June 28, 2021 Jurisdiction J (JJ) Open Meeting Transcript

Dr. Volkar:

I have just started the recording of this open meeting 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 I consented on behalf of Palmetto GBA. I will now introduce the speakers one at a time. I would like to remind the speakers to please keep your presentation to 15 minutes, at most, so that all the speakers may present. Our first speaker is Dr. David Kennedy speaking about epidural procedures for pain management on behalf of Vanderbilt University, Dr. Kennedy.

Dr. Kennedy:

Thank you so very much. I'm honored to be here. I really want to thank everyone who worked on this, from the expert command panels, to staff time, etc. This is a very challenging topic and I commend everyone for their outstanding work today. My name is David Kennedy and I am presenting on behalf of the Spine Intervention Society. I do work at Vanderbilt University Medical Center where I'm Professor and Chair of the Department of PMNR and an active clinician who does injections. And that is probably my biggest disclosure, that I actually do these as part of my living. I have no relevant disclosures otherwise. I know you all have this slide deck from which I'll be presenting will also present to you formal written comments before the deadline.

Going through covered indications, the first one, number one, imaging to support radiculopathy. I suggest changing to radicular pain rather than radiculopathy. Many patients can have severe radicular pain and the absence of classic radiculopathy, which by definition is a reflex change, a motor deficit, or a sensation deficit. And neurological deficits themselves are not necessarily an indication to support radicular pain. Tests like straight leg raise is a specific test for radicular pain, but not very sensitive, thus it is often not present. Most important patients with radicular pain who do not have a positive straight leg raise or neurologic deficits are just as likely to respond to epidural injections as those who do not, In fact, most of the studies showing positive response, enrolled people with radicular pain rather than frank radiculopathy if you truly read what their inclusion criteria were. So, it would suggest rewording to say, "History and or physical examination, diagnostic imaging supporting one of the following lumbar cervical thoracic radicular pain." At a previous one of these events, additional comments were made about removing that word central from disc herniations, which I would concur with, because there is no difference between a central and a paracentral disc herniation in terms of epidural outcomes in the literature, and adding spondylolisthesis, which should also be appropriate.

Number one requirement of four weeks duration of pain, while I agree, this is actually common practice for many, for people with acute severe radicular pain from a herniated disc, waiting to delay an epidural steroid injection, which does have some at a higher level of evidence for it, is tricky. So simply suggest rewording to the following, "Pain duration of at least four weeks with the exception made for severe radicular pain or a four week delay cannot be tolerated." These are in patients that can't tolerate physical therapy, are not doing well with meds, or putting them on meds is not a great option, and it's not the majority of patients, but there is a number of patients that are in severe pain that waiting this long for an effective treatment is not ideal.

Covered indications number two, requirement to use contrast. We fully support the use of contrast. I think it's essential as a safety mechanism and as a therapeutic to make sure the medication is going to the right place. However, there are people with documented contrast allergies, and although not necessarily in this population, the insurers follow up pregnant patients, would also be a contraindication of fluoroscopic or CT guidance. So, to simply suggest rewording of the following, "ESI must be performed under a CT or fluoroscopic guidance with contrast, unless the patient has a documented contrast allergy or pregnancy, at which time ultrasound guidance without contrast may be considered, in these and similar circumstances." And we all know ultrasound guidance does a lack compared to a fluoroscopy or CT guidance. So, we're not hoping that it is standard, but in these limited restrictions, I think it's reasonable to consider it. Repeat injection is another big point, that it says, "After an initial injection, the patient's pain returns prior to three months, it is reasonable to reinstate relief with a repeat injection."

So, if we require a three month threshold, there's a significant number of people who would otherwise obtain relief from a second injection that will precede the surgery in that interim. There are people that are managed with epidurals. It's not many in my practice. However, there are people, as we talked about before, they have this acute, subacute pain that you're trying to get over or through the disease process with one or two injections. And it may be, they may be spaced a couple of weeks apart. I think that's a better way of doing this when we're trying to get somebody over that acute pain, instead of saying, "We're going to manage this with every three months injections." Suggest rewording to the following, "Repeat ESIs are appropriate. One to two prior ESIs promoted for a long radicular pain, 50 percent for three months, for the condition to be treated. ESI should not be repeated within 14 days. If a patient fails to respond to a single ESI, a repeat ESI after 14 days can be performed using a different approach, and/or medication. With the rationale, a medical necessity for the second ESI being documented in the medical record." We also know that people respond to different medications differently. The same as true with input, some people respond to Ibuprofen and others respond to Meloxicam differently. So, it makes sense that we can try different medications or different routes and approaches in hopes of avoiding a more costly surgery.

The injected, number six, if the injections don't include steroids then they're not really epidural steroid injection. So, we suggest replacing, ESI injectant, with epidural injectate. The current wording is confusing, it stipulates that anti-inflammatories are required, and it says plus or minus contrast. So, it might be implied that contrast does not, but anti-inflammatories are. So, suggest rewording, "The epidural injectate must include contrast agent, unless the patient has a contraindication contrast. And injectate may also include corticosteroids, local anesthetic, saline, and/or anti-inflammatories. Although the anti-inflammatories, aside from the corticosteroids, I'm not aware of anybody really injecting those. Most people are injecting corticosteroids or local anesthetics and saline.

Number seven, requirement of other conservative treatment. I say this as a rehab doctor who does a lot of conservative treatment and tries to avoid both injections and surgery for my patients. It says, "But while some patients benefit from the multimodal treatment, there are plenty of people that experienced relief from an epidural and may not require other conservative treatment." So, suggest rewording to indicate that, "ESI may be performed in conjunction with other conservative treatments." Requiring it may just be requiring unnecessary treatment when it's not needed. The data on this comes from chronic pain conditions and very different patient populations in the Medicare population. So hopefully, you can treat someone with the least amount of treatment that is effective and offering long-term response. We do recommend a new indication for diagnostic spinal nerve block. Suggest including

the following, "Diagnostic spinal nerve block are performed by injecting anesthetics onto a single nerve to help confirm or rule out the source of the patient's pain, often to assist in surgical planning." These blocks utilize the same CPT codes as transforaminal epidural steroids and should be allowed in patients that have failed a therapeutic ESI when the medical necessity is documented in the record.

The most common place for this, for me, is somebody that is going to get an L5, S1 surgery. And the surgeon wants me to inject L4-5 because they have some radiographic abnormalities there, and if they don't get some relief with it, then they usually will avoid doing the second level surgery. There's no steroid or no anticipated therapeutic benefit from it. The goal of it is purely operative planning. This does play into a little bit of our recommendation for numbers of injections later.

Limitations, number one, injections performed without image guidance or by ultrasound. Again, suggest a line for ultrasound guidance and patients with documented contrast allergies or pregnancy. Number six, limit four ASI to 12 months. As I mentioned before, diagnostic selective nerve root blocks, which can be used for surgical planning and have the same codes. We really suggest considering the allowance at three ESIs for six months, and six for 12 months, regardless of the number of levels involved. This would be a rare case from a therapeutic standpoint, but occasionally needed from a planning perspective, meaning the number of people that are going to need six ESIs in 12 months, in my own clinical practice from a therapeutic standpoint, is it almost none.

Limitations, number 11, a series of epidurals. While we do not support a series of three, and even in the slightest, we do support repeat injections if previous injections were successful in achieving pain relief and functional improvement, or only one prior injection was unsuccessful, and again, something was changed. So, suggest rewording the follow, "It is not medically reasonable or necessary to prescribe a predetermined series of epidurals." The predetermined is where people go awry with this, I think.

Number 12, limitations in the steroid dose. The dosages recommended are, quite bluntly, inaccurate. Data from studies, looking at doses implemented and transforaminal injections had been inappropriately extrapolated here to interlaminar. Suggest rewording the following, "To allow for slightly higher doses, consistent with the previous version of the LCD, steroid dosing should be the lowest effective amount, not to exceed 80 milligrams of Triamcinolone, 80 milligrams of methylprednisolone, 12 milligrams of betamethasone, 15 mg of dexamethasone per session." This is consistent with the best literature in the topic, and it is consistent with practice patterns and local environments that I've seen around the nation.

Number 13 in limitations, treatment exceeding 12 months. This a tough one. You know, it is a little challenging given natural history. If you inject someone and then they're better for 12 months or 15 months, and they come back with a recurrence of the same pathology, are you now treating them beyond 12 months or not? There are clearly people that are trying to avoid surgery and you are treating beyond 12 months. And the requirement to communicate with the primary care provider to discuss if a patient is eligible, really is challenging in a lot of ways. Many people do not have a primary care doctor. And I do expect the injecting physician who is injecting steroids, generally in the epidural space, to be a source of knowledge and a high source of knowledge, as to is that appropriate for a patient and coming through. Obviously, communication is ideal, but to require this in the setting is really different than any

other areas we're going through in medicine, where we're expecting the specialists to coordinate with the primary care doctor, which doesn't always happen.

And lastly, provider qualifications, consider replacing "healthcare professionals" with "physicians." Physicians do have the requisite training to accurately select patients, safely perform technically demanding procedures, immediately recognize, evaluate, and address serious life altering complications. My whole career has been on the safety and efficacy of spine injections, has been the main focus of mine. I've published over a hundred articles on this and these injections do have real risks. They can paralyze people; they can cause all kinds of problems. And we clearly do not have an access issue. Given the number of injections done nationally, there's not an access issue and we should require and demand the highest level training possible for our patients.

So, if we recommend adding the following language, "Patient safety and quality of care mandate that healthcare professionals who perform epidural injection procedures for chronic pain (not surgical anesthesia) are appropriately trained by an accredited allopathic or osteopathic medical residency/fellowship program in an ABMS or an AOA accredited specialty whose core curriculum includes the performance and management of the procedures addressed in this policy. If the practitioner works in a hospital facility at any time and/or is credentialed by a hospital for any procedure, the practitioner must be credentialed to perform the same procedure in the outpatient setting. At a minimum, training must cover and develop an understanding of anatomy and drug pharmacodynamics and pharmacokinetics as well as proficiency in diagnosis and management of chronic pain related disease, the technical performance of the procedure, and utilization of the required associated imaging modalities."

Again, someone that has two years of post-undergrad training with no sub-specialization cannot replace somebody who's gone through medical school, combined with a residency, and generally a fellowship. Lastly, society guidance, the North American Spine Society revised their coverage policy recommendations in 2020, and these should be reviewed or ideally replace the 2013 and 2011 references on pages 25 and 26. And there were typos on society names, American Society of Anesthesiologists, American Association of Neurologic Surgeons, and Congress of Neurologic Surgeons, and Spine Intervention Society. Thank you all for your time. And I hope you all have a wonderful day and I appreciate the ability to present this.

Dr. Volkar:

All right. Thank you, Dr. Kennedy for your presentation. Our next presenter is Dr. Robert Wilson speaking about epidural procedures for pain management on behalf of the Pain Society of the Carolinas. Dr. Wilson does not have a formal PowerPoint presentation, Dr. Wilson.

Dr. Wilson:

Thank you. I appreciate the opportunity to speak here today. Again, Robert Wilson, I do represent the Pain Society of the Carolinas. I'm president of that society. It comes at about a thousand members, mostly North and South Carolina, but also the surrounding states as well. My background is anesthesiology and interventional pain management. And I have board certification in both those fields. I'm a private practice physician calling you from Salisbury, North Carolina. And, again, approximately this is a city of about 30–40,000 people and the only board-certified pain doctor in this community. I was

glad that Dr. Kennedy spoke first, I've been reviewing his letter, his information that he just went through. And if I had to sit and type out a letter that would cover all the points that I would like to cover, it would be that letter. That information that he told the committee today, I would just add some personal comments about it.

The thing that I see in my clinic every day are people who come in and they will, he alluded to it, but said that some people would call and they'll have an acute pain, that's just started a day or two before, and try and get into clinic or their primary care gets in here. It hasn't been four weeks and they can't go to physical therapy. They can't even lay in an MRI machine to go and get a study done, see exactly what's going on. Purely by history and physical examination, it appears to be a radicular pain problem. So, it does occur. We have other patients that come into our clinic and we ask them, how long have you been having pain? They'll say, "Well, it's been going on for six months, just now getting worse. And to the point where it's just not going to go away, I've tried everything else." Then we go and move forward with it. But I do agree with the point of the requirement four weeks. There needs to be some verbiage in there and the way it's written by him. I agree some exceptions where the acute pain is there, where they can't go through physical therapy, etc., that we would be able to move forward with that and not be stuck on requiring four weeks. The contrast, I agree. I use contrast in virtually every one of my patients unless they have a documented allergy to it. I do agree with it, but there were circumstances that do come up, whether it be allergy or pregnancy, like you stated. And I agree that we could have some give that way as well.

Repeat injections. The one thing that I read when I read through the proposed LCD is, I'll give you my scenario of when I see a pain patient that comes in for lumbar radicular pain, they will come to me, getting worked up, MRIs down, etc. They tried over the counter medications, maybe some prescriptive things from their primary care or their surgeon. They're sent to me for a diagnostic or therapeutic block. When we do that procedure, it is a rare event that one injection will take care of it, whether it's an interlaminar epidural steroid injection or a transforaminal block. When I do my first procedure on that patient, I generally will schedule them routinely to come back at three or four weeks and schedule a second procedure. And I tell my patients, I said, "My hope is that you will come back and you will feel improved from this and not have any more pain," but when they do come back, majority of them are better, 20, 50, 70 percent better maybe, or they felt better for the first week or two. And then the pain has returned three or four weeks later. May be improved over baseline but still there causing significant pain and we'd go on and do the second one. I said, when they do come back to me, the one out of 50 or so that do come back to me. You say, "I really don't hurt at three and four weeks," and they have no pain. I certainly, as I said, this is great information. We don't want to move forward and do a second one. It's a waste of steroid. You don't need it in your body if it's not going to be working on anything, doing anything good. But I tell them, we'll make an appointment a month later, if you're doing well at that time, you can simply call and cancel. But to do one injection, have a guideline that says three months before you can do another one, it would change course of how I treat my patients, my Medicare patients in particular, it is a restriction that I just don't know how I'd have to handle it.

One thing I worry about in this setting, if the LCD would be enacted, we've been battling an opioid crisis now for some five years or so. Those in my line of work, when I was trained 21 years ago, we used to write a lot more opioids than we do now. I've leaned more on doing procedures now than I've ever done before, because we just simply don't write near as much opioid as we used to. My concern about this, when I see restrictions that would be placed on the amount of medications that we use, on the

frequency of epidural steroid injections, limiting it to four a year. I'm just concerned that people are going to be needing some of the type of care. What I don't want to do is re-initiate more opioids, especially in the elderly. So, it's a concern of mine.

The other concern I have, if this were to become enacted the way it's written, is that we would find more patients who are going to be strongly considered for surgery. I don't know if that is the right avenue. Some of these patients I take care of, are in their eighties, they've got other comorbidities and they're going to be candidates for an operation, especially anything of any magnitude. So, I think that in the efforts of trying to maybe curtail some of these injections that we do every day, Dr. Kennedy, people like myself, if we depend on the ability to have this in our bag of tricks, to use on these patients, to avoid that. If we go on to say we have to wait three months, to do the second one, the limit of four per year. What I routinely do with so many of my patients is, I will do one, I'll do one three or four weeks later, and then we'll follow up with them.

Generally, by that time, they're 75 to 90 percent improved. We'll see them back in about three months. And it is a rare exception in these chronic, degenerative lumbar spines that we see in the elderly population that, around that timeframe, they may start having pain again. And so, we'll routinely do another epidural at three months and they see a real pattern and practice in patients to get these therapeutic injections. If we have a limit to four in a year's time, if I do one, do one a month later, and then every three months thereafter within a 12-month period, that alone is five in a year. Dr. Kennedy mentioned, I think, those of us who practice the interventional pain medicine in a responsible manner, I don't line up a series of epidurals. I do line up a second epidural, because I see it day in, day out in my practice, where we need to have that epidural done most of the time.

But again, we don't do it if we don't need to. We certainly are physicians that practice medicine in a way that just to have a recipe cookbook for it. But at the same time, it's patterned somewhat by what we see day in, day out. I do agree also, the wording of the ESI injectate versus the epidural injectate. Most times when we do our injections, we use it with or without local anesthetic in the epidural space, but generally it's with a steroid solution. But we do have patients who are sent to me by physicians who want simply a local anesthetic block to find out. So, the change of wording on that would be something that'd probably be beneficial. I deal with this with insurance companies too, and that they have come down with the idea of doing physical therapy first and out of the conservative care.

And believe me when I say that I'm all in favor of that. But generally, by the time they get to a clinic like mine, they've been through all the things that they can tolerate. And by that, I mean, doing physical therapy sometimes accomplished, a lot of times, by the time they come here that has been tried. And because of the pain, they have acute radicular pain, they have had to stop it. And so, I think using it along with injection therapy, medications, etc., is more an appropriate way. However, the wording should be put to reflect that. I know that one insurance company I deal with now simply makes them hold out for that. And a lot of times the patients are just miserable. So it's my belief that if you can do an epidural injection or two, and get someone doing better and getting on a home exercise routine, I feel a lot of times the physical therapy is pushed so much up front that our interventions are so effective, that they can be taught at a time when they're not, and they do a lot better etc. So, I agree to have that performed in conjunction with other conservative care.

I touched on the other points here, the limitations number six, about six in a year's time. I do have one lady in my practice, I'll make a personal note about that. I was doing her injections every three months and she would come to me and she'd say, "Doc," she said "It's six more weeks, I just can't get out of bed. I can't do my laundry. I can't make my meals, etc., etc." And so, given the current guidelines, doing six a year, it's rare, but I have one lady in my practice that I do that with. And that keeps her off of all of her opioids. It keeps her more active and functional in her house. So, it goes back to the point we'd like to make that four in a years' time it can be too restrictive in a lot of cases.

I try and tell patients, we do inject you with steroid medication, especially if they're diabetic, etc. We try to use as little as we can with each injection. And do as few of them as we can, but we have to do at the same time to improve their function. And I hate to be restricted with that.

The point I also want to make, and then the very last point here about the provider qualifications. My background, before I went to medical school, I was a nurse anesthetist. And I see across the country, I've seen in this region here where mid-level providers, advanced practice providers, are trying to get privileges to do things like pain medicine, like we're talking about here today. I can talk from a personal standpoint that in my training, as an undergraduate nursing degree and degree in nurse anesthesia, I had no real ability to help differentiate, diagnose, and treat conditions. I certainly wasn't trained in the anatomy and physiology that I got in medical school. I know it's kind of a sticking point these days when I speak to this topic, but the reality is if we're trying to limit the amount of potential harm that could be done, the amount of epidural that would be done in non-qualified hands. I think the wording that Dr. Kennedy spoke of, were you are a trained accredited allopathic or osteopathic medical residency or fellowship and or fellowship program, like I went through. It is something that I think will be better served to the Medicare patient population if we do that. I think if we open the doors and let other lesser trained nonphysician providers to provide this care, I'm concerned about the safety to the patients quite honestly, and concerned about sham procedures that don't really get performed in a qualified manner, etc.

I think we need to, it's time that if we can, word this in a way that will allow the physicians to be the personnel to perform these procedures. Simply based on my background, my experience that I can attest to, but also knowing how nurse anesthetists are well-trained for what they're trained to do, administering anesthesia in operating room setting. But even with their additional training programs that they have, I don't know much about it. Who monitors that, if there's an overseeing organization outside of the American Association Nurse Anesthetist, that oversees it? I think it would be best for our patient population if we were to curtail that activity.

So, that concludes all that I have to say. I appreciate the opportunity to speak here today. Again, I hope that we can come to common ground on the way the wording is now and what we see in daily practice. What I see here, certainly, because if it stands the way it is proposed I have concerns that it'll change the course of how my patients are taken care of, going on to surgery quicker, etc. Having more advanced, minimally invasive surgeries in my hands, etc. When they could just easily get by with this more conservative interventional therapies that I performed on. I thank you all for your time and attention.

Dr. Volkar:

Great. Thank you, Dr. Wilson. Does anybody have any comments or questions? All right then, given that, thank you all for coming and participating in the open meeting for JJ, and this will conclude our meeting. Thank you.