# November 1, 2021 Jurisdiction M (JM) Open Meeting Transcript

Dr. Stroud:

I 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 consented on behalf of Palmetto GBA. So again, welcome everyone to this afternoon's meeting. We have two presentations scheduled for this afternoon, both addressing the proposed LCD Treatment of Varicose Veins of the Lower Extremities.

For the presenters, you will have 15 minutes for your presentations. I will give you a 2 minute warning if you're getting close to the time limit. If we have any extra time left during the 15 minute time block, we can take questions. So again, we have two presenters and it will be Dr. Jaff and if Dr. Gasparis is able to join us he will present as well.

Before we start, I just want to let everyone know that this an important part of the LCD process, having this open meeting today. And it's an important part, given that it's a way for stakeholders to provide us here at Palmetto GBA with feedback and any comments or concerns that they may have pertaining to our proposed LCD's. Ultimately what we obviously want to be able to do is provide the best coverage decisions for our beneficiaries and this is one of the methods for us to be able to do that.

So, with that said, let's go ahead and start our presentations. First up will be to Dr. Michael Jaff. Dr. Jaff. I'll let you introduce yourself, where you're from, and you can begin your presentation.

Dr. Michael Jaff:

Thank you very much doctor and to all participating. I appreciate this opportunity. So you have the presentation that was previously provided. I'm on slide one, which is the cover slide. This slide deck represents Boston Scientific's comments regarding Palmetto GBA proposed LCD and LCA, titled Treatments of Varicose Veins of The Lower Extremities, LCD DL39121 and LCA DA58876.

And I'll go to slide two. Allow me to introduce myself. My name is Dr. Michael Jaff. I'm the Chief Medical Officer and Vice President of Clinical Affairs Technology and Innovation for Boston Scientific Corporation. I am a practicing Vascular Medicine Specialist with board certification by the American Board of Internal Medicine and the American Board of Vascular Medicine. I have 27 years of practice in both the private practice hospital and academic medical center settings, having run the Vascular Center at the Massachusetts General Hospital in Boston. I am also a member of the board of several organizations. And as full disclosure, you may be able to tell, I am a part-time employee of Boston Scientific Corporation.

Let's move on to slide number three. Let me take a moment to thank you on behalf of Boston Scientific. We'd like to thank Palmetto for the opportunity to provide comments by this transparent termination process. March 10th, 2020, the Palmetto GBA retired their past LCD and LCA for the Treatment of Varicose Veins and Lower Extremities with the following statement, "Due to controversies in varicose

vein treatment, as well as our desire to more deeply engage stakeholders in the LCD process and maintain consistent coverage policies across MAC jurisdictions, Palmetto GBA is retiring the present draft policy, as well as the active policy."

Slide number four is a disclosure provided by Boston Scientific regarding their work and the work around their products, specifically in Varithena. The Varithena prescribing information is in fact available at the link on the bottom of this slide.

Let's go to the next slide. The topic title of this slide is a proposed LCD. Boston Scientific agrees with the proposed components of conservative management and have no further comments regarding this. Let's go on to slide six, which is titled Proposed LCD - Suggested. In an effort to maintain consistent coverage across MAC jurisdictions, Boston Scientific proposes the addition of the following information currently included in the First Coast LCD Jurisdiction JN and Novitas Jurisdiction's JH and JL. For patients who meet any of the following criteria the mandatory conservative therapy prior to the invasive procedure may be waived. C4 to C6 disease, hemorrhage or recurrent superficial thrombophlebitis.

Let's go on to slide seven. Again, entitled Proposed LCD. The Palmetto GBA's current LCD includes the following descriptors of different forms of sclerotherapy. These are just for your reference and I'm not going to read these verbatim. I'm sure the committee is well aware of this.

Let's go on to slide eight. This title says Proposed LCD - Suggested. Boston Scientific proposes adjusting the wording found in the UGFS section to include a differentiation of the types of foam created for ultrasound SF. This differentiation is recognized in CPT coding guidance offered by American Medical Association in their March, 2018, CPT Assistant article. This wording also appears in the First Coast and Novitas jurisdiction LCD's and thus would be consistent across MAC LCD's. We will make a similar coding clarification recommendation for your corresponding LCA in the next slide. I do have one final comment on this slide, specifically in the foam's sclerosis section. We would suggest that the minimum vein size criteria be modified to three millimeters or greater, rather than six millimeters, as six millimeters is too large as the minimum vein size criteria, even for truncal veins.

Let's go on to slide nine. This also is entitled Proposed LCA - Suggested. Continuing the theme of maintaining consistency across MAC LCD's and LCA's, Boston Scientific recommends the following clarifying statements be included in the Palmetto GBA's associated LCA DA58876, Billing and Coding: Treatment of Varicose Veins of the Lower Extremities. These comments reflect American Medical Association guidance included in the March, 2018, CPT Assistant article entitled Coding and Competent Veins Treatment, and will help with coding accuracy per AMA guidance.

Let's move on to slide ten. The title of this slide is merely three additional references to consider for the proposed LCD. The first by Jimenez JC and colleagues, published in July 2021, the second is Vasquez, et al in Phlebology in 2017, and the third is Kim PS, et al, Journal of Vascular Surgery, 2020. The references are listed on that slide. We'd recommend these being added to the bibliography section of the proposed LCD.

Again, on behalf of Boston Scientific, I personally thank you for the opportunity to comment. I've provided my email here should you have any questions or comments regarding these requests. Once again, thank you so much. I'll turn it back to you.

Dr. Stroud:

Thank you Dr. Jaff. That was an excellent presentation and thank you for the comments as part of your presentation. We do have a couple of minutes here remaining in this block. Does anyone have any questions for Dr. Jaff? If there are no questions we can move on. Dr. Gasparis were you able to get on the line?

Dr. Tony Gasparis:

Yes, I'm on the line.

Dr. Stroud:

This is Dr. Stroud. I'm one of the Contractor Medical Directors at Palmetto GBA. Thank you for being with us today. Dr. Gasparis I will let you go ahead and just like Dr. Jaff introduce where you are from and you can go ahead and start your presentation. You have 15 minutes.

Dr. Tony Gasparis:

Thank you very much for the opportunity. So, my name is Tony Gasparis. I'm a practicing Vascular Surgeon at a Stony Brook Medicine. I've been in practice for over almost 20 years and have dedicated my career in the last 7 years only to venous therapies and evaluation and management of patients with venous and lymphatic disease. I founded and am the director for The Center for Vein Care at Stony Brook. Been on multiple boards and venous societies and I'm currently the President for the American Venous Forum. I'm also the course director for major venous educational programs, both in the U.S. as well as outside the U.S. So thank you again for the opportunity. And really my goal was to, after reviewing the proposed LCD, is to really outline what concerns and express some of my suggestions regarding some of the CVD statements in the document, as well as the treatments that are discussed.

We'll jump to page or slide number four, where represents page two and three and comment one of the LCD, and that's the current description of that comment. And slide five is what my suggestions would be, where in the current document it talks about superficial deep venous obstruction under venous reflux and I've narrowed it down to venous reflux in the superficial or deep veins and separated and or venous obstruction, which is basically a definition of chronic venous disease. Under CEAP, CEAP is in the LCD is described as categorizing so various CVD, but it actually categorizes the clinical presentation of a patient, what the underlying etiology of CVD is, what anatomic veins are affected as well as the underlying pathology of those veins. So that really is the true definition of what CEAP represents.

On slide number six is, again, the current language in comment in page number three, talking about conservative therapy and the requirement of conservative therapy for intervention. But if you look at the AVS, SVS guidelines published in 2011 on slide number seven, compression therapy is suggested for patients with symptomatic varicose veins but recommend against the use of compression as the primary treatment of symptomatic venous disease in those patients who are candidates for saphenous vein ablation. And that's a 1B recommendation.

I know for many years many policies have mandated the use of compression stockings but we have very strong data with, and guidelines suggestion from SVS and AVF, that this is actually a 1B recommendation not to require compression therapy for patients who are candidates for saphenous or varicose vein therapies. So I would suggest or consider eliminating the requirement for conservative therapy.

Now on slide number eight, it talks about liquid sclerosant and foam sclerosant and that's the exact language in the policy suggested. And slide nine are my comments regarding that in that one of them being that for liquid sclerotherapy we limit it to patients with varicose veins that are small, meaning less than three millimeters.

Now I know in some of the guidelines and some of the data talk about using liquid sclerotherapy for perforator veins. And I'm not quite sure how that has kind of incorporated in some of the policies but really sclerotherapy should not be used for perforator veins. Perforator veins are very close to the deep veins and expose the patient at high risk for sclerosis going into the deep system, potentially leading to deep vein thrombosis. So, I would eliminate that part with respect to either liquid or form sclerotherapy. Under the description of foam sclerotherapy I think we need to separate physician compounds to non-compound foam. And this is a language kind of I have put in as far as my suggestions separating those two out.

Here and slide 10 talks about radio frequency ablation and endovenous ablation as per the policy. And then slide number 11, just a few additions I would add where in the examples they talk about great, small and accessory saphenous veins, I would be more specific to naming the truncal accessory veins, which are the anterior accessory and or poster accessory great saphenous veins, which are different than any other accessory vein or tributary that people often have used the system and treat multiple accessory veins in a single patient.

So, I would be very specific in the language there talking about anterior accessory or posterior accessory, which are truncal veins. Same thing on the laser ablation, specifically calling out anterior accessory, great saphenous and or posterior accessory great saphenous, rather than accessory veins. On slide number eight talks about the final acrylate per the policy. And 13, same here, instead of accessory saphenous vein, calling out the saphenous veins as great saphenous and or accessory and small saphenous veins.

Slides 14 and 15, similarly here with mechanochemical ablation. And slide number 16 discusses stripping. Here I would begin talks about detachment of any specific vein, whether it's a great saphenous, angio accessory, small saphenous, and it's really because it could be small saphenous, it really shouldn't call out common femoral vein. It's the saphenofemoral or saphenopopliteal junction.

On slide number 18 is really the only addition, which I mentioned earlier, adding to the list of therapies which are laser RF, MOCA, stripping and VenaSeal. Add onto this non-compound foam as a therapy for saphenous vein ablation. Slide number 19 discusses liquid sclerotherapy for the treatment of varicose veins. Again, here I would change the size to three millimeters, less than three millimeters for saphenous and for varicose vein treatment and also consider removing perforator veins.

Slide number 21, there's the current policy regarding, on page five of the LCD. And on 22, I just, again, some minor changes to call out specifically the anterior accessory versus broad verbiage of accessory vein, and also adding non-compounded foam as part of the list of therapies that are currently available for treatment of saphenous vein ablation.

Slides 23 and 24 are meant to discuss perforators. 23 being the current policy and 24 is the suggestions where I really would not say that incompetent perforators are the most common cause of recurrent varicose veins, there's multiple causes. And I would put strict requirements based on the SVS, AVF guidelines which mentioned the need for perforator reflux over 500 milliseconds, that there is no saphenous or symptomatic varicose veins contributing, that that's been previously treated and that there's an active ulcer present with the perforator in the vicinity of the ulcer rather than, let's say, in the thigh. So those are the requirements or the definition of a pathologic perforator for the AVS, SVS, and really should be followed in the policy.

The last slides talk about limitations for therapy. And on slide number six I've crossed out what actually is not a limitation. I mean, inability to wear compression stockings is actually, if you consider that conservative therapy for patients if they can't tolerate it then obviously the only other option they'd have would be to be offered them treatment if you will have compression as a requirement. Evidence of ablation of a deep venous system really it's more for acute situations, if they have an acute DVT or acute superficial vein thrombosis. KTS is actually, these patients would highly benefit from many venous therapies. So I would not put them as a limitation unless they have absence of a deep system, which is pretty rare. So just a few suggestions as far as what I think falsely have felt to be limitations, but actually these are patients actually that would benefit.

And the last slide talks about absence of deep venous obstruction as a requirement. Unfortunately a significant number of patients with chronic venous disease, about 20% of the patients, will have combined superficial and deep venous reflux. And when you have two different systems being involved, the venous hypertension is additive and treating one of the systems will actually benefit them. So having absence of deep venous obstruction as a requirement is really not appropriate. And there's several papers that show therapies of the superficial venous system in patients who had a previous deep venous thrombosis is not only safe as far as risk of postoperative thrombosis, but actually does not make the patients worse, but actually improves their outcomes. So that's kind of the summary of my comments and suggestions, and I'll be happy to take any questions and thank you for the opportunity to present.

Dr. Stroud:

All right. Well, thank you Dr. Gasparis. Again, another excellent presentation with some very helpful comments and we do appreciate it. Any questions for Dr. Gasparis?

All right. Well, hearing none that concludes both of our presentations for this afternoon. I do want to let everyone know that, that's on the line, that both of the proposed local coverage determinations, the one that we have discussed today, Treatment of Varicose Veins of the Lower Extremities and then our other proposed LCD Treatment of Males with Low Testosterone, the comment period ends on November the 6th, 2021. So there is still some time to submit comments for these LCD's.

All right, well, I'll just open it up one more time. If there are any questions we can take them. We have just a couple minutes. Okay. Well, if there are no questions, I appreciate everybody again for calling in today. Dr. Jaff, Dr. Gasparis thank you very much for taking time out of your day today to present to us. We are going to take a break and we will reconvene at 2:30 for our next open meeting for Jurisdictions J. With that, I'll wish everybody a pleasant afternoon and thank you again for joining us.

Dr. Michael Jaff:

Thank you very much.