literature, and I gave you a bunch of references here, is advanced imaging. It’s the best indicator of ongoing injury. In addition, this exclusion based on time, there are six references that the LCD has as the source of the exclusion, but yet five of them don't mention it. Some of them mention the opposite and only one of them barely mention it. So, let's go over those. This is next slide. Bar in 2014 has no mention per 2018. That was the land study and one of the other speakers in this call was an author in that, Dr. Beall. He can speak to this as well, but the bottom line is that there were two main contributors. Number one, advanced imaging placed well ahead of duration of pain. So timing was not important.

The panel’s recommendation barely varied at all, depending on timing. Now we have to remember that these fractures a definitive time sort of going back to the definition of this actually migrates. We know from multiple trials that once a fracture occurs, that does not mean another fracture in the same part of the body won't occur. That has been shown in numerous studies, including some randomized trials where patients would get a fracture and fracture on down. Is that day one? Was day one the initial fracture? The panel's recommendations did not vary with time. Next slide. McConnell, again, no mention. Clark, yes. Mentioned we'll get to that in a second. Some not only don't mention it, but actually on the contrary, suggest the exact opposite. And they do talk about chronic fractures. The Clarke paper, which it is mentioned, is not mentioned as it shouldn't be done, but it is mentioned as a possible consideration for why some of the sham trials showed no improvement over a sham.

Again, what the LCD is recommending is not a sham, but in fact, non-surgical management. So, I'm not sure those are irrelevant. Let's go to the next slide. On the contrary, there certainly is some evidence to the contrary, okay. What do we know from these three studies? That vertebral argumentation was better than what the LCD is recommending non-surgical management and these things sustained over

two years or one year. And it did not matter. So again, we should focus on the advanced imaging. Next slide. Where is cancer? I'm assuming that it's not currently mentioned in either the LCD or the coding and billing articles, this suggests non-covered. And this frankly goes against American guidelines, the NCCN guideline document. There is level one evidence from the cafe trial. Next slide. Here is the Café Trial. This is 134 patients randomized to non-surgical management versus balloon kyphoplasty. And as you can see, in pain, back function, quality of life, activity, bedrest activity, and using of analgesic, mostly opioids, the patients did better in the balloon augmentation arm. Next slide. Here the NCCN Guidelines clearly stated in their algorithm is vertebral augmentation. So how we can have an American Cancer Guideline saying one thing without coverage from a Medicare carrier makes no sense. Next slide. This is an article I just published on a prospective multicenter trial with 100 patients. 96% of them were treated with vertebral argumentation. And we had amazing pain improvement, quality of life. Even up to three days extended out for six months. Next slide. This is further references for vertebral augmentation and neoplastic disease. Next slide. The next thing I want to discuss is limiting of treatment due to the fracture location.

So, as it stands now in the article, instead of a lumbar spine, it says T5 to L5. Again, the references that are listed in the LCD do not support this. There are patients that get this. Now, admittedly, it is less common from T1 to T4, but it's certainly happened. Next slide. Here are your six references that are listed in the LCD to support this exclusion. I call it an exclusion because if it's not an inclusion, it's an exclusion. Next slide. Real world study on Medicare patients in the article that was published earlier this year and pain physician, those patients were treated from T1 through L5.

Again, it may not be as common, but somebody who has a T1 fracture that is not dissimilar to anywhere else. Next slide. Limiting it to the number of fractures. So, this one has a couple of problems. One is the way it is worded. I do believe that your intent here is to not allow treatment of more than three, but as it stands now, it would be a patient cannot have more than three fractures. So that would mean somebody who has four fractures, three of them are chronic with no pain or edema, but your intent was to treat the new fourth fracture, can't get treatment. This example is chronic T5, six, and seven with an acute T12. Unfortunately, this patient wouldn't have coverage. Assuming I'm right, and you change the verbiage to treatment. It's still an exclusion.

I am assuming that this is about safety and cardiopulmonary risks. However, we need to balance the risks of both alternatives. So, what are those alternatives? Non-surgical management and the significant deconditioning and cardiopulmonary risks in that patient population who is going to be worse with multiple fractures. This cannot and should not be an absolute contra-indication. Next slide. So, here are your five references limiting the number of fractures. Again, not a single one of them support this exclusion. And in fact, one of them says five or less, not three. Next slide. What about evidence? Well, the evidence supports the contrary. We should not be excluding these patients. Here are four studies, and I'm going to mention a fifth in a second. These are four studies. The middle two actually compare outcomes in patients with few levels treated versus multiple levels treated.

The two on the top and the bottom were just treatments of multiple levels. What do we see? Well, in the comparative trials, there were no difference in effectiveness, no difference in segment lead score complications. In the two treating multiple levels, again, significant improvement. There was one recommendation of no more than six levels or possibly consideration of the amount of cement. In another, it was considered a safe and effective trial. Okay? Safe and effective without any significant morbidity. Just this month after I sent in the lecture, there was a paper from a French group, Duchamp's

Journal of Vascular Interventional Radiology, stating safety and effectiveness for patients with more than six vertebral body treatments. And they had zero complications, significant, zero serious complications. That was just published in 2020 October, JAVIR. Next slide. Limiting the access to the number of fractures.

What can we do? Well, number one, we need to work on the wording. Number two, it can't be an absolute contraindication. We might consider moving it to a relative contra-indication, but then we need to deal with how we treat relative contra-indications. Maybe we need to allow stage procedures, but most importantly, we need to allow the physicians and the patients to balance the risks of non-surgical management versus treatment in this very sick population. The SAR was able to get from CMS data, that this is not an insignificant number of patients that would be left without coverage to this life-saving procedure. Next slide. I'm going to get to the absolute versus relative in a second, but I do think that we need to include the negative effects of a narcotic in the outpatient setting. We have an inpatient inclusion criterion in the outpatient, and then the outpatient.

We only have four, two of which have to be there, progression of height loss, etc. What is not mentioned though and is mentioned in every single one of the society guidelines that the LCD has referenced, is for patients with unacceptable side effects, predominantly to opioids. We are in the middle of an opioid epidemic. I don't understand how this could not be mentioned, but we need to add so that it would be two out of the five of the following for anyone with excessive sedation, confusion and or constipation. That is directly from a multi society position statement that is listed in your references. Next slide. I'm going to finish off by saying, why do we have relative contraindications treated the same as absolute? Here is directly from the LCD can have none of the following. So, the absolute and the relative. Number one, they're greater than three vertebral factors needs to be removed.

That is not an absolute contraindication in any guidebook and relative contraindications, that's exactly what they are, they're relative. So, people need to, if you look up the definition of a relative contraindication, it does not mean cannot have. So, I think it is very important that we do that, remove that. So that is the summary of my comments attached to the slide deck are multiple other comments and references regarding the literature. In addition, if we haven't already said it, the Society of Interventional Radiology will be following up with a letter. I thank you and I guess I will pass it on to the next speaker.

Dr. Shane Mull:

All right. Well, thank you, sir. That was very helpful. It's particularly helpful to have those references referring back to the literature. That's very important to us, as well as sending those written comments, because those will be individually responded to in a response to comments article. So, thank you and we will move on to our next presenter who is on the same subject and that's Dr. Douglas Beall. Are you on the line, sir?

Dr. Beall:

Yes, I am.

Dr. Shane Mull:

All right. Well, you can go ahead then.

Dr. Beall:

All right, so I'll be a little bit shorter. Dr. Levy covered some of the territory that needs to be covered. Essentially the main issues with inclusions and exclusions are the fracture levels T5 to L5, the consideration for periosteal infiltration of the pedicle, and then only acute or subacute vertebral fractures are included in the inclusion criteria. So, to address that first topic, fractures T5 to L5. That completely capricious and arbitrary, there's no need and no rationale for limiting it to T5 to L5, none. I'm an author of the comprehensive guide to vertebral augmentation. The primary textbook in this area, we wrote a book chapter that had 42 references that focused on augmentation outside of these levels. In fact, there's 12 good papers on this that discuss treating outside of the T5 to L5.

I would have to point out that of the six references listed in your LCD, justifying this, not a single one supports limiting it to T5 to L5. It's not designed to be limiting this to treating the T5 to L5 minute. It will limit it to fractures that will occur inside that, fractures or crowds by that typically occur in people with malignancies and severe osteoporosis. In other words, people that really need to be treated. So, to limit that is not only unsupported, it's nowhere in the literature. The second inclusion criteria is for including periosteal infiltration. So similar, there's absolutely nothing in the literature that uses periosteal infiltration as a treatment for vertebral compression fracture pain and references that were listed said, “Well, the trials aren't at the penny.”

There are bone needles into the periosteum there's infiltration of the skin and subcutaneous tissue, but not the single cross reported pedicle infiltration of the periosteum. In addition to the ones that had a poster in the trials by Wilson, Wang and M. These all have this as an inclusion criterion, as an option for infiltration, pedicle is completely unsupported by the literature. So only acute or subacute fractures are treated in this. That is completely not founded by the literature. There's data on acute fractures, which we agree with. This is a level one trial and a sham trial. There's also a ton of references that support treatment of subacute fractures. And there's also references that support treatment of chronic painful vertebral fractures. There's as many references, credible references, including sham trials, supporting treatment of chronic fractures as there is treatment of acute fractures.

So just arbitrarily limiting these to acute and subacute while excluding painful chronic vertebral fractures is not appropriate and there's data to back that up. In addition, it's very difficult to actually age that the fracture and people could present with multiple fractures and different ages and so the ability to treat these should be done. With painful fractures, not based on age, especially when it's difficult to age, and then there are supportive data for treatment of fractures of all ages, as long as they're painful. Finally, the exclusion criteria to limit fractures to no more than three is a complete mistake. It's a misinterpretation of the literature. Limiting fractures to three or more at a time is a relative safety recommendation. It should not even be listed as a contraindication. This is not listed in the contraindications that were produced by UCLA at ran appropriateness criteria that were published by experts.

It's nowhere to be found there and its relative safety limitation based on pulmonary marrow uptake. So, this is, out of the five references supporting this as a contraindication in the LCD, not a single one supports this suggestion. In fact, only one of those five references that are found in the supportive data in the LCD has addresses of limit on the number of levels treated and that limit in that paper was five, not three. There are other credible trials where you are studying people that are on steroids, where the average rate of number of fractures per patient ranges from five to six. And there's a good trial on multiple myeloma by greatest, that has the average number of fractures upon presentation is 5.4. So,

there are a number of patient types that will present with more than three fractures, just to arbitrarily limited at three as not appropriate. Especially given the fact that these will be people with steroid induced, osteoporosis, the severe osteoporosis, multiple myeloma and other forms of cancer.

This contraindication will hit square on to prevent treatment in the most vulnerable of the patient populations, just to recap in to pull it all together, arbitrarily limiting treatment from T5 to L5 is arbitrary and the literature has good evidence supporting treatment outside of this range. There's nothing supporting in the literature that was given for the supportive literature for the LCD that addresses this at all. The second item periosteal infiltration, completely unsupported in the literature and even offering that as a treatment option is something that's not supported and should not be offered. Treatment of chronic vertebral fractures has about as much literature to support. It's all already been presented and as part of the public record. So chronic painful chronic fractures have as much support that in other trials as treating acute fractures and just to limit it to the treatment of acute and subacute fractures is baseless. But based on the data that we have and then limiting fractures to treatment of up to three should not even be a contraindication. This is relative a safety suggestion. This is not a contraindication at the very most. This should be a relative contraindication, which I would disagree with that, but having it listed as a contraindication, will put the most vulnerable patient populations at risk, including the ones with severe osteopetrosis and cancer. And with that, thank you for your attention.

Dr. Shane Mull

All right. Thank you, Dr. Beall. Since we're a few minutes ahead of schedule, I will just open up, if there's any questions for Dr. Beall. Alright, hearing none we will go ahead and move ahead to our next presentation.

Dr . Neal Shonnard

I'll start with slide number one, and what slide number one is, is a reference to the LCD. Just for everyone's information, I am the original clinician who worked with Bernice Hecker, Gary Oaks, and Dick Whitton to gather this coverage with evidence development for the vertebral compression fracture registry, which is founded on Noridian starting from the LCD back in 2014, April 2014. The material that I'm referencing is Noridian material, so it is exactly the material that you all have in your database.

Slide two gives some of that collaborative information with regard to Bernice, myself, and Justine Norwood. Justine was part of the original Washington State Registry Movement that developed registries in Spine Surgery, Urology, Vascular, and General Surgery, and those were the original registries that rolled out across the US and that's why Bernice asked us to do this, because we had expertise in this.

Slide number three, reviews these criteria for her original LCD. I want to go down these criteria because some of the points that Dr. Beall mentioned are precisely correct. When he talks about the capricious and arbitrary definitions of levels, when he talks about the restriction of T5 to L5, when he talks about chronic vertebral compression fractures, those are in fact, capricious and arbitrary based on discussions between me and Bernice, who is now retired.

Acuity was defined based on bone scan and MRI criteria, not on pain criteria. So, this acuity criteria were capricious and arbitrary. The three levels were based, as Dr. Beall mentioned, on a hypothetical

concern for safety. There was no data on this, but Bernice was a Pain Anesthesiologist, she was concerned about having patients prone, little old ladies being prone, for an extended period of time. We came to an agreement that three levels could be safely done. There was absolutely no data justifying the three level. It was a capricious and arbitrary definition that was accepted.

Conservative treatment and retropulsed bone are just part of the things that eventually got dismissed. This was coverage with evidence development. It was a surveillance tracking effort so that there would be information around treatment controversy. That controversy has now resolved. Dr. Beall and I are coauthors on the world's largest vertebral compression fracture registry, and we'll show you that data. It is data that comes from experiences just like yours.

You must understand that when you exercise LCD, you impact vulnerable populations, so this is data from Noridian. The authorizations plummet, so even when you add restrictions as small as you are contemplating, you are affecting elderly women with painful fractures. And you should be mindful that we recorded 5,300 women suffered and died unnecessarily because of the LCD that Noridian and I'm part of that. I was responsible for participating in that. Be mindful that LCDs have impact on people's lives.

In the state of Montana there were 0 out of 100 authorizations that were sought, and in the state of Washington, 6 out of 310, and I had 3 of the 6 because I knew how to get authorization compliant with the LCD.

The registry, as I said, is the world's largest. The Medicare data is your data, and it has proven that PVA is safe and beneficial. Be mindful that when you're looking at restricting T5 to L5, you are restricting a proven safe treatment, and you must have justification for doing so, because you will be called into question about doing it.

If all other treatments, T6, T7, L4, are genuinely beneficial, the same will occur for T1, T2, T3, T4, T5. So, when you're looking at capricious arbitrary definitions in an LCD, recognize that the fundamental treatment is safe, beneficial, and hugely impactful on pain relief and function. The most impactful of any recorded procedure.

Slide seven, are the data from Noridian. Notice in the bottom line, there is a two to five-fold improvement in the minimally clinically important difference. That is a massive benefit for patients. The pain relief score is the NRS. You'll notice it's red at the top, and then it turns green. The red zone is the MCID zone, minimal clinically important difference, and it turns green rapidly and continues to turn green all the way down to the bottom of the scale at six months, for both pain and function, which means this is a hugely successful procedure. So, when you're looking at limiting number of levels to three levels or limiting T5 to L5, recognize you are not allowing women to benefit from this procedure. Be mindful when you look at the healthcare utilization costs associated with this.

Realize, this is slide number eight, that we tracked this accurately, and in slide number nine what you find is the quicker you treat these fractures, the less costly it is and the higher the outcomes. Remember, an LCD causes delay in authorization, so be mindful when you're doing your LCD that you do not want this to happen to elderly women with painful fractures. Delays are destructive. In all osteoporosis it's well-known that delays in treatment lead to disability, destitution, and death. And

these are women who are no longer married. Their spouses have died, so they are now alone. They are highly vulnerable.

The next slide actually highlights it. This is slide number 10. And what I've done is encapsulated what the data shows. So, when you take care of this early, the day it occurs, which is what all orthopedic surgeons recommend you do with fractures, treat them early. Hip fractures, knee fractures, wrist fractures, treat them early.

Notice when you look at the impact on life, the function, they are decimated. These women are almost bedridden. Remember Roland-Morris goes to 24 and between 20 and 22 is hospice level terminal care. So, these are devastatingly painful injuries. Their pain level is very high, 8 out of 10, and notice how dramatically they are improved. The function score plummets, and the pain score plummets.

Now I'm going to have you look over at the delay of care, which is a six-month delay. What you see is your costs triple. What you see if you go to the bottom is, they are still severely affected. So, the original proposal of Culmas and Bookbinder was fallacious. These are not pain-free injuries, they're painful and debilitating. And notice that they still get good results. Not as good as treating them acutely, but it's still two to three-fold of the MCID.

What that means is, you've spent a lot of money waiting to get the same benefit. So, the LCD needs to be viewed in that perspective. That delay actually costs you as a payer, and it costs the patient with pain and disability. And although you're able to snatch victory from the jaws of defeat, you paid three times as much to do so.

The next slide summarizes that delay results in misery, durability, destitution, and death, and the highest healthcare utilization costs. Mostly from repeat image, skilled nursing home placement, and readmit to hospital for pain management. So, the unintended consequences of restricting authorization for three levels is you will deny appropriate care of a painful condition based on an arbitrary decision. I know it's arbitrary, because I participated in that decision, as did Bernice. That the impracticality of periosteal infiltration actually violates orthopedic principles.

There are no examples of Orthopedic Surgeons, and I am one, and I am on call today, so this is my daily practice, where we infiltrate the periosteum of a bone, say a wrist or a knee or a hip or an ankle, and that's all we do. We never do that. We always reduce the fracture and stabilize the fracture as quickly as possible. Percutaneous vertebral augmentation done promptly, reduces the fracture and stabilizes the fracture. It is historical orthopedic practice.

Lastly, be mindful of the liabilities when you're engaging in LCD. Be mindful of the unintended consequences and recognize that the proof of the Noridian data is these are profoundly beneficial treatments, and there is no gain from an LCD that restricts, delays, or impedes prompt care.

Now, what I've mentioned to you here is entirely about acute care, but what you need to recognize, and this is the final, is that acute and chronic vertebral compression fractures respond to treatment. So, the chronic vertebral compression fracture has ample data justifying it. The periosteal infiltration has no orthopedic justification or support.

A capricious and arbitrary limitation of T5 to L5 runs counter to your own data on efficacy of treatment and the arbitrary definition of three levels was originally Bernice's idea, which we agreed to in building a registry, because you have to negotiate. But now that we know that it's capricious and arbitrary, I recommend you dismiss it. Any questions for me?

Dr. Shane Mull

Hearing non, I appreciate your presentation. I appreciate you taking time out of your day. So, with that we will move on to Dr. Byron Schneider on Facet Joint Interventions for Pain Management DL38765. Are you on the line, sir?

Dr. Byron Schneider :

I am. Thank you for having me. I will not reference my slides as they pretty much follow the format of the LCD. I will point out, I know this is not a CME talk, but I will point out personally that I have no relevant financial disclosures pertinent to this procedure. I am speaking as a representative of the Spine Intervention Society. I do have a research grant from them pertinent to radiofrequency neurotomy, but I do not receive any industry funding for any procedures, and the one question I'd probably have for any other speakers today would be if they have any relevant disclosures.

But moving on. The first subtopic here within LCD is, under diagnostic facet joint procedures, including intraarticular or medial branch blocks, the recommendation that a second diagnostic procedure is considered medically necessary to confirm the validity of the initial block, SIS's position is that we agree with this statement and support it.

The second statement, noting that a second diagnostic procedure may only be performed a minimum of two weeks after the initial block, we disagree with for three reasons. Namely, there's no medical rationale for requiring two weeks in between diagnostic procedures, the only medical justification for a temporal dispersion between the two would be that you need to allow for the therapeutic effect of the injectate to wear off, so in the vast majority of cases, diagnostic injections utilize a short acting anesthetic or a medium acting anesthetics, such as Lidocaine and Marcaine that have reasonable effects on the order of hours, or maybe a day at most, and requiring someone to wait two weeks before having two injections of Lidocaine and Marcaine has no medical justification, but may not only delay time to treatment for people with painful conditions, but also provide significant restrictions for patients that have significant limitations, such as traveling distance, to seek care, or taking time off of work, or requiring family members to accompany them to their medical procedures.

Again, to clarify that point, we agree that two diagnostic injections are needed, but do not see a medical reason for spacing them out by two weeks and believe 48 hours would make more sense, given the injectate commonly used for these procedures.

Regarding the criteria for a second diagnostic facet procedure, the point that the patient must still meet criteria for the first we agree with. The second point that the results of the first diagnostic procedure must include at least 80% relief of the primary or index pain, we agree with this. The next proposed criteria listed as at least 50% consistent objective improvement in the ability to perform ADLs, we have concern with.

For one, without listing what measurement is going to be used to define this is problematic. So, there

are a number of outcome measures that look at function, but they all have different scorings, different levels of MCID, and it would be incorrect to assume that a 50% improvement on one is as meaningful as 50% improvement on the other. Our other main concern with this is that, given the difficulty or the lack thereof within this LCD on how to quantify or measure this reliably, we think actually poses significant risk to over-utilization and allows for treating physicians to state in some form that a patient had a 50% improvement in their ability to perform ADLs without having this documented using a verified or verifiable outcome measure, and therefore believe that including this, while we agree with the sentiment that functional improvements should be necessary to consider a block positive, the inability to measure this at this point likely will allow for physicians to over-perform second blocks and over-utilize this procedure.

Moving on to the next point regarding therapeutic facet joint procedures. I think to clarify my points here in the next two or three slides, if anyone on the call is following my slides, this LCD, for many reasons, I believe practical amongst them, considers an intraarticular injection and a medial branch block the same. And from a therapeutic perspective, considering these to be one in the same is a misnomer, as potentially injecting a corticosteroid within a joint may provide therapeutic benefit, and that is a well-used procedure throughout the Orthopedic world. Whereas the therapeutic benefit of injecting corticosteroids around a nerve that innervates a structure does not really have any face validity. There is no other joint in the body where we inject corticosteroid to the innervation of that joint with the expectation of therapeutic benefit, and I think some of that confusion has led to FIS having some concern over how this is worded.

That said, when considering any therapeutic facet joint injection, the current LCD recommending two diagnostic medial branch blocks prior to a therapeutic injection, we feel is unreasonable. This is largely founded on the fact that if someone were to perform an intraarticular injection of local anesthetic and steroid that this can be both diagnostic and therapeutic at the same time, so therefore it makes much less sense when considering intraarticular injections to perform two injections of anesthetic and potentially corticosteroid to then allow for a third injection of potentially the same injectates.

Moreover, if physicians are electing to use corticosteroid when they do an intraarticular injection, that first injection may provide therapeutic benefit in and of itself, and this must be considered in a number of ways. So, for one, if that procedure is done and effective, then it may allow for subsequent injections to not be done, and this includes, in theory, that if a successful intraarticular therapeutic injection of steroid is successful, then a radiofrequency neuroanatomy may not be needed.

Conversely, medial branch blocks are diagnostic only. There's no documented therapeutic effectiveness of this. So, while these slides seem somewhat theoretical, I think it's important to delineate the difference between a diagnostic injection, which medial branch blocks are, and only are, there's no therapeutic benefit to them, versus the consideration of a therapeutic intraarticular injection of corticosteroid. There's no literature supporting that these patients do better if selected on based on prior therapeutic injections.

In that vein, listing the same criteria to perform a therapeutic intraarticular injection in the same vein as the diagnostic, or the, sorry, the indications to perform diagnostic medial branch block.

Moving on to facet joint denervation or radiofrequency ablation, we agree with the as stated, that

patients must have two medically reasonable diagnostic medial branch blocks both resulting in 80% relief. We agree with this. Again, the other potential criteria that they may have consistent 50% improvement in ADLs after diagnostic injections, we have concern over how this will be reliably measured and quantified. That 50% improvement has not been validated for the various outcome measures looking at ADL and that this, in fact, risks significant over-utilization of this procedure.

Moving on to limitations that are listed at the end of the LCD. In the setting of a successful radiofrequency neurotomy, it is both listed that if it is successful for six months, but less than two years, that repeating medial branch blocks will not be covered and the radiofrequency procedures should simply be repeated. And yet within the same limitation, it is mandated that if a radiofrequency neuroanatomy is successful for greater than 24 months, then both medial branch blocks have to be repeated again.

The position of SIS on this is that this is inconsistent, and that if a procedure, say, has a therapeutic benefit for 23 months versus 25 months, going through the entire diagnostic algorithm makes no sense to be doing this in someone who has had actually a better outcome. So, we do agree that there may be times that they're a repeat diagnostic algorithm indicated. Simply saying that the patients have longer duration of relief with the neurotomy, then all of a sudden need to repeat it does not make clinical sense.

A limitation listed includes documentation of why the radiofrequency neurotomy could not be performed. SIS believes that, for one, this creates unnecessary documentation for the physician. This has nothing to do with improving patient care, nor does it have anything to do with over-utilization. In fact, while SIS is a strong proponent of radiofrequency neurotomy, if there are limitations put in place that are going to limit the use of potentially therapeutic intraarticular injection, this will likely lead to simply greater utilization of radiofrequency neurotomy, and the documentation of such does not provide any patient safety or outcome benefit.

The last part of the LCD that we would like to comment on regarding provider qualifications, SIS would like to have the term healthcare professionals replaced with physicians. Most physicians that perform interventional pain procedures not only complete residency, but they complete at least a year of dedicated training on the effective and safe implementation of these procedures. We believe physicians are best suited to accurately select patients for these procedures, they're the best suited to safely perform them, and, most importantly, while rare, complications may exist and physicians are the best suited to immediately recognize, evaluate, and address potentially serious complications that may occur during procedures, and given the bar of training required to do these from a physician, we do not believe that other healthcare professionals are equipped to do so, given that they would not complete a fellowship in these.

That summarizes the points that SIS would like to address regarding interventions for pain management. Happy to answer any questions should anyone have any.

Dr. Shane Mull:
Yeah. Thank you, Dr. Schneider. We do have just a couple of minutes. Does anyone have any questions for Dr. Schneider? Well hearing none. We'll move on. Again, thank you for your time. Our next presenter is Dr. Francine Kaufman. How about Implantable Continuous Glucose Monitors. Are you on the line,

ma'am?

Dr. Francine Kaufman:

I am. Okay. So, thank you for this opportunity to present on the LCD DL38743, concerning Implantable Continuous Glucose Monitors, or I-CGM. Today, I will be specifically speaking on the Eversense Continuous Glucose Monitoring System, the first long-term implantable CGM system in the US. My name is Francine Kaufman. I'm the Chief Medical Officer of Senseonics, and I'm also practicing as a Chronologist at the University of Southern California, and Children's Hospital Los Angeles. I do want to add that there are a number of Senseonics leaders on the call. I can guarantee you, they are all on mute, including our president at Dr. Tim Goodnow. So, I'm going to slide two. This slide conveys that Continuous Glucose Monitoring (CGM) is really considered the standard of care for Type 1 and Type 2 diabetes patients. The American Diabetes Association, that amends their standards every year, has recommended CGM as a tool to improve glucose control, lower A1C, and mitigate against hypoglycemia.

The American Association of Clinical Endocrinologists and the Endocrine Society developed their standards in 2016. And again, both saw the benefits of using CGM to reduce hypoglycemia and to improve diabetes control and outcomes. So, slide three, this slide describes the FDA indications for Therapeutic CGM. It's indicated for adults and for up to 90 days. The system provides real time glucose readings, glucose trends, and alerts to detect and predict episodes of high and low glucose values. The data can be shared with up to five care partners in real time, and the data is retrievable by patients and healthcare providers to adjust diabetes regimens and behavior. So, they can look at retrospective data up until three months, or actually go all the way through a year, depending on how they set the parameters. The device is used as a non- adjustive system, which means it replaces information from standard home glucose monitoring, and it does require calibration.

So, slide four. This slide shows the components of the Eversense CGM System. There is a sensor which is implanted subcutaneously and measures glucose in the interstitial space. The smart transmitter is worn above the sensor on the skin and held in place with a mild silicone-based adhesive. It has a very unique feature of vibratory alerts. So, if the system is triggering a high or low glucose value, the transmitter itself will vibrate right on the arm, which means that the person using the system does not have to have their smartphone with them all the time. But when they do have this smart phone, the mobile app is on the smartphone. And again, displays the glucose values, the glucose trends, and also triggers the alert. As well, there's a cloud-based data management system and the main features, again, are that the system lasts for three months. Up to three months is fully implantable. This has a unique feature of vibratory alerts, and the transmitter can be taken on and off.

So, slide five describes how the Eversense System works. The on-body transmitter placed over the sensor wirelessly powers, the implanted sensor. The antenna on the sensor receives this energy and allows the sensor to be activated. The indicator polymer on the sensor fluoresces when glucose is present in a reversible reaction. The sensor then sends that live data to the transmitter that calculates the glucose value. The value is then sent to the mobile device where it's displayed, and trends and alerts are shown.

Slide six shows the Eversense insertion and removal procedures, all done in a sterile field set up in the healthcare provider's office. A small five-millimeter incision is made after numbing with local anesthesia. A sterile tool is inserted to create a pocket and the sensor is placed in that pocket. The skin is closed

with steri-strips, and a small bandage is placed on top. The removal procedure is essentially the same done under sterile conditions in the doctor's office, involving anesthetizing the area of the five to six-millimeter small incision, which is usually the same incision that was used for insertion. A clamp is placed that grasps the sensor and removes it. And then the incision is closed with steri-strips and a small bandage is placed on top.

The next slide actually shows real world data from the first US commercial users of the Implantable Continuous Glucose Sensor. It was published in Diabetes Technology & Therapeutics in 2019 and described the first 205 patients analyzed using the system in the United States. What I've displayed is a number of metrics. These are all showing that the sensor can be used to manage diabetes. The data is very comparable to what is available by the other CGM systems that are all transcutaneous and it shows that a good mean glucose can be obtained, that there's a good level of glycemic variability. So, not too much glycemic variability, and that measures of control of glucose value, that different glucose measurement is actually also quite good. There are safety data also display that shows there is a very rare reaction to the packing adhesives and that there's rarely any other negative events that can be seen during this study.

On this last slide, I just wanted to share with you an example of a patient who is intensively managed, a 71-year-old from our VMS system with longstanding diabetes. It shows she wears a transmitter almost all the time, that the glucose levels she achieves are very close to the target range, although most of them are in the target range, but it's been determined by an international consensus of Endocrinologists. Remarkably, her mean glucose value was 134, which is an excellent result and as a result, her overall control has been deemed to be excellent.

I do want to emphasize that these CGM reports have been very valuable during the time of COVID, when patients have not been willing or able to go get laboratory tests or be seen in person by their healthcare providers. They prove particularly not able to get an A1C. And as a result, these glucose metrics that really show the overall glucose status of the patients, enable the telehealth visits to be undertaken though me and allowing the health providers and patients. So this last slide just shows the importance of how we can use this data during the time of COVID and really be able to have a meaningful encounter, particularly those done through telehealth visits and because the data is so robust, decisions can be made between the patient and their healthcare provider to really optimize their overall diabetes control.

So, that was my last slide. I just want to thank you for this opportunity to report on this LCD and on the Eversense Continuous Glucose Monitoring System. I'll be able to answer any questions if you have them.

Dr. Shane Mull

Alright, thank you, ma'am. Anyone have questions for Dr. Kaufman? Hearing none. Thank you, ma’am. Next we will move on to Mark Gallardo on the Glaucoma Surgical Interventions. Are you on the line, sir?

Mark Gallardo:

Okay. I just want to thank you for allowing me to speak today, but I am a board-certified Ophthalmologist and I've been practicing for 14 years. I'm also the Glaucoma Fellowship Director at my

institution and hold faculty appointments at the University of Texas Health Science Center in San Antonio, as well as two campuses at Texas Tech. I'm a referral center; 80% of my patients are Medicare beneficiaries and have been heavily involved in evaluations for the safety and efficacy for all MIGS devices. Today I want to specifically talk about canaloplasty and doing canaloplasty since it's FDA approved in 2006 and was one of the pioneers for performing the procedure used in the Aventura approach back in 2015. I have published and presented my work at multiple national/international meetings and I would like to share that with you today.

So, on slide two, which is what we'll be next. As the Medical Directors know, the proposed LCD adopted its own definition of a canaloplasty, and it's limiting it to the performance of the procedure. In my experience, writing manuscripts and reviewing the medical literature is a limited definition is not one that you've really seen, nor does it present any clinical guidelines and the term viscocanaloplasty and phacoviscocanaloplasty don't exist in an Ophthalmologist or a specialist's vocabulary. We just haven't used those terms. We are requesting that those terms be eliminated from the LCD. But there are three main factors of canaloplasty, the first being the access to Schlemm's canal. The second being the intubation or capitalization of the canal with a very innovative, flexible microscopic catheter, and up to 360 degrees of Schlemm's canal, and these tests are true regardless if they're performed via ab-interno or ab-externo approach.

Research has actually shown that throughout the globe, that the two approaches are similar in their ability to reduce a patient's eye pressure as well as their medication burden. But equally important, and something that I really see in my clinical practice every day is that when the procedure is performed via an ab-interno approach, the patients recover so much more quickly and their visual rehabilitation occurs in a much quicker fashion. So, based on published evidence in my clinical experiences, this newly proposed definition of canaloplasty should include the value of the ab-interno approach, or just eliminate the approach altogether. So that it's simply just canaloplasty that provides for certain the ability to determine which method of approach is actually best and safest for the patient.

If you go on to slide three, you can actually see the disease that exists in the patient with Glaucoma. It's something that we really don't discuss in medical school, or even in residency for Ophthalmology. The goal of canaloplasty in general is to dilate that canal, somewhat in a way in which we dilate coronary arteries with a balloon angioplasty. And you can see on the left, there's a photo of a patient with Glaucoma that has a collapsed canal in on itself. In patient's post-treatment in the middle and right photograph, we can actually see that expansion of Schlemm's canal and it's pretty amazing. This is an area that's 250 microns in diameter. So, we can actually see the pre-imposed treatment of these patients, regardless of the approach that we're taking to dilate the canal.

If you go onto slide four, you can really experience the difference between the two dissections. In The photo on the left, this is the ab-externo approach in our ability to catheterize the canal and this type of dissection actually predates canaloplasty. But in the prior procedures, we actually were able to identify that we were able to deal with Schlemm's canal and gain access to the canal, but this is a very large five-millimeter dissection that inherently is associated with a significant amount of post-op recovery.

But in addition to that, when we make these dissections, we are violating the conjunctival space, which is precluding us from performing other forms of filtration procedures in the future, and I know you're going to go over this procedure in a upcoming presentation, but in general, when we catheterize Schlemm's canal, we introduce the catheter, you can see that fiber optic flashing with that arrow. Once

the catheter reaches 360 degrees, we tie attentions, or we tie a proline suture to the catheter, withdraw the catheter, dilate the canal upon withdrawal of the catheter, leaving that suture in place so that we can tie it tight with a specific amount of tension.

What we thought was required to maintain vacancy of the canal, what we learned through the pivotal trial was that tensioning suture was not necessary because the percent reduction of pressure, as well as the medication pressure reduction with equal, and those patients were merely dilated with the catheter versus dilated and leading in the tensioning suture. And that made us really rethink how we approach the patient and dilation. And it took us to the photograph on the right where we began to catheterize the canal through an ab-interno approach, and simply just going through a cataract incision or make an incision within the cornea. In these patients, recovery is much, much quicker, but it still allows us that ability to catheterize the canal and dilate, achieving the same results.

If you go onto slide number five, after performing several hundred procedures through an editorial approach, we conducted a very small, paired study of 10 patients. I'm sorry, of 12 patients, that had canaloplasty in ab-externo approach in one eye, and canaloplasty via ab-interno approach in the fellow eye, and you can see at one year the pressure reduction was almost identical, as well as their medication burden reduction. They did start with very similar pressures and medication burden. But importantly, if you look at slide six, you can look at their post-op recovery and just the complications that occur with the ab-externo approach, because that incision is so big, some patients actually develop a fistula and the filtration blood. So, they have almost like a trabeculectomy, and all of the risks associated with that procedure. In addition to that, because that incision is so big, we have to secure it down with up to five sutures, which induces a significant amount of astigmatism. But we'll do the procedure and we subject them to needing a higher prescription because of the induced astigmatism. But the patients that also have this large incision tend to spike in the pressures a little bit more, which puts a patient more at risk.

If you go onto slide seven, I would like to discuss a few terms that are in the LCD that may be confused with canaloplasty. As I mentioned before, the term viscocanaloplasty, phacoviscocanaloplasty, that they don't exist in our literature, that they don't exist in our vocabulary. It's really not synonymous with canaloplasty. Viscocanaloplasty is a surgery that's about 30 years old. That was a predicate procedure to canaloplasty but in that same, very large incision was performed, but canal dilation was performed through it through a metallic cannula.

The area of the dissection was so far removed from where the actual dilation and collector system is. It wasn't as effective as we wanted it to be. But now with the new technology that we have with these microcatheters, we can actually introduce a catheter into the canal 360 degrees. And because of viscocanaloplasty and phacoviscocanaloplasty are not in our normal verbiage, we're asking for that to be deleted from the LCD. And we again, want to point out the viscocanaloplasty is also not synonymous with canaloplasty.

So, if you go on to slide number seven. Establishing the appropriate coverage for a canaloplasty is really critical to maintain the access to micro basic procedures for our patients. We've had a significant paradigm shift in how we're managing our patients. As you know, radical mastectomies used to be done in the past, but now they're not needed. Now we're doing lumpectomies. Not every patient with coronary artery disease needs to have a cardiac catheterization prior to cracking open a chest. So, limiting coverage to those and I'm going to quote, "not eligible for any other IOP-lowering procedure"

will force many of these patients into these larger, more destructive procedures. A p patient with angina, shouldn't automatically have to go to getting cabbage. And of course, the LCD does recognize the safety advantages, but it fails to extend the coverage to the implant three approach.

So, my last slide is really just a conclusion that the proposed LCD inaccurately defines what canaloplasty is, and it only defines it as being an ab-externo procedure despite there being a significant amount of literature. I know the American Academy of Ophthalmology has set your reference list that also lists some of these publications in AVID Journal, canaloplasty is an approach that's consistent with accepted standards of practice. There's a significant amount of published evidence. So, we humbly requested Palmetto revise their definition of canaloplasty to recognize both approaches. Really, access to canaloplasty is critical for patients with all stages of Glaucoma and with further requests that Palmetto does adopt coverage criteria for canaloplasty that recognizes the procedure as a first line surgical treatment. So, if you have any questions, I'm available for any, and thank you.

Dr. Shane Mull

Thanks, sir. Does anyone have questions for Mr. Gallardo? Hearing none, we will move ahead to our next presenter. We are a little bit ahead of schedule. So, Jessica Holmes, are you on the line?

Jessica Holmes:

Fantastic. Thank you very much. My name is Jessica Holmes. I'm Vice President of Health Policy and Reimbursement with Sight Sciences, a medical device company dedicated to developing technology for ocular diseases like Glaucoma. I will be talking about the proposed LCD for Glaucoma Surgical Interventions DL38759. I have over 25 years' experience in health policy and reimbursement and I lecture for Stanford University's bio design program, for the University of California at Davis' Program on Innovation and Technology Commercialization, the Fogarty Institute in California Life Science Institute. I really appreciate the opportunity to talk to you today and welcome any questions that you all may have. For Palmetto personnel, I'll go ahead and reference the slides as we go along. So, if you could please turn to slide two. That would be fantastic.

While weighing, because we believe that there are areas within the LCD proposal that need to be addressed with additional research and analysis and with the expert opinion of the relevant societies, namely AAO, AGS, and ASCRS. The areas that we believe are problematic are first that the proposed LCD distinguishes between ab-interno and ab-externo approaches to canaloplasty when both procedures ultimately do the same thing in terms of microcatheterization and viscodilation, of up to 360 degrees of the canal. Second, the LCD includes terminology. that's simply not used in the medical community or in research. And, as the previous speaker actually discussed, that would be viscocanaloplasty and phacoviscocanaloplasty. Third, the LCD identifies ab-interno trabeculectomy, but not ab-interno trabeculotomy. And likewise, it doesn't include the largest body of evidence for ab-interno trabeculectomy as discussed earlier today in the New World Medical presentation. And, last but not least, the result of the LCD is that it would eliminate coverage for implant-free minimally invasive procedures. That would leave surgeons with only the more invasive surgical interventions for most all Glaucoma patients.

If you could go to the next slide, please. In Glaucoma, we know that there are three points of resistance that can obstruct the aqueous fluid from flowing out of the eye properly. It can cause the increased intraocular pressure that would be the trabecular meshwork. You see that on the left-hand side of the slide, and that is treated by a trabeculectomy and then Schlemm's canal and the collector channels

behind the canal treated via canal. We'll see those in the center and the graphics on the right.

Peer-reviewed literature shows that 50 to 70% of resistance to outflow resides in the trabecular meshwork. 30 to 50% of resistance resides distal to the trabecular meshwork in the canal and the collector channels. And the two minimally invasive procedures that address this pathway, the ab-interno canaloplasty and trabeculectomy or goniotomy, would be non-covered under the proposed LCD. There are currently no diagnostic tests that can identify the source, or the sources, of obstruction, and, consequently, which of these sources would need to be treated. It is distinctly possible for all three sources to contribute to increased IOP and being able to treat these sources concomitantly if appropriate for a patient and to do so in a minimally invasive manner is critical.

Okay, go to the next slide please. Sight Science has developed the OMNI Surgical System, which received its original FDA 510(k) clearance in December 2017. It did receive an updated 510(k) clearance in August of this year. The OMNI device was based on the company's two proceeding devices, the VISCO360 and the TRAB360. These two devices are mentioned in the LCD but were replaced with the innovation of the OMNI Surgical System that integrates the functionality of those two devices so that a surgeon can target all three sources without resistance with a single device. Now, through the traditional 510(k) FDA process, OMNI reached the market in January of 2018 as substantially equivalent to iTrack and the primary predicate for OMNI was the iTrack. And you'll see here, the iTrack can be used ab-interno or ab-externo approaches and the OMNI for ab-interno. Now, the information on the slide here is taken directly from the FDA clearance. And as you can see, well, if you have a magnifying glass, I think you can see, that the devices are exceptionally similar. The mechanism of action between the OMNI and the iTrack is the same, both microcatheterize the canal, and deliver the viscoelastic fluid to achieve the transluminal dilation up to 360 degrees.

A primary difference between the MLA listed for the two devices is that the Omni Surgical System also does include the ability to cut the specular meshwork, which was FDA cleared for clear corneal ab-interno approach. If you could go to the next slide, please. There's a significant body of published literature for canaloplasty and trabeculectomy separately. I think this was touched on by the last speaker with various devices, both ab-external and ab-internal approaches. So, in addition to that significant body of evidence, here what I'm showing you on this slide is really just specific publications that are studies of these two procedures performed with the Omni device and the ab-internal approaches during the same operative session. So, what you can see here are consistent results across the studies. In terms of IOP reduction, you see between 27 and 41% IOP reduction. In terms of medication reduction, you see a 35 to 50% medication reduction across studies. And where you see the more modest five and 10% reduction, you'll notice that that is actually in patients who are already controlled on medication.

So, this was really a goal of simply a reduction in medications due to either intolerance or to simplify their medication regimen. The durability that you're seeing here is up to two years. So, you have two of these studies at one year and one of the studies at two years, these are all well-respected journals, the studies representative version group of surgeons from different geographies, and they reflect different patient populations with different clinical trial sites and different authors. So, if you could go to the next slide, please. Now what we're seeing is the Medicare claims frequency data from the RBRVS database and that's up to the most current data, which is 2018. And from this, we see a significant decrease in utilization for the more invasive treatment options. With the top row, you'll see, in the dark gray 66170, that reflects a trabeculectomy in the absence of a previous surgery.

And you'll notice that between 2008 and 2018, there was a 57% drop in utilization. The second row, 66172 shows the trabeculectomy with scarring from either previous surgery or trauma. And that demonstrates a 62% drop in utilization between 2008 and 2018. And then the last row in the darker gray, 66175, that is the ab-externo canaloplasty procedure. And we know it's the more invasive approach, because it includes the use of a suture, which can only be performed ab-externo. Since the code was published in 2011, we don't have data for this going back to 2008 because the code was just published in 2011. But since then, there's been a 78% decrease in utilization in that more invasive procedure. And at the same time, you can see in the light gray 66174, the utilization for the canaloplasty the procedure that can be performed with either the ab-externo or the ab-interno approach.

So, what's really important I think here is you can see the increasing importance of the procedure to patients and surgeons as we've heard from the previous speaker and as we, as a company, hear from physicians in the medical community regularly. If you could go to the next slide, please. The previous speaker actually did talk about this, so I won't really go into detail, but I do just want to acknowledge that unfortunately, there is a bit of confusion around the terminology being used largely to represent canaloplasty. There is some confusion around trabeculotomy and goniotomy that here, we're just focusing on canaloplasty and the term viscocanaloplasty, which unfortunately is not a term that's used in the medical community or in research, which is why, according to the LCD, no studies were found using this term for publication search. The publication simply exists in the literature as canaloplasty. When I say there's been a bit of confusion, I think it does largely come from, as the previous speaker was alluding to, the confusion of canaloplasty with viscocanalostomy, a completely different outdated procedure that predates canaloplasty and was never clinically validated.

So, the only nomenclature used in research communities to appropriately represent the micro catheterization is canaloplasty. You will notice here on the slide, three references to viscocanaloplasty, these were all in European publications. Two were in a German publication and one was in another European publication. And again, we believe that this is chopped up to simply confusion between the two procedures. If you could go to the next slide, please. Surgeons rely on ab-interno canaloplasty as the only MIGS procedures for treating a key segment of mild to moderate Open Angle Glaucoma patients. Those patients are, first of all, not scheduled to receive cataract surgery. Second of all, currently being treated with ocular hypertensive meds, and thirdly, those whose Glaucoma continues to progress. So, by eliminating coverage in this cohort, the proposed LCD would leave many mild to moderate patients with no minimally invasive Glaucoma surgical options whatsoever, unless, or until they either one, become a factory to meds or other IOP lowering surgery, two, they actually get to the point where they need a Cataract Surgery.

At which point, the only MIGs option is to drain each device, and three, their diagnosis includes a complex form of Glaucoma. You can see here on the slide in yellow, the significant proportion of OAG patients who are mild to moderate who do not have a need for Cataract Surgery, they would completely be without a minimally invasive option. In the green, you can see those mild to moderate patients that do require cataract surgery that would, under the other MIGS policy, the other LCD, they would have at least the option to have an implant based MIGs procedure. And then you have finally the smaller group of patients who would at least have some opportunity for minimally invasive procedures under this this proposed LCD or the other MIGs policy. And I think at the end of the day, what I really would like to focus on this slide is that for more than a decade, medical companies like Sight Sciences have been

developing this kind of technology and clinically validating minimally invasive Glaucoma surgery options so that surgeons and their patients have viable treatment options beyond the more invasive, complicated and riskier interventions.

The proposed LCD could jeopardize the clinical advancements made for patients at risk of losing their sight to Glaucoma. So, if you could go to the last slide, please. Ultimately, we are respectfully requesting that Palmetto withdraw the LCD until further evidence can be weighed and analysis performed including critical input from the societies like AAO, ATS, and ACRS. We request that you remove the inaccurate terminology, specifically viscocanaloplasty and phacoviscocanaloplasty. We ask that you recognize the ab-externo and ab-interno approaches to canaloplasty equally, and moreover that you recognize canaloplasty as an earlier intervention, since it can be performed in a minimally-invasive manner and should not be relegated to a late stage procedure. And finally, that you include ab-interno trabeculectomy as a covered procedure for appropriate patient candidates. And with that, I want to just thank you again for your time and your consideration.

Dr. Shane Mull

All right, thank you ma'am, I think we have one or two minutes. Are there any questions? If not, thank you, ma'am. Next we have Dr. Jeffrey Kammer to speak about the Glaucoma Surgical Interventions as well. Are you on the line, sir?

Jeffrey Kammer:

Yes, sir how's it going?

Dr. Shane Mull:

Very good, you can go ahead with your presentation.

Jeffrey Kammer:

Thank you for having me. My name is Jeffrey Kammer. I'm an Associate Professor of Ophthalmology at the Vanderbilt Eye Institute at Vanderbilt University Medical Center in Nashville, Tennessee. Again, I'd like to say I'm humbled to be asked to speak today, it certainly is an honor. I believe I was asked to speak today because I'm deeply familiar with all the procedures considered in the proposed LCD and the clinical evidence associated with each procedure, having practice and research in this space for almost 20 years. So basically, I'm old. That being said, I'm concerned that the LCD DL38759 may include some language that is a bit incomplete.

I hope to clarify some misinformation about the procedure and provide exposure to peer reviewed data that justifies the safety and efficacy of their concern procedures. I'd like to quote a line from the LCD, and it said, "The approach and technology utilized should be expected per the weight of the medical evidence to produce a reliably safe and efficacious outcome for the patient with Glaucoma." I hope to demonstrate that canaloplasty, goniotomy, and trabeculectomy all meet this burden in patients with mild to moderate Glaucoma. I'd like to jump ahead to the third slide, slide number three, if you will. We jump back and forth a little bit. Again, we're discussing at first CPT code 66174 and that's canaloplasty. Canaloplasty dates back, the origin date back to the late 60s, it really wasn't popularized until early two 2000's with the introduction of Ellis' I-track, and it was a great procedure, however, because you had to dissect through the conjunctiva and then create a scleral flap, when this procedure did fail, it made subsequent surgeries that much more difficult.

So, because of that, it fell out of favor. This evolved into ab-interno I-track, which was definitely a great innovation. There were two clear corneal incisions, so there was no conjunctival dissection, but there was a bunch of micro gymnastics involved intracamerally or inside the anterior chamber and so a lot of people didn't feel comfortable. It really didn't take off until the Viscodilate 360 and then subsequently the Omni, which was a one single 1.8 millimeter clear corneal incision, which would access the anterior chamber, it was easy to access Schlemm's canal and relatively easy to Viscodilate 360 degrees. So, it really took off with those two procedures. I'd like to jump back to slide two, if you will. A couple of concerns with the LCD. First and foremost, the proposed Palmetto definition of canaloplasty specifically classifies it as a non-penetrating ab-externo procedure and does not include the ab-interno approach, which is much less invasive with almost equal efficacy.

This is inconsistent with the state of the classical literature and current practice regarding this procedure. Personally, I've not performed an ab-externo canaloplasty in four to five years and I would suspect that ab-externo canaloplasty accounts for less than 10% of all cases here in the United States. The proposed LCD would also limit coverage of canaloplasty to patients that are not candidates for any other IOP procedures. This restriction was based on a literature review that failed to include many peer reviewed studies of canaloplasty. It was based on certain fundamental misconceptions regarding approaches to this procedure. I can assure you that nobody in the US uses canaloplasty as their last chance hail Mary option for Glaucoma surgical care. That would be a traveler tube. As was discussed, published evidence strongly supports canaloplasty's ability to lower intraocular pressure while also reducing the utilization of anti-Glaucoma medications, which is obviously in the patient's best interest by decreasing their medication burden.

But it's also beneficial to the patient and for the system or society by decreasing costs. I think the literature will demonstrate that canaloplasty's efficacy is comparable to other covered procedures while also offering the safer, less invasive surgical options as indicated for patients with mild to moderate Glaucoma. Again, Palmetto's proposed LCD does not reflect demonstrated efficacy of canaloplasty and the limitation on coverage to patients that are not candidates for any other IOP procedures should be revised to reflect the current standard of practice. And that is ab-interno canaloplasty is a first line surgical option for patients with mild to moderate Glaucoma. I'd also like to point out that the most popular MIGS procedure two years ago was a procedure called the CyPass and this was pulled from the market secondary to a high rate of endothelial cell loss, or the cells on the back of the cornea.

Unfortunately, this can theoretically be an issue for any implanted device. So, this is yet another benefit to any MIGS procedure that does not leave a retained implant in the eye. I'll try to address that a little bit more later. Next slide, if you would. This is slide four. This slide and the one that follows summarizes findings from numerous studies of ab-externo and ab-interno canaloplasty. The top half of the chart shows the results of a combined sample of almost 800 subjects across five studies of ab-externo canaloplasty. The bottom half, which continues on the subsequent slide, shows results from a combined sample of a little over 600 subjects across 10 studies of ab-interno canaloplasty. In summary, we see that the effectiveness of canaloplasty measured in terms of average percentage change in IOP is comparable for both ab-interno and ab-externo. On average, across these studies, both approaches achieve roughly a 29% reduction in IOP with follow-up between six months and 60 months.

Next slide, if you will. The canaloplasty studies cited here confirm the efficacy of canaloplasty in mild to moderate Glaucoma and demonstrate the comparability and outcomes between canaloplasty and

makes implant procedures, which are currently covered by Palmetto. Certainly, if you're comparing canaloplasty to the initial eye stent, it's much superior to that and you can see that in comparison to the 2011 Tom Samuelson article. Even when you compare it to the latest iteration, the eye stent inject, which documented a 42% reduction in IOP, and this was from a paper by Lindstrom and Associates, it's very comparable to the Ray Brown article that was also published in 2020 in the Journal of Cataract and Refractive Surgery. That's a very well-respected journal.

So, it was a 50% complete success rate with canaloplasty and a 33% complete success rate with hydra. So again, canaloplasty was better than hydra's. Again, this is a procedure that's covered by Palmetto at this point in time. Next slide, please. While ab- externo drainage procedures can produce greater IOP reductions, these procedures are generally reserved for the more severe Glaucoma patients. These procedures are often accompanied with significant complications. Certainly, it can be associated with endophthalmitis, which is an infection in the eye, hypotony, which is low pressure in the eye, or super coil hemorrhage, which is a bleed behind the eye. These in many case cause blindness. On the flip side, canaloplasty, the most common complication is hyphema or some blood in the eye, which this occurs in about one to 15% of the time. This tends to resolve on its own after a week or two.

That's all I have to say about canaloplasty, let's go on the next side. And again, we're discussing CPT code 65820. This is the code for goniotomy and trabeculectomy. So, this was first described, believe it or not, in 1893 in Italy. It was really popularized by Auto Barkan in 1938. And it's really been the standard of care for congenital glaucoma since that time, they just use a little blade or a little needle, to be honest with you to incise the tissue. Unfortunately, it hasn't worked quite as well as the adults. The tissue curls inward and then scars down.

But over the past 20 years, there have been four different procedures developed that have helped mitigate these scarring issues, these procedures are again, simply tools, like we discussed in the definition of a goniotomy and tracheotomy, that have enhanced the efficacy of goniotomy's and trabeculectomy's in adults, and those are omni, dual blade, trabectomy, and GATT, which is a gonioscopy assisted transluminal trabeculectomy.

The main concern here is that the proposed LCD would eliminate coverage of ab-interno goniotomy, trabeculectomy, with the claim that there's insufficient evidence to support the use of this, and then reaching this conclusion, the proposed LCD omitted a significant number of published studies from consideration. There's additional clinical evidence that shows both ab-interno trabeculectomy and ab-interno trachelectomy is effective in reducing IOP and AGM utilization, producing outcomes that are comparable to other MIGS procedures. Again, these are covered by Palmetto and given the limited citations in the LCD, I would hope that Palmetto would revisit this coverage analysis with the full universe of peer reviewed studies, evaluating goniotomy and trabeculectomy. I remember specifically one of them regarding a Kahook Dual Blade.

They had those four citations, three of them were from presentations that were not in peer reviewed literature. Next slide, please. This should be a slide 12. So, one of the main criticisms within the LCD was that the available studies for these devices were case reports, were short-term, did not compare these procedures with trabeculectomy, and I'm not sure why that was requested, and that there were no perspective studies. I believe that I can provide evidence that each of these is covered. You can start with the Trabectomy. I think it was the early 2000's when this was released, there are 141 peer reviewed articles about this. And in fact, there are studies with a significant long-term follow-up. One

has five years, one has six years, and one has over eight years of follow-up.

There's another great article by Casa Hora published in 2019, the Journal of Glaucoma that demonstrated minimal effect on the corneal endothelial cell. Again, very important when you consider what happened with the CyPass two years ago. The Kahook Dual Blade has 31 peer reviewed, and these publications detail the safety and efficacy of the dual blade in over 1400 eyes. The peer reviewed literature includes a prospective level one randomized controlled trial, which I believe you heard about earlier today, that demonstrates favorable efficacy and safety of the Kahook Dual Blade as compared to the eye stent. It also is a little offshoot of this study was performed by Duraj. He's a Glaucoma specialist in Jacksonville, Florida who performed a small perspective comparison of Kahook Dual Blade versus the eye stent. He demonstrated significantly less endothelial cell loss in the Kahook Dual Blade by as compared to the eye stent group.

Again, very important when you consider what happened with the CyPass. With GATT, gonioscopy assisted transluminal trabeculotomy, there are 41 peer reviewed studies. There was one study that compared GATT to ZEN, which is again, a Palmetto approved procedure, and the complete success rate in this was 51% for GATT and 34% for ZEN. There was a prospective study in patients with Pseudoexfoliation Glaucoma out for 20 months. And again, this was a prospective study and shows significant efficacy. And finally, there was a GATT procedure compared with the trabeculectomy. Again, trabeculectomy fared a little bit better, but the complication rate was much more benign in the GATT group. And finally, I know they've spoken a bit about the Omni before, but to date there are nine peer reviewed articles all showing significant efficacy with the Omni device. Next slide please. So, in conclusion, the proposed LCD displayed some fundamental misconceptions about the nature of canaloplasty and ab-interno trabeculectomy and goniotomy as well as the state of the clinical evidence.

I think the evidence of treatment success with ab-interno canaloplasty and trabeculectomy among patients with mild to moderate Glaucoma supports coverage for this procedure as a first-line surgical option. I would humbly request that Palmetto consider recognition of the appropriate definitions and consider the evidence related to both ab-interno and ab-externo canaloplasty as well as ab-interno trabeculotomy and goniotomy, and hopefully reestablish coverage for both procedures consistent with the current literature and the current evidence. Thank you very much for your time and consideration.

Dr. Shane Mull:

Alright, thank you, Dr. Kammer. Does anyone have any questions for Dr. Kammer? If not, that was our last presentation. I want to thank again all the presenters for taking time out of their day and providing us with some great information which were used as we move forward in discussing these draft policies.

We also encourage you to submit written comments. The comment period is still open, and we will respond to all those comments in a response to comments article. That is all, and that will conclude our Open Meeting for Jurisdiction J. Everyone have a great day.