August 2, 2021 Jurisdiction J (JJ) Open Meeting Transcript

Dr. Lisa Banker:

Okay. So again, my name is Dr. Lisa Banker. Welcome to our JJ Open Meeting for August 2, 2021. I have just started the recording of this open meeting in compliance with CMS, and for the record prior to doing so, I did announce that Palmetto GBA would make an audio recording of the open meeting and consented on behalf of Palmetto GBA. We have a single presentation that is scheduled today. So there will be no other formal presentations or other opportunities for verbal comments, but we will be hearing from that single presenter.

Before we do that, just wanted to let you know, and I'll try to remember to do this at the end as well, that certainly if you have any additional comments you wish to add to any of the proposed LCDs that are in the comment period, you certainly have that opportunity and you can do so through B.Policy@palmettogba.com. I'll repeat that at the end as well. The last housekeeping item is please take this opportunity right now to mute your phones. It can be very distracting and a lot of background noise if we don't take the opportunity to do that as a courtesy to our presenter. So today we have Dr. Carlton Reckling. I believe he's with SI-BONE, and hopefully he is on the line. Dr. Reckling, are you with us?

Dr. Carlton Reckling:

Yes, Dr. Banker, I'm here. Thank you.

Dr. Lisa Banker:

Okay, great. Well, we're going to let you get started and just to let you know, I and my Contractor Medical Director colleagues do have a copy of your PowerPoint so you can proceed.

Dr. Carlton Reckling:

Okay. I'll try and put the slide number in my communication as we go through here. So thank you very much for allowing me to present to your group today. As Dr. Banker mentioned, my name is Carlton Reckling. I'm a fellowship trained orthopedic spinal surgeon, and I am currently employed as the Chief Medical Officer at SI-BONE. SI-BONE is a manufacturer of innovative medical devices used in the treatment of sacral pelvic conditions and diseases affecting thousands of Medicare eligible patients each year.

So, onto slide two. Our comments today relate to the draft LCD DL39025 detailing MIS SI joint fusion criteria. We would like to offer an update and overview of recent trends for these procedures in terms of patient volumes, adoption rates by surgeons and coverage by commercial insurers. There are some CPT coding updates related to this topic, and some very recent AMA activity on the topic that are relevant to Palmetto's draft policy. Professional societies, insurers, health technology assessment firms, and specialty benefits management companies have all been evaluating the evidence for this procedure over the past several years, they have been publishing on it and we believe it will be a benefit the Palmetto team to hear what they are now recommending in terms of patient medical necessity criteria and specific language about procedures they're willing to cover. Finally, we have some updated literature that was not referenced in the Palmetto draft that we would like to discuss.

Slide three. The AMA created CPT code 27279 to describe MIS SI joint fusion in 2015. The published clinical evidence has grown substantially since that time. This has led to the evaluators of the evidence recommending support and coverage of the procedure for their organizations. In 2017, NICE in the UK recommended the procedure, but only when the iFuse triangular implant system was utilized. This trend has continued over the past five years with many organizations deciding that only the evidence for the iFuse implant system with triangular implants was sufficient to confer support or coverage. Groups like Evercore, AIM SpecialtyHealth, Humana and Anthem have all said they support the procedure, but only with the triangular implants. In a moment, I will share the distinctions between triangular and cylindrical implants in terms of evidence that led to many of these decisions.

Next slide, four. Today, there's nearly universal coverage for the MIS SI joint fusion procedure for patients needing medical necessity criteria established by their health plans. This includes patients covered by commercial insurance and those who are under government eligibility programs. Recently, New York State Workers' Compensation Board also recommended positive coverage.

Slide five. Importantly, in 2018, the BCBS Association published an evidence opinion 6.01.23 on this topic. For the past three years, they've stated that evidence for the procedures using triangular MIS SI joint fusion implants, currently the iFuse system, have sufficient evidence to confer a meaningful improvement in net health outcomes, other device types, including cylindrical implants or other products in this MIS procedure, do not have sufficient evidence.

Slide six. The shape of the implant in the context of MIS SI joint fusion procedure is important, and triangular shape even intuitively allows more resistance to rotation. SI joint motion is primarily rotation and threaded implants and screws sometimes back out after being implanted. This can be a reason for revision surgeries. The increased surface area of the triangle is also important to promoting long-term fusion and bone integration with the implant. Prospective data on patients treated with the iFuse triangular implants now extends to five years. Clinical results are durable with high patient reported success rates, and with high rates of radiographic fusion confirmed by bridging bone across the joint as seen on CT scan. Clinical outcomes for triangular shaped implants include level one and level two studies, including the long-term five-year results that had been recently published. Some evidence for cylindrically shaped implants does exist, but it is lower level of evidence, typically level three, or level four case series.

Slide seven. The unique shape of iFuse, amongst the approximately 20 or more competitive lateral transfixing implants, is also distinguished. This is a table of the top four competitive implants to iFuse used in the lateral trans iliac procedures. They are all screw based and cylindrical in cross-section. The laterally placed implants have been available and in broad use since around 2010, and were the subject of the AMA CPT panels deliberation when evaluating the temporary and subsequently the permanent code for this procedure. The evidence the AMA panel evaluated in 2013 and again in 2014 was primarily based on the iFuse procedure, a lateral transiliac approach to the joint.

Slide eight. In terms of the published clinical evidence for lateral transiliac product, iFuse today remains the lion's share of the entire body of literature and iFuse is the only implant with level one clinical evidence, two RCTs, one in the US and one in Europe, support the use of triangular titanium implants.

Slide nine. A quick scan of the other LCDs on this topic reveals moderate discussion about patient requirements and Medicare beneficiaries. Notably, most Medicare administrative contractors do not require a set of specific imaging or specifications as to the conservative therapies. Instead, they rely on the opinion of the provider as to what is reasonable, and necessary care for their beneficiaries. We believe that Palmetto is doing the right thing by conducting an update on this topic. Much has changed since the majority of these LCDs and LCAs were first drafted. Importantly, the procedure itself has evolved. There is now a new emerging SI joint procedure that is significantly different than MIS SI joint fusion with placement of lateral transfixing devices. We would like to illustrate how the procedures are different. The AMA will actually be taking up this topic at the next panel meeting in September. We are hopeful that Palmetto will consider this new procedure in their review.

Slide 10 is an illustration of the new procedure on the right, the dorsal procedure, compared to the existing procedure, the lateral transfixing procedure that has existed since 2010. So the new emerging procedure is a posterior or dorsal MIS SI joint stabilization or fusion procedure. In this dorsal procedure, the implants, or in many cases, bone allograft products are placed from a different trajectory and approach than the lateral transiliac procedure. A different part of the joint is accessed. Bone allografts or implants actually sit within the ligamentous or articular part of the joint, distracting the joint, rather than being placed across the joint transfixing it like the iFuse or these other products. The products placed dorsally into the SI joint are bone allograft or sometimes biomechanical devices that are small enough to fit in between the bone of the ilium and the sacrum.

There are a few FDA cleared devices used in this procedure, but the majority of these new procedures are performed with 361 HCT/P bone tissue products not regulated as devices, but rather being used and billed as if they were devices. We are aware of these competitive products that there is not a significant literature base describing their use. However, as an orthopedic surgeon, I believe that there remain several major questions regarding patient safety and clinical outcomes with this new and significantly different procedure. The surgical principles for stabilizing and fusing the joint with the new posterior procedure, this would be ligamentotaxis and distraction arthrodesis, similar to the old strategies are very different than the principles of the lateral transfixing devices and the lateral procedure. We are not aware of any high level clinical data supporting the use of these products.

This new procedure is very different from the lateral trans iliac procedure using iFuse or the other cylindrically shaped implants that have been on the market for over 10 years. The market has seen a significant increase in the use of these new dorsal MIS procedures. Over the last couple of years, these new procedures are typically performed in the ASC or outpatient setting. We also note that many of these companies market the procedure to non-surgical physicians such as PMR or anesthesia trained pain physicians.

Slide 11. In December, the International Society for the Advancement of Spine Surgery, ISASS, issued updated recommendations on the MIS SI joint fusion procedure. They published a thorough review of the literature for lateral trans iliac MIS procedures, as well as searched the literature on the dorsal or posterior MIS procedure. You see on this slide on the left is VAS, on the right is ODI. There is a summary of the literature for lateral MIS SI joint fusion with transfixing devices. That's the top of each of the two boxes. So, there's about 30 publications for lateral. And then underneath are the dorsal procedures. Again, on the left is VAS. On the right is ODI. And you see that in addition to the differences in the

volume of literature, the change scores are less for the dorsal procedure, the bottom of the two graphs, compared to the lateral, the upper of the two graphs. The blue is the beginning, and the green is the final or final outcome described in each of the studies. And you see that the delta is significantly larger for the lateral procedure than the dorsal procedure for both VAS and ODI.

Next slide. Also, in the December update, ISASS formally recommended that surgeons report the MIS dorsal or posterior SI joint procedure using an unlisted CPT code. They believe the dorsal procedure is very different from the lateral procedure and that the CPT code 27279 used for MIS SI joint fusion describes only the lateral or posterior lateral approach with placement of transfixing implants. 27279 does not describe the dorsal MIS procedure. This opinion is shared by many coding experts.

Next slide. This is 13. Current SI joint procedures and CPT terminology. Since the December ISASS publication, other coding experts have stated the new dorsal procedure is not described, by either 27279 or by code 27280 used to describe open SI joint fusion procedures. The American Academy of Professional Coders Journal Healthcare Business Monthly has seen multiple submissions by coding expert authors agreeing with ISASS's recommendations.

In 2020, the AMA CPT knowledge base recommended... We responded to an inquiry about these dorsal bone allograft procedures, and they stated the use of CPT 27279 should be centered on the patient being yet in the code 27279, that all describe a lateral transiliac procedure only. At the upcoming September CPT panel meeting, the AMA CPT Editorial Panel will review a proposal to create a T code for the MIS dorsal or posterior procedure. If expected, the T code would be effective for these procedures effective July 1, 2022. For these many reasons, we believe that the Palmetto draft LCD at least mention the new dorsal procedure, so that a placeholder for the T code in the coding section would be possible and it would fit with the final LCD on this topic, which may be in force for the next several years.

Next slide. This is a little bit about the ISASS compared to the NASS coverage recommendations. The ISASS guidelines updated in December 2020 are obviously much newer than the guidelines for MIS SI joint fusion published by the North American Spine Society or NASS in 2015, five years newer. The Palmetto draft LCD relies more heavily on the NASS criteria, which are older and do not rely on the significant updates to the literature on this topic that have occurred since it was published in 2015. This includes the long-term five-year follow-up of iFuse patients. The ISASS update states that the iFuse literature makes up most of the high level clinical evidence on this topic. Patients treated in the iFuse prospective studies, including the long-term follow-up study protocols, did not require certain criteria that NASS currently recommends. If Palmetto adopts the current draft LCD language, which is based on the more rigorous NASS criteria, it may be overly restrictive and stringent than is necessary for Medicare beneficiaries who may benefit from the procedure.

Next slide. 15. We strongly support Palmetto's update on this topic, and we believe that in the LCD based on the latest evidence is important. We feel the LCD would benefit from additional update, including number one, requiring only one diagnostic injection and require that that injection specify only a 50% pain reduction. And we recommend removal of the requirement for therapeutic SI joint steroid injection. There is no high level clinical evidence that demonstrates the health benefit of a steroid injection. We would also ask that the LCD distinguish and discuss the new MIS dorsal procedure as different from the lateral transiliac procedure. To be the most evidence-based LCD, coverage criteria

should only apply to triangular implants, a distinction that many organizations, including BCBSA, and some of the large national players like Anthem and Humana have already made. It is the triangular shape they're referring to rather than a specific manufacturer or product.

Slide 16 illustrates the slight differences in the NASS coverage criteria compared to ISASS. And you see on the bottom of that cascade that ISASS differs on two points. ISASS recommends only a single diagnostic injection rather than the two diagnostic injections in the NASS criteria. ISASS requires only a 50% pain reduction. ISASS does not require therapeutic injection. Rather, the use of a therapeutic injection is left to the discretion of the physician provider.

So next slide. Slide 17. In summary, we have discussed a number of points in this presentation. We recommend the draft LCD require only one diagnostic injection, not two, that the threshold for pain improvement from the injection should be 50%, not 75%. We recommend there be no therapeutic injection requirement. Rather, a provider may provide the injection if desired. The draft LCD should mention triangular versus cylindrically shaped implants used for lateral transiliac procedures. This would reflect the level one clinical evidence from two RCTs and multiple prospective trials on the triangle. And we recommend the draft LCD mentioned and exclude the dorsal posterior MIS procedure in this LCD. A t-code decision from the AMA CPT panel should be revealed shortly, potentially as early as November.

Slide 18. The clinical literature references. We did make a number of suggestions for additional literature to be included in the LCD. That's in the bottom row highlighted with the red title. The literature on the iFuse implant system on the triangle titanium implants. There are over 95 published articles worldwide on the iFuse implant. Data includes 10 level one papers and 12 level two papers. No other SI joint device has level one data at all. The data shows significant patient improvement, which is sustained to five years post-operatively through multiple prospective studies. And finally, I'd again like to thank the group today for allowing me to speak. Thank you for your time and the opportunity to address these important topics. If there are any questions, I'd be happy to answer them. And we would, of course, be happy to follow up with you after the meeting, if desired. Thank you.

Dr. Lisa Banker:

Thank you, Dr. Reckling. Palmetto certainly appreciates and very much values the input you provided today. So thank you very much. I am presuming that none of my professional colleagues on the line has any direct questions at this point. So, this is going to conclude the open meeting for today. Again, we thank everyone for listening in and appreciate Dr. Reckling's input again. In conclusion, if you do have any follow up comments on any of the policies that are being proposed and are the subject of this open meeting today, please again, feel free to submit them in written fashion to the B Policy. That's B.policy@palmettogba.com. Thank you very much for being here today, and I hope you all have a lovely afternoon.

Dr. Carlton Reckling:

Thank you very much for your time. I appreciate the opportunity. Take care.

Dr. Lisa Banker:

Thank you.