November 1, 2021 Jurisdiction J (JJ) Open Meeting Transcript

Dr. Stroud:

I just started the recording of this open meeting 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 once again, I want to welcome everyone to this afternoon's meeting. We have one presentation this afternoon, addressing the proposed LCD Treatment of Varicose Veins of the Lower Extremities. Dr. Daugherty, you'll have 15 minutes for your presentation. I'll give you a two-minute warning if time is running out. If we have any extra time left during this 15 minute time block, we can take questions.

As I mentioned at a previous meeting, we really do appreciate everyone being a part of this meeting today. This is an important part of the local coverage determination process. 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 regarding our proposed LCDs. Obviously, the ultimate goal here is to make the best possible coverage decisions for our beneficiaries. So with all that said, Dr. Daugherty, I'll let you introduce where you're from and you can begin your presentation.

Stephen Daugherty:

Thank you. I'm Stephen Daugherty. I'm a surgeon from Clarksville, Tennessee. I am the chairman of healthcare policy and advocacy for the American Vein and Lymphatic Society. I've served on the Carrier Advisory Committee in Tennessee under three Medicare administrative contractors for the last 25 years. So I'm representing the AVLS, we are working closely with the American Venous Forum, the other major vein society in the country and we even very likely will submit joint comments in our written comments on Friday. I thank you for the opportunity to talk with you all about something we think is very important. Conservative management is a critical part of managing these patients, but there's no evidence that conservative care will prevent the need for treatment of the conditions that are covered under the policies. Compression might be useful for selective trial to discriminate ambiguous, lower extremity symptoms. Some patients only need conservative care.

Others need significant treatment and compression is an adjunct for care of many of those patients. Compression also may be used to treat edema, lymphedema pain, management of venous thrombosis, and some postoperative patients. Graduated compression stockings are one option, and you list that in your policy, but you don't mention any elastic compression or compression wrapping, which may be more appropriate for some patients. Some patients just cannot tolerate compression because of anatomic characteristics, arthritis, shoulder, back pain, obesity, neurologic disease, some kind of disability, which limits their ability to actually don and wear the devices. A 2 to 4 week trial of weight loss is a condition of treatment just isn't realistic while weight loss for many of our patients is ideal, and we encourage it. A 2 to 4 week trial is just not going to mean anything in terms of weight loss for these patients. The prescribed exercise plan is useful, but it's not feasible for a lot of patients and it's difficult to document.

Periodic elevation's not possible for some patients, especially for those with severe cardiac or respiratory disease. The key thing is that the ability to manage those elements of conservative care varies so much from patient to patient, that rigid rules as a prerequisite for vein treatment just aren't

reasonable. We think that the LCD language should encourage those elements of conservative care to be individualized to the patient, but the LCD needs to be clear that these are things that are useful for some patients and that these are not things that should be used to deny care on a part of the LCD or a future auditor.

Sclerotherapy is the only necessary treatment for some venous efficiency and it's adjunctive after other treatment of some veins. It's the only useful technique and the preferred technique for treatment of many abnormal extremity veins. Liquid sclerotherapy has been around a very long time. It's generally appropriate for veins, no larger than 3 millimeters in diameter with modern care, but there're some physicians who use it for larger veins, typically up to about 6 millimeters in diameter, and it does work, but the problem is that the larger the vein, the more the liquid is diluted by the blood and the less effective it is. So foam sclerotherapy's been around for about 25 years. It's a much better option than liquid for veins, typically over about 3 millimeters in diameter and it's considered by many to be appropriate for veins 2 millimeters in diameter or larger. Ultrasound-guided foam sclerotherapy is a critical part of much of what we do.

It allows us to treat veins that are too deep to see through the skin. It allows visualization of the movement of foam into the target veins and with imaging to see the foam, we can utilize manipulation techniques to limit the foam passing into non-target veins and perforating veins. So that's important to get the results in for safety. There's no actual CPT code that covers ultrasound-guided foam sclerotherapy. The 3 codes that I'll list: the pre-procedure mapping, the target non-target perforated and deep veins, the ultrasound-guidance for needle placement and injection of veins describe some of the work involved and that's all we have right now until CPT actually writes a code that is accurate and describes all the work involved in ultrasound-guided foam. Foam sclerotherapy may be physician-compounded, which we call PCF, it is made at the bedside, forms some kind of gas, which may be room air, carbon dioxide, oxygen, or mixture and it can be used in nearly any vein or venous malformation.

Non-compounded foam is a term that was developed for proprietary foam. Varithena, the proprietary foam, was FDA approved in 2014 for use in the great saphenous, the accessory saphenous veins and the varicose saphenous tributaries. CPT 36465 and 466 describe use of Varithena and the truncal veins only and CPT refers to codes that are just simple sclerosant injection if Varithena is used in varicose veins, which makes it not useful for varicose veins from the economic standpoint because the drug is more expensive than the procedure actually pays. Vein diameters get some discussion. The definition of a varicose vein is somewhat arbitrary, 3 millimeters of diameter with an abnormal wall and valve function. It's not really feasible to expect to do doppler exam on every varicose vein and it's administratively difficult to distinguish between necessary treatment and cosmetic treatment for veins less than 3 millimeters in diameter.

So commonly, veins under 3 millimeters in diameter are not covered for sclerotherapy. What we suggest is liquid sclerotherapy be covered for veins 3 to 6 millimeters in diameter. Foam sclerotherapy for veins, 3 millimeters or larger in diameter and that either foam or liquid be covered for veins less than 3 millimeters in diameter, if there's spontaneous or traumatic hemorrhage or where there are bulging veins with thinning of the skin, threatening hemorrhage in the elderly. Additionally, non-compounded foam should be covered for treatment of great saphenous, anterior accessory great saphenous,

posterior accessory great saphenous and interceptive veins. All of which are FDA approved indications that are well accepted.

Saphenous vein ablation is typically done with radio frequency or laser to heat the vein, seal it shut with tumescent anesthesia or local anesthesia around the vein. Cyanoacrylate glue is utilized to treat the saphenous vein. Mechanochemical Ablation is used to treat the saphenous vein and you all cover this appropriately so. Non-compounded foam is covered under your policy. One question is whether you want to cover it for treatment in a small saphenous vein, which is not approved under the FDA approval. It works, but it's not FDA approved in that utilization, so that's a question that needs to be resolved. We think it's reasonable to cover it. Physician-compounded foam does not have FDA approval because there's no financial incentive for a company to make the expenditure to get FDA approval for it, though it's the standard of care for many varicose veins and it is an accepted alternative for treatment of saphenous veins.

Perforating veins are described in section 3 of your LCD and you say to cover treatment of veins near an active venous ulcer after 3 months of failure of compression therapy, that is really old in the way of recommendation. There is randomized controlled trial, published in 2018 in the New England Journal Medicine, which showed very clearly that treating the venous insufficiency does speed up ulcer healing. The same kind of treatment should be applied for a healed ulcer, which is C5 disease. These patients simply heal faster if you treat the venous insufficiency that's the underlying cause. Recommendations come from several sources. One of the important ones is a paper, which was published this past summer in the Journal of Vascular Surgery: Venous and Lymphatic Disorders, which comes from the American Venous Forum and the AVLS. It suggests covering treatment for patients who have incompetent perforator veins, which are an important source of reflux and a symptomatic reflux in veins, which is not resolved after treatment of other regional venous incompetence. So we think those are important.

Diagnostic venous ultrasound is not referenced standard proposed LCD, and we think it should be. It's essential to be able to treat these patients in the first place to get a good diagnostic ultrasound study. These are some of the more prominent indications, of course that you study. Imaging at the time of the procedure should be described in its codes 93971 for mapping for physician-compounded foam sclerotherapy is an essential part of the procedure, 76942 for ultrasound-guidance to inject the sclerosant is essential to place the needle for the injection is essential, but ultrasound-guidance in mapping are included in saphenous vein ablations with non-compounded foam, thermal ablation, MOCA and sclerosant closure. It's useful for that to be referenced in your LCD. Finally, follow-up exams are limited exams done typically 3 to 7 days after an ablation of a truncal vein to assure the vein is occluded and there's no deep vein thrombosis.

It's not clear how soon that should be. The Welch paper does not put a timeline on that, just says follow up whenever necessary. There's no agreement about other follow-up exams, but we think a diagnostic exam after defined course of treatment, which is often several treatments is valuable, if there's residual recurrent symptoms. Limitations are problematic. You say you don't cover if a patient cannot tolerate compressive dressings or stockings. Well, some people just can't, no matter how hard you try, some people have these problems, which make it impossible for them to don the stockings, to get them off. Same as true of the other compression devices and some just have enough discomforts problem.

You don't want to cover if there's a blood erosion in the big venous system or acute DVT. We agree with limitation for acute deep vein thrombosis, but there are specific reasons for treating acute superficial venous thrombosis to prevent embolization of large saphenous vein traumas. Additionally, patients may have chronic vascular vein obstructive changes which are best treated when they have venous insufficiency that's complicating a venous hypertension, but the key is to be sure that the collateral deep vein outflows developed for treatment. You don't want to cover treatment of Klippel-Feil syndrome, I understand if it's purely cosmetic, but there's evidence, including randomized control trial, demonstrating the value of bone sclerosis for these patients who have significant venous malformations and foam is much less morbid than absolute alcohol injections or extensive surgery to treat these patients. It's inexpensive and it makes a big difference for patients who have pain and tenderness or reflux through these venous malformations on down the leg causing problems more distally.

Finally, you want any amounts of treatment to use equipment that is FDA approved and that's fine. It's important and many of our colleagues have commented on this, that ultrasound-guided foam sclerotherapy is not FDA approved. The foam is not FDA approved and yet this is a standard care for treating many kinds of venous insufficiency and it's important that this language about equipment not be confused with ultrasound-guided sclerotherapy. Medicare would not expect its language as problematic to us. We worry about an audit nightmare someday, several years down the road. What about 3 sessions per leg for sclerotherapy? Does that mean per year, per wise? Per episode of care? I've asked that question several times of Palmetto Medical Directors over the last 3 years and I haven't gotten an answer yet about what that means.

These phrases need to be specific enough that everyone understands what they mean now for you, for us and for all cultures down line. Finally, if there is a reason to do more than 3 sessions of sclerotherapy for whatever timeframe is specify, we need to be able to document somehow reasons for additional treatments for these patients, since we don't have a means of getting prior authorization.

Thank you for the opportunity to talk with you. I'd be happy to answer any questions I can. We will be providing significant references. The most important of which are the Cartee paper on ultrasound-guided foam sclerotherapy, published this year. The Welch paper published this year regarding medical policy. These are in Journal Vascular Surgery: Venous and Lymphatic Disorders, and it's important to bring up the Novitas policy, which was published in November of last year. That's a very well written policy. We were involved in development of that policy. We can live with it, the key difference between it and what I've described to you is simply that patients with C2 and 3 disease in a venous clinical severity score less than 6 do compression for 2 to 4 weeks and those with C4 through C6 disease are not required to do the compression. We can live with that, although there's actually no evidence that the compression trial is of real value for these patients. Thank you.

Dr. Stroud:

All right, well, thank you very much, Dr. Daugherty. That's an excellent presentation. A lot of information in there. A lot of comments which we certainly do appreciate and we'll look through. Does anyone have any questions for Dr. Daugherty?

Dr. Maria Lenaz:

I do. Dr. Daugherty, this is Dr. Maria Lenaz. I appreciate listening to your presentation. I agree with Dr. Stroud, it was excellent. May I ask you a question? And since this is your area of expertise, on your slide 11, sir, you talk about more than 3 sessions per leg, per year, per life, per episode of care, as a clinician and as an expert in this field, how would you define that if you were writing this?

Stephen Daugherty:

I would say per episode of care, when you evaluate a patient clinically, and with ultrasound, you come up with a plan for treatment for the things that you know will make the most difference, that you can accomplish. Usually at a few months, that may be one treatment in one leg, it may be 4 or 5 in one leg, if they have a very extensive disease, but at some point, decide how far you're going to go and then stop and reassess. Some payers will say, "we'll allow 3 or 4 procedure per leg", and then you have to have a period of observation and then for those that do predeterminations, then ask for preapproval again to treat additional veins. Now that commonly is sclerotherapy for those additional procedures, and that's not unreasonable to require one to map out a plan of care over a period of several months, then do a reassessment after that care has been delivered and then justify in the record, what additional might be necessary if there is anything that's still necessary.

So I would really like to see something developed where we at least have a way to justify and where we know we have a way to justify what we're doing. I realize that you won't be doing preapproval, but if we have in the LCD, some mechanism that if we follow will allow us some presumption that we're being response about how we're treating the patient. Some reasonable expectation that if we document again, the appropriate indications for treating additionally, that we will not be drawn and quartered in an audit 3 years down the line.

Dr. Maria Lenaz:

Thank you.

Stephen Daugherty:

I'd like to treat people who need it, but I also like not to worry about what I'm going to be liable for years down the line.

Dr. Maria Lenaz:

Sure. Thank you. Appreciate your comments, sir. Thank you.

Stephen Daugherty:

Thank you.

Dr. Stroud:

Any other questions? I'm hearing none. Dr. Daugherty, thank you again for taking the time out of your day to talk to us again. Very fair, a very excellent presentation. We appreciate it. I want to also thank again, everyone for being on the line and joining us today. If there are no other questions, we will call this meeting adjourned and everyone have a pleasant afternoon. Thank you.

Stephen Daugherty:

Thank you all.