

# Open Meeting: Oxygen and Oxygen Equipment

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**Meeting Date & Time:** August 26, 2026, 12:30 pm ET

**Location:** Virtual Meeting

**Michael Hanna:** Thank you for joining us today for the open meeting for oxygen and oxygen equipment proposed LCD L33797. At this point time, I'd like to turn it over to Doctor Smitha Ballyamanda, with Noridian Healthcare. Doctor Ballyamanda.

**Dr. Smitha Ballyamanda:** Thank you, Michael. Good morning everyone. Welcome to our virtual open meeting. Today we will be soliciting public comments regarding the proposed Oxygen and Oxygen Equipment Local Coverage Determination. My name is Doctor Smitha Ballyamanda and I'm with Noridian Healthcare Solutions, the Jurisdiction A DME MAC and also for Noridian is Doctor Angela Jenny with Jurisdiction D. Representing CGS Administrators are Doctor Sunil Lalla and Doctor Robert Hoover with Jurisdictions B and C, respectfully, I'm sorry, respectfully.

We look forward to your comments regarding the proposed LCD updates but please remember to submit these comments and send them to us via e-mail at TOTRecon@noridian.com again TOTRecon— R-e-c-o-n@noridian.com. Again, please remember that we can only respond to written comments. These comments are due by Saturday, September 5th, 2026 when the comment period closes. Also as Michael had stated, we will record the meeting today which will be posted on the DME MAC websites and you're giving your consent to use the use of your recorded voice and comments by signing into this meeting. Please also be careful about sharing any personal health information in your verbal comments, and we only allow registered commenters to speak at today's meeting, but anyone can submit written comments to the e-mail address as I mentioned earlier. For our speakers today, we ask that you please introduce yourself, the organization that you represent, and any potential conflicts of interest that you may have with this particular topic. For those who are listening, please mute your phone line and computer if applicable. And speakers should be prepared to begin their comments immediately after being called upon.

Now let's take a little moment to discuss, uh, the proposed LCD. For Oxygen and Oxygen Equipment LCD, the DME MACs are proposing a new defined coverage category - a Group 5 for topical oxygen therapy as an adjunctive treatment for chronic diabetic foot ulcers that have failed to heal despite adequate blood sugar control and blood flow to the affected limb after four consecutive weeks of optimized diabetic foot care. Coverage is restricted to a carefully selected population. It requires objective evidence of healing for continued payment and excludes use of all other wound types and indications. The proposed oxygen LCD shifts topical oxygen therapy from non-coverage to coverage for carefully selected Medicare beneficiaries with refractory diabetic foot ulcers using entry criteria, monthly evidence of benefit requirements, and exclusion of all non-diabetic foot ulcer indications. Please remember this is a proposed LCD, so we don't take any actions until we finalize the policy in the near future based on comments that we have received during this open comment period. And with that, I'll now turn it back over to our moderator, Michael, to introduce our speakers for today. Thank you.

**Michael Hanna:** Thank you, Doctor Ballyamanda. Our first speaker— stakeholder for comments is John Fritz. John if you would unmute your line for us, please.

**John Fritz:** Alright. Good afternoon everyone. My name is John Fritz. I represent Mölnlycke Healthcare as the senior director for government and market access. Since I know there are several other commenters yet to come, I'll keep my feedback relatively brief and high level as I think we will have plenty of time to get into the more detailed talking points around this issue but just to kick us off, Mölnlycke strongly supports establishing a clear coverage pathway for topical oxygen therapy and appreciate and recognize that patients with chronic wounds need additional treatment options when conventional wound care alone isn't sufficient. So as the LCD is finalized it is our hope that coverage remains flexible enough to support continued innovation, clinical decision-making, and of course practical patient access. We also want to recognize that topical oxygen is, you know, seen as an adjunct to comprehensive wound care not a replacement, right? Appropriate wound management continues to include all the traditional services like debridement,



infection management, vascular assessment, etcetera. And this provides a new pathway for DFUs that, you know, may have, have, not been able to heal at an appropriate rate through those traditional therapeutics. From an ask perspective, we just ask that the final LCD should be technologically inclusive and really be designed to be flexible enough to accommodate future innovation. So focusing on clinical benefit, evidence, and therapeutic function rather than where we stand today, have an eye towards the future because this is a, especially from the diagnostic side, a rapidly evolving space. And when we look at new technologies like infrared imaging, there's a lot of exciting things here that I think would pair nicely with topical oxygen. And some of these different technologies may actually, you know, help bolster one another over the course of time especially as they become more sophisticated. So calling out and providing reasonable flexibility for clinicians to assess and then select the appropriate technology for the patient would be, you know, extremely critical in the future. Hand-in-hand with that, we'd like to avoid creating a very rigid step therapy pathway. Obviously, there need to be appropriate controls around utilization and when this therapy should be applied. But I think there's also something to be said for recognizing when you know is the appropriate time to select the right treatment for the right patient. So reflecting wound characteristics, comorbidities, contraindications, previous for supposed to treatment - all that I think should be, you know included in however the, the, final LCD comes out and hand-in-hand with that, as we look at a market perspective, just making sure that the reimbursement is, is set at an appropriate rate to really incentivize market adoption because while a lot of these technologies have been on the market for some time, obviously the financials play is pretty significant role in how quickly that technology may be adopted by the provider and really the spread of use across the general patient population. So threading that needle appropriately I think is obviously a tricky thing to do. But if it's something that we can get right on the first go, I really think that there's, there's quite a bit of benefit that can be had at the bedside level. And a decent chunk of that does in some way relate back to the economics and market access considerations.

Finally, just making sure that documentation, you know, is appropriate to one demonstrate that the patient really needs this type of treatment from a medical necessity perspective but also is not so specific that it creates additional barriers to care. Wound care, as we all know, is not always linear and the way that these policies are written should really allow clinicians to consider the totality of documented clinical improvement rather than relying on exclusive, you know, numerical measures or key performance indicators of the healing path of the wound itself. So ultimately, you know, I think we had a really good opportunity here to create a, a long standing pathway for this evolving category of care and, you know, we want the LCD to be clinically rigorous, but not restrictive and just keep an eye towards the fact that this is a very evolving space. And if possible, take that into consideration as things get finalized down the line. So with that I will take my time and cede it back to the, the next commenter please.

**Michael Hanna:** Thank you so much, appreciate that. Our next commenter is Windy Cole. Windy, if you would unmute that line for us, please.

**Windy Cole:** Yes, thank you and I did have slides. Do you have them?

**Michael Hanna:** Windy, I do. If you'll just let me know when you want me to go to the next slide, I will be more than happy to do that for you.

**Windy Cole:** Okay. Thank you so much. So, I'm Doctor Windy Cole. I am a wound care clinician podiatrist with over 25 years in practice. I serve as the director of wound care research at Kent State University College of Podiatric Medicine and I also serve for the global medical affairs director for NATROX Wound Care. Uh, next slide.

I think is my introduction slide actually. You can skip through that.

I want to thank Noridian for the opportunity to speak today and I appreciate all of the hard work that you did on this draft LCD. There is just one provision I'd like to discuss with my time and that's the language around the qualifications needed to continue topical oxygen therapy in beneficiaries. So, according to the LCD language, it would require a reduction in ulcer area of greater than or equal to 20 percent from the most recent month's measurement or improvement in the diabetic foot classification on a clinically validated standardized grading scale. Next slide, please.

So, there is an established predictor in the medical literature by Sheehan that shows that there is the potential for healing in a great number of diabetic foot ulcers that show greater than or equal to 50 percent area reduction at four weeks. However, the proposed LCD language of greater than or equal to 20 percent month over month has no validation in the literature, so this is not a validated healing predictor. So a monthly 20 percent cut off appears nowhere in literature and it's not been validated and it doesn't tell us if the wound is going to heal or if it's going to go on to failure. As we all know, those of us in practice that treat these patients, wound healing is nonlinear. Oftentimes a diabetic foot ulcer will plateau and then resume wound healing and it doesn't mean it won't go on to ultimately complete wound closure. Next slide, please.

So the other provision in the LCD is using a standardized grading scale and downgrading them. Now the standardized grading scales are not used to predict healing. They're actually used to assess and triage patients and assess their risk of amputation. And by rule, we do not downgrade any of these grading systems. If a patient presents with a Grade 3 Wagner diabetic foot ulcer, that patient always has a Grade 3 Wagner diabetic foot ulcer but it can be improving and obviously healing, but it never is downgraded. So that's a flaw in this provision. Next slide, please.

So my ask is just some minor modifications to the proposed LCD. I'd like to ask that the MACs replace that 20 percent or greater monthly threshold with documented cumulative clinically meaningful progress and we already have a predicate for something like this. The proposed CAMP CTP LCDs that were published had similar language showing reduction in ulcer area but removing that strict greater than or equal to 20 percent. Increased granulation, epithelial advancement, decreased slough or necrotic tissue also show improvement with this decrease exudate volume or improved quality of exudate. Edge contracture, decrease in depth and undermining, improved Periwound skin, and then quality measures that are very important to the patient - pain reduction, improvement in function or ambulation, and then increased tissue oxygenation with our imaging technologies such as NIRS infrared spectroscopy. We'd also request that you remove that revised classification scale alternative because that's not how we clinically practice. Next slide.

And I just want to close with a couple of photos to show you that through my practice, these are very similar scenarios that we encounter and these patients who are actually progressing well with topical oxygen therapy would not be able to continue with topical oxygen therapy if the provisions remain as is. So the first patient you can see has a diabetic foot ulcer with exposed tendon and bone. You can see the measurements at day zero and the patient's pain score is 10, probably 10 plus, plus, uh, by day 49, using topical oxygen therapy, the wound clinically has improved dramatically. But those measurements have not moved that 20 percent or more, but the pain score has decreased to two and the patient is way more functional at this point in time. On the right hand side we have another diabetic foot ulcer patient who underwent a partial amputation and I and D due to an abscess. You can see it day zero, the patient measurements, and the pain score. You can see the quality of granulation tissue isn't very robust. There seems to be slough and it was heavily exudating. After 36 days of topical oxygen therapy, that granulation tissue is nice and robust. We have an advancing epithelial edge, but the measurements haven't changed all that dramatically because we measure the longest width and the longest length. So again, the pain score went from eight to two. Both of these patients are doing significantly better using topical oxygen therapy, but given the provisions in the draft LCD, they would no longer qualify to continue on with topical oxygen therapy. Next slide.

That's it and I thank you for your time and appreciate the opportunity to speak to you on this very important topic.

**Michael Hanna:** Thank you so much. Appreciate that. Our next stakeholder is Mark Niederauer. Mark if you would unmute your line for us, please.

**Mark Niederauer:** Thank you. If you wouldn't mind starting my presentation as well.

**Michael Hanna:** Perfect. I'll do so now. Thank you.

**Mark Niederauer:** Thank you. Good afternoon and thank you for the opportunity to present on this very important topic. My name is Doctor Mark Q. Niederauer and I'm the President and Chief Technology Officer at EO2 Concepts - a Manufacturer of CDO Therapy Systems. Next slide, please.

Just a moment. We sincerely appreciate the careful consideration and analysis of the relevant data and the creation of this proposed LCD. EO2 supports the proposed Medicare coverage for DFUs and is presenting three targeted recommendations. The following presentation's intended to create a coverage policy that offers the most benefit to constituents while ensuring judicious application of topically applied oxygen therapy. Next slide.

The three topics include creating flexibility and documenting adequate perfusion, modifying infection exclusion criteria, and including venous leg ulcers in covered wound types. In this presentation, two acronyms for intermittent topical oxygen - iTO and continuous diffusion of oxygen - CDO will be used. Next slide.

With regard to oxygen monitoring criteria, we acknowledge that adequate perfusion is clinically relevant and that much of the evidence applies to sufficiently perfused wounds. From a policy standpoint, topically applied therapies generally monitor the perfusion status, yet do not preclude treatment based on that status. As an example, negative pressure wound therapy does not impose mandatory numerical perfusion threshold and the LCD does not make coverage for diabetic or neuropathic ulcers contingent on a specified ABI, toe pressure, TCOM, or pulse-volume threshold. Instead, the policy requires a complete wound care program, including comprehensive diabetes

management, appropriate offloading, and continued professional evaluation. Note that in this presentation the comparison with the NPWT is limited to coverage policy architecture. EO2 is not asserting technological, mechanistic, coding, or payment equivalence. Next slide.

Furthermore, CDO and iTO are applied topically, as are the majority of advanced wound care therapies. Because topical oxygen is delivered directly to the wound surface its route of administration does not depend upon the systemic oxygen delivery as do other advanced wound care therapies. In fact, oxygen has been shown to penetrate rapidly into tissues. This oxygen penetration occurs via diffusion as a function of concentration and pressure and importantly, CDO therapy has been shown to result in statistically significant increases in growth factors and cytokines associated with positive wound healing. Given all these factors, the current proposed requirements may be more inflexible than necessary and could exclude patients based on the selected or available test rather than the training practitioner's overall vascular assessment. Next slide.

We therefore recommend using the following language or similar - adequate arterial perfusion to support healing has been documented by one of the listed measures, or by another—other validated noninvasive vascular assessment. When a listed measure is unavailable, contraindicated, or clinically unreliable, the medical record must identify the alternative assessment, its result, and the clinical rationale for its use. Clinically significant ischemia must be evaluated and treated, including revascularization, when appropriate. This would maintain an appropriate vascular safeguard without denying coverage based exclusively on a limited menu of tests and fixed numerical values. Next slide.

With regard to infection exclusion criteria, the current draft proposal excludes osteomyelitis and gangrene without any qualifiers. Current policy or other advanced topically applied therapies do limit exclusion to untreated infections. For example, the current negative pressure LCD uses the following wording - osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure, or untreated osteomyelitis. Next slide.

We recommend modifying the draft proposal to include and clarify language for osteomyelitis and gangrene to be similar to existing policy for advanced wound therapies. A couple of examples include osteomyelitis within the vicinity of the wound that is not concurrently being treated with intent to cure and a prior diagnosis of osteomyelitis or gangrene that has resolved or has been definitively treated does not constitute a continuing exclusion when the beneficiary otherwise satisfies all coverage criteria. This would maintain appropriate safeguards against worsening these conditions without denying coverage for actively treated infections. Next slide.

Our final topic is with regard to leg ulcers. The evidence supporting the efficacy of both continuous and intermittent topical oxygen therapies in VLUs warrants consideration for inclusion as a covered wound type. Recent publications have shown similar efficacy between VLUs and DFUs using Kaplan-Meier analysis of real world clinical data. The average efficacy was reported at 71 and 72 percent for VLUs and 76 and 63 percent for DFUs using CDO and intermittent topical oxygen respectively. Note that the use of evidence across topical oxygen modalities for coverage purposes does not imply technological coding or payment equivalence. Next slide.

This table shows an overview of these two studies along with two additional open-ended real world studies for a total of 826 VLU patients. We can see that in multiple studies, the average healing rate ranges from 71 to 83 percent for venous leg ulcers in open-ended studies. Now let's look at the two recent larger studies with Kaplan-Meier analysis in more detail. Next slide.

This study involved a prospective database of real-world clinical application of CDO in 764 patients that was retrospectively analyzed for robustness and significance. The prospective database did not include patients from any clinical trials, only real-world results. It found the results to be extremely robust with CDO having more advocacy across all wound types, ages of patients, and areas of the body. This is shown in the graph for various wound types. With regard to VLUs and DFUs, the average healing rate was similar at 71 and 75 percent respectively, with similar healing times. These results support the high efficacy of CDO therapy reported in prospective RCTs. Next slide.

This study for intermittent topical oxygen was a large retrospective analysis of real world clinical results of over 3000 patients. As was seen in the CDO study, it showed similar healing trajectories over time between DFUs and VLUs. The overall healing rates were similar, as well, at 63 and 72 percent respectively.

**Michael Hanna:** You are just under one minute remaining in your time, sir.

**Mark Niederauer:** Thank you. And this— and go to the next slide, my last slide. Given the evidence of supporting the efficacy of topically applied oxygen in VLUs, we respectfully request that VLUs be added as a covered wound type. The proposed framework could include a complete

wound care program and continued professional evaluation using the parameters listed here. I welcome any questions and would like to offer assistance in crafting the final LCD and thank you for your time and consideration. That's it from me.

**Michael Hanna:** Thank you, sir.

**Mark Niederauer:** Thank you.

**Michael Hanna:** Appreciate your commentary. Our next speathicker— next speaker is Matthew Regulski.

**Matthew Regulski:** Hello. How are you? I do have slides as well. Thank you.

**Michael Hanna:** Okay. Just let me know when you'd like me to move them forward, sir.

**Matthew Regulski:** Please go right ahead. Good afternoon. Thank you everybody for allowing me to participate today and thank you to Noridian for crafting this LCD. It is my honor to be here to explain a little bit of the intermittent topical oxygen with cyclical compression. I was a CAC member for this meeting last year as well. And I have used all forms of topical oxygen in my practice. I've been in practice now 23 years as the director of the Wound Institute of Ocean County here in uh New Jersey and I'm the— also the chairman of the Scientific Committee for the Federation of International Podiatry as well. Next slide, please.

I have done some speaking as well for AOTI on the intermittent topical oxygen with cyclical compression boot. Next slide.

You know, I— I teach resident physicians as well as giving lectures throughout the world on wound healing, as my practice is combined to limb salvage and wound healing and I developed this little mantra that— what oxygen does and it's easy for my resident physicians to understand as well as for patients to understand what, what oxygen can do and thus I've labeled it as topical wound oxygen CARES because it translates this very complex science into something that's very palatable and easy, especially for patients to understand and that's where we get the CARES from - the collagen synthesis, angiogenesis which is making new blood vessels, revving up your immune system to fight infection, increasing skin cells to migrate across and epithelialize or cover the wound and the sustained and, and, simplistic action of healing that it does perform. Next slide, please.

I was fortunate enough to be an author of this paper looking at the duality of this approach of this device with high pressure oxygen that this does provide of around 800 milliliter— 800 millimeter of mercury to depth within this wound, putting about 10 liters a minute, that's 600,000 ccs per hour, 900 liters in a 90 minute treatment period and doing all of those functions in the oxygen CARES mantra, but also having an incredible point of doing cyclical compression on it that can do a lot of things such as reducing edema, restoring perfusion to these very hypoxic tissues which means very low oxygen tissues and it also, uh, regulates interstitial fluid balance, removing that edema as well. And then also, uh, restoring cellular function to modulate inflammation, immune function, and tissue repair. Next slide.

This is an important slide to understand that all phases of the wound healing are critically dependent upon oxygen. All the enzyme systems that catalyze the conversion of phase to phase and ultimately producing a healed wound are all critically, critically oxygen dependent. And having that adequate tissue oxygen is going to be critical because even when you look at normal tissue, that's approximately 100 millimeters of mercury, but even that's level key oxygen dependent processes function well below their maximal efficiency. At about 100 millimeters of mercury, your ability to fight off infection is about 60 percent capacity, to make new collagen is only about 80 percent capacity, and we talk about ATP production that you can see there, which is required for all protein synthesis, cell proliferation, and repairs only functioning about 90 percent of its activity. So, well vascularized tissues have about an oxygen tension of a 40 to 80 and even in chronic wounds the oxygen tension falls well below 10 millimeters of mercury. Tissue oxygen tensions below 30 are generally insufficient for effective wound healing, leaving fibroblast function, collagen synthesis, angiogenesis, and prolongs inflammatory cascade which means things do not heal. So, every phase of the wound healing cycle is critically, critically oxygen dependent. Next slide, please.

When we have edema, another great feature of the intermittent oxygen with the cyclical compression removing that edema. When you have edema in your tissue, it is going to pull these arterioles further apart - these small capillaries in the tissue that means a greater distance that oxygen has to diffuse across that— that barren landscape in order to get to the wound to effect all of the functions that it does with oxygen as in that mantra of oxygen cares. So, the intermittent compression compli— uh, with this boot removes that edema, allows more, uh, oxygen, more blood flow into that wound as well as more healing factors and more cells, uh, to complete the

healing process. Next slide.

I know this is a little bit of a busy slide, but it's, it's fascinating when we look at the, the synergistic, the symbiotic relationship between this highly pressurized topical oxygen as well as having these cyclical compression. They do so many things on the macroscopic level. When you reduce edema, you can, like I said, you regulate interstitial fluid balance and tissue homeostasis and that— that effect of reducing edema decreases the diffusion distance of oxygen, it normalizes capillary pressure gradients which restores tissue perfusion, restores that blood flow into that area and on the microscopic level with the intermittent compression as well, fueling microbial defense. It also modulates pain. It— It resolves inflammation, it revs up the formation of new blood vessels, and it creates increased tissue viability and tissue perfusion. It accentuates tissue repair, epithelialization, and also promotes remodeling. So with— another feature too with the— with this intermittent topical oxygen cyclical compression, p— patients use this right in their very own home. They don't have to travel, they don't have to get a ride, they don't have to pay for a medical van or something of that nature and go someplace and stay for hours and then rely on rides home. They can use it in the safety and comfortability in their home and I like it as a physician because I don't have to change what I am doing, I don't have to alter anything. This oxygen boot, because it is so pressurized, it can diffuse through all gas permeable dressings. It can diffuse through a multilayer compression and total contact casting. You can put this right over your cast, sit in the comfortability of your home, and in 90 minutes get 900 liters of oxygen in your wound to affect the wound healing cascade.

So, thank you very much for your time. It was my honor today to present it and thank you for organizing this meeting.

**Michael Hanna:** Our next speaker is Karen Ravitz. Are you ready to speak Miss Karen?

**Karen Ravitz:** I am. Thank you so much. Good afternoon everybody. My name is Karen Ravitz and I am the health policy advisor for the Alliance of Wound Care Stakeholders. I have no conflicts of interest. On behalf of the Alliance, I want to thank you for establishing coverage for topical oxygen and for the opportunity to provide our feedback on the draft policy. [inaudible] The Alliance is appreciative [inaudible]. We also however want to continue to be a resource to you in order to have the best possible outcome in patients and to ensure that the coverage parameters within this policy are clinically sound. Although I will raise several issues briefly here today, the Alliance will provide more details in our written comments, but there are six areas where we believe the draft LCD needs clarification or revisions before it's finalized that I'd like to outline today.

First, the organization of the policy is a bit problematic. as currently defined, the topical oxygen therapy provisions are mostly placed in section five of the draft LCD, but there are other provisions that apply to topical oxygen that are located elsewhere in the policy and the same is true of the billing and coding article. As a result, it's difficult to locate all of the provisions that are [inaudible] topical oxygen within the [inaudible] oxygen LCD, which is built primarily around respiratory oxygen therapy. So, we respectfully request that when finalized that all topical oxygen therapy provisions be consolidated under a single clearly labeled heading. And we believe that doing this will allow those who are reading the LCD and the billing and coding articles will be able to do so correctly. So that would be very helpful.

Second, there are several inconsistencies between the LCD and the billing and coding article. We've identified provisions where the draft LCD and the draft article do not align. For example, the policy article states adequate arterial perfusion is present to support healing as defined by one or more of the following within the past six months, and then it identifies ankle brachial index or ABI of greater than or equal to 0.7. However, the draft LCD states greater than 0.7 and not greater than or equal to. So, if we're going to keep that in there, then we do recommend that the LCD be revised to state greater than or equal to as stated in the draft article. And this is only one example where there are inconsistencies. There are others. [inaudible] We encourage the DME MACs to do a careful side by side comparison or review of both documents before finalization and ensure that any given coverage requirement is stated consistently and unambiguously between the two documents and again the Alliance is going to identify all the inconsistencies and provide recommendations in our written comment.

Third, the LCD identifies diagnostic modalities accepted under criteria 4 for establishing adequate arterial perfusion. As drafted, criteria 4 permits qualification through toe pressure, ABI, pulse-volume recordings, transcutaneous oxygen measurement, or skin perfusion pressure. The Alliance recommends the DME MACs also recognize point of care imaging technology including, but certainly not limited to, near infrared spectroscopy or NIRS as an additional acceptable pathway for establishing adequate microvascular perfusion. These technologies directly assess tissue level oxygen delivery at the point of care without the calibration and handling limitations associated with transcutaneous oxygen measurement and without the risk of falsely elevated

readings that ABI testing can produce in patients with needle arterial [inaudible]. The Alliance is not asking that point of care imaging replace any of the existing accepted modalities, but rather the Alliance recommends that it be added as an additional option, which would give clinicians appropriate flexibility to use the diagnostic tool that might be best suited to their patients and their practice setting.

Fourth, the infection exclusion needs to distinguish between active untreated infection and infection that is being appropriately managed. As drafted, the LCD does not make this distinction. A patient whose infection is under active clinical management should not be automatically excluded from coverage in the same way as a patient with an untreated infection. Others have raised this issue on this call today, and we agree with them, so we also ask that the DME MACs clarify this distinction explicitly in the final policy.

Fifth, the exclusion for limb involvement in the past three months should be limited to untreated conditions. The current language is [inaudible] on the same limb within the past three months without qualification. This risks excluding patients whose DVT has resolved or whose malignancy has been surgically excised, who may otherwise be excellent candidates for this therapy. Again, this issue was also raised earlier. We agree with the other commenters, and we recommend that the exclusion be revised to apply only to untreated DVT or untreated malignancy.

Sixth, clarity on bundling payment and billing codes is necessary. The LCD states that oxygen reimbursement is a bundled payment covering both inhaled and topical modalities, and that all options, supplies, and accessories are included in the monthly rental payment. It is unclear whether this bundling language, which appears to carry over from the respiratory oxygen provisions, is intended to apply to topical oxygen therapy in the same way, and if so, how continuous versus intermittent oxygen—topical oxygen therapy will be distinguished at the billing and coding level. We recommend that the final policy make clear that HCPCS code E0446 serves as the bundled code for the continuous approach consistent with its established use for continuous delivery oxygen with accessories included, and that A4575 continue to serve as the bundled code for the intermittent approach consistent with its historic—historical use. Clear delineated codes for each modality will also resolve a related ambiguity in the draft, which is whether a switch from one topical oxygen modality to another constitutes a new initial coverage period or a continuation of existing therapy.

And finally, the Alliance would encourage the DME MACs to tie the term optimized diabetic foot ulcer care to an authoritative—authoritative external source such as the American Diabetes Association or the International Working Group on the Diabetic Foot Guidelines and to ensure the definition—that that definition is stated consistently in both the LCD and the billing and coding article rather than just in the article. As mentioned before the Alliance will be submitting detailed written comments elaborating on each of these points and several more. We thank you for your time today and the consideration. I'm happy to answer any questions you may have.

**Michael Hanna:** Thank you for your commentary, Karen. We appreciate it.

**Karen Ravitz:** Thank you—thank you.

**Michael Hanna:** Our next stakeholder comments come from Joseph Larsen. Joseph, are you on the line today?

**Joseph Larsen:** I am. Can you hear me?

**Michael Hanna:** Yes, your audio is fine. Go ahead, please.

**Joseph Larsen:** Thank you. My name is Joseph Larsen, a podiatrist at Optimal United Health Group. I've been doing wound care for, uh, the greater part of my career which is about 28 years. I'm happy to be on the call to support the use of topical oxygen and the wording in the LCD and I've been listening to some of the comments and some of the presentations so far and I just want to say that they've been excellent, with a lot of clinical data. So, I do not have slides. I am a consultant for uh, um, NATROX and have been a consultant for EO2 in the past - as of reporting my, my, uh, interests.

I'd like to address a couple of concerns. One is the monthly in-person reauthorization requirement. The requirement for monthly in-person visits for continued topical oxygen coverage creates a significant burden for my patients. Many of the diabetic foot ulcer patients are—they have a trouble with transportation, they have trouble with mobility, and they can't always get to the office. In addition to that, virtual medicine is now a very popular tool that we can use to assess these patients and their wounds. The clinical trial evidence cited inside in the LCD's own summary of evidence assessed outcomes at four weeks and 12 week intervals. Neither the ADA nor

the Society for Vascular Surgery mandates monthly in-person reauthorization once advanced wound therapy has been initiated. I feel the coverage assessment should continue in four week intervals during the first 12 weeks of treatment and transition to monthly evaluations thereafter. A continuing— continuity of care provision should also be included to ensure the topical oxygen therapy is not interrupted while reauthorization requests are under review or pending. In addition, telehealth wound assessments as previously mentioned should be accepted for interim evaluations when supported by standardized digital wound photography, allowing for timely monitoring of wound progress while reducing barriers to ongoing care.

My second concern is the greater than 20 percent monthly wound area reduction threshold and classification scale alternative. The requirement for greater than 20 percent wound area reduction each month is overly rigid and not supported by validated wound healing literature. The established benchmark is by Sheehan in diabetes care in 2003 and endorsed by the ADA and the International Working Group of the diabetic foot is a 50 percent wound area reduction at four weeks as a predictor of healing at 12 weeks. A monthly 20 percent threshold has not been validated as a predictor of healing value. Wound healing is nonlinear and in my practice and in many other practices I'm sure I've observed patients whose diabetic foot ulcers will be slow to heal even with the initiation of advanced wound therapies such as topical oxygen. Each patient seemed to heal at their own pace with— whether we're using a topical oxygen on skin subs and should not be relegated to a 20 percent reduction in four weeks. Additionally, the alternative criterion improvement in diabetic foot ulcer classification of a clinically validated standardized grading scale is fundamentally flawed. Validated diabetic foot ulcer classification systems such as Wagner, Wifl, and SINBAD were designed as prognostic and severity staging tools to assess the presentation, not as serial measures of healing progress. A healing diabetic foot ulcer does not downgrade on these scales because the grades are based on the deepest anatomic structure involved or on fixed patient characteristics such as their vascular status and neuropathy, not the wound— not current wound bed status. The interna— the International Working Group on Diabetic Foot 2023 classification guidelines explicitly concluded that no existing classification system can be recommended for predicting the outcomes of an ulcer in a specific individual. The policy should replace the requirement for 20 percent reduction in wound area each month with a potentially accumulative, uh, a more cumulative healing assessment. Wound improvement should be evaluated using comprehensive clinical assessment rather than relying on a single metrics. Measures of progress may include but are not unlimited to changes in dimensions, surface area, wound bed characteristics such as the appearance of granulation tissue, reduced necrotic tissue or advancing epithelialization, exudate amount and type, and improvements in periwound skin condition. The classification scale alternative should be removed or substantial— or substantially revised as it is generally not clinically achievable for healing diabetic foot ulcers. The other concern I have— or another concern I have is the blanket infection exclusions. The exclusions of all patients with abscess, osteomyelitis, joint sepsis, or gangrene does not distinguish between active untreated infection and infection that is being currently managed. Many of our chronic diabetic foot ulcer patients have chronic osteomyelitis or osteomyelitis that is being treated conservatively with antibiotics while we are treating their wounds. Furthermore, the International Working Group on Diabetic Foot in 2023 guidelines recommended antibiotic treatment without surgery for foot osteomyelitis in selected cases and does not prohibit topical oxygen as an adjunctive wound healing therapy when infection is being concurrently managed. Excluding these patients would deny topical oxygen to substantially proportion— to a substantial proportion of population the LCD is intended to serve. I request modification to active untreated abscess or active untreated osteomyelitis or active untreated joint sepsis or wet gangrene with a clarifying statement that diabetic foot ulcers with adequately treated concurrent infection are not excluded. I would also like to conclude with uh, I feel as th— along with much of th— many of the other speakers today that more inclusion should be considered for topical oxygen use, including venous leg ulcers, pressure ulcers, and chronic hard to heal wounds. Thank you.

**Michael Hanna:** Thank you for your comments, Mr. Larsen. Our next speaker is Paul Geary. Paul, would you unmute your line for us, please.

**Paul Geary:** Sure. Thank you very much. Uh, I guess I came in a little differently so I have my slides here but if you want to throw them up I'll have the two slides that'd be great and I'll just go off my slides here if that'll work and let me know when you have obviously the title slide, then you just go right to the first slide, if that's OK. Just let me know when it's up for everyone cause I cannot see it for some reason on your—.

**Michael Hanna:** It's on the screen now.

**Paul Geary:** Oh great, okay.

**Michael Hanna:** The title portion is GWR Medical, Inc., some background on it. Is that correct?

**Paul Geary:** Okay. If you just want to skip to the very first one with all the presentation, that's great. Well thank you very much, I appreciate this. This is very exciting. My name is Paul Geary. I am an owner, uh, vice president of sales of GWR Medical and, uh, we have been at this a long time. So I, I was happy when I saw this LCD. Uh, believe me, uh, it's been a long time coming and we're very, very excited at the potential to be helping a population of diabetics that suffer with these open wounds. Uh, I just wanted to put our thoughts forward and, uh, a couple other points, uh, from one of our providers and we'll have some other comments from other providers that will be submitted, uh, during the open comment period. But just a little background on who we are. Uh, GWR Medical was founded in 1996, umm, and we pioneered the topical oxygen studies out at Ohio State University with Chandan K. Sen and Gayle Gordillo doing all that work. And basically those were the studies that laid the groundwork, basically what is topical oxygen, what are the mechanisms, and why does topical oxygen— if it did work and does work— what was what was behind it all? So we did those studies and we continued to push on and we got early adoption through the federal supply schedule and the VA hospitals and the DOD facilities. So we have been providing top collection into those facilities and for our veterans since 2000. Uh, We then— uh were providing topical oxyg— oxygen into the New York Medicaid and New York Medicaid managed care organization populations since 2008. So we've been at this for quite a while. And then in about 2017, a independent retrospective study was conducted of the New York Medicaid Medicare patients that were treated by GWR with topical oxygen. And I found two key points. The first key point I wanted to point out like— is that diabetes mellitus patients were the most likely to experience partial or complete healing when compared to other diagnosis. So obviously this is goes hand in hand with what this LCD is trying to accomplish at another point that I did not and I forgot to put on there, but I'd like to point out it is number four one— 4127 wounds treated over nine years in this retro— retrospective study. So that's a lot of wounds. And the study revealed healing and amputation rates similar to those reported in controlled clinical studies using topical oxygen for chronic wounds. So as I said, we're excited and that that study I do not see in your list of [inaudible]. So I will be submitting that study as well as long as we have the original topical O2 studies done at Ohio State. If you want to go to the next slide, that'd be great.

Uh, this slide - this is basically we wanted to get a comment from one of the users of topical oxygen. This is [inaudible] Christina. She is a DPM attending podiatrist at Queens Hospital Center Medical, which is the Mount Sinai affiliate and her request, she took a look at the LCD and her request is for reconsideration of the ABI threshold in coverage for, uh, topical oxygen. Uh, and I'm just going to read this, uh, for those of y— for everyone. But she's writing as a podiatrist specializing in wound care and limits— limb salvage to respectfully request reconsideration of the current ankle brachial index threshold [inaudible] .7 required for coverage of topical O2 therapy in diabetic foot ulcers. Her rationale is basically that multiple systematic reviews and meta-analysis demonstrate improved healing rates compared to standard of care. And the effectiveness in moderately ischemic wounds uh topical oxygen therapy improve local oxygenation and granulation even in patients with moderate ischemia. The limitations of the ABI - the ABI may falsely [inaudible]— be falsely elevated in diabetic patients, and does not reflect microvascular oxygenation. And inconsistency with hyperbaric oxygen therapy or actually criteria - HBOT is used in more ischemic patients, yet topical oxygen requires a higher perfusion threshold. The impact on patient access that the ABI .7 requirement excludes patients with moderate peripheral arterial disease who may benefit from the therapy and she would like to propose a revision that the perfusion criteria to allow ABI of point fi— equal to or greater than .5. Toe pressure of greater than or equal to 30 millimeters of mercury. And then the uh TcPO2 of greater or equal to 30 millimeters of mercury or normal Doppler waveforms. Conclusion - aligning TOT criteria with physi— physiological evidence would improve access to care and support limb salvage. And I'd like to add that GWR has [inaudible] program over the past 30 years - we have to always used an ABI of .5 or greater in assessing our patients and those were used during those studies at Ohio State and we have had great success and I'd also actually like to add as some of the other speakers did - we have treated a large, large swath of wounds, including amputations, uh, diabetic ulcers, gangrene, uh, and we do burns so we do a, a pretty wide spectrum and all these have showed remarkable healing. So, uh, I would also like to put in that we would like to open this to more than just diabetic foot ulcers umm, and the such because I think there's a great number of Medicare recipients out there suffer with of, of with a vast majority of these other ones includes— including venous stasis as well. So with that, that's all I wanted to say and I appreciate the time and the opportunity to present. Thank you very much.

**Michael Hanna:** Thank you for sharing your commentary this afternoon. The next stakeholder comment comes from Vincent Rowe. Vincent, are you on the line? If I need to ask you to unmute your line, you can raise your hand using the React functionality on the toolbar at the bottom of your screen. Don't see any indication that Vincent Rowe is on today, so we'll move to the next speaker in line. I'll go through Vincent's slides quickly. The next speaker is David Dexter. David are you available today? If you're on the line and would like to raise your hand, I can ask you to

unmute your line. You can do that via star 6 as well. David Dexter. Not hearing from David, I'll quickly go through the slides he had provided for us until we get to the next speaker in line. And my slides stopped. The next speaker on the docket is Anahita Dua. Are you available today, please? Raise your hand if you're available and need assistance with unmuting your line, please. Hearing no response, we'll move forward to the next speaker. Jeffrey Niezgoda, are you available this afternoon, please?

**Jeffrey Niezgoda:** Yes, sir. I'm here.

**Michael Hanna:** Thank you. Go ahead with your commentary, please.

**Jeffrey Niezgoda:** Excellent. If you could bring up my slides, please. Thank you very much. I do certainly appreciate the opportunity to present to this meeting and I'm certainly in agreement with many of the comments already shared. And I'll probably reflect on those as I move through the presentation. Next slide.

A disclaimer, I'm going to be talking a little bit about near infrared spectroscopy and as a disclaimer, I am chief medical officer for Kent Imaging that produces such devices. I also have been a clinician for 40 years, have used a variety of topical oxygen and I again, I applaud the MAC for this LCD. I think it's well overdue. I also want to give a pat on the back to all of those clinicians that have been advocates of this technology for many years. It's really a blessing for our patients to have this LCD come about. Next slide, please.

So we'd like to, uh, I'd like to voice my support for the, the proposed LCD. Umm, as stated, I've used this therapy, uh, often and, and it works well. Umm, it's certainly appropriate for diabetic foot patients. Uh, but I also would like to suggest that we broaden, uh, the coverage for that and I'll comment on that at the end. I think this policy reflects significant stakeholder clinical engagement and we certainly echo the comments that were made earlier to not only introduce this LCD, but to allow this technology to reach our patients. My comments are going to focus primarily on issues that have been raised by prior speakers and that is looking at the arterial perfusion criteria. Next slide, please.

So the proposed LCD requires objective evidence of adequate perfusion. I'd like to spend some time talking about that because I think that this is an area that clearly we, we have technologies that do a much better job than some of the listed criteria in the LCD. I'm going to speak to some of the weaknesses of toe pressures and ABIs, pulse-volume recordings and TcPOs, and our ask here is that we add near infrared spectroscopy. This issue has already been. Delivered by Doctor Cole and Doctor Niederauer and the Alliance. Raising the importance of the technology and how it could complement the patients using topical oxygen and certainly improve the LCD wording. Next slide, please.

So what I'd like to do is suggest including near infrared spectroscopy as an arterial assessment of perfusion. I've been using this technology clinically for about 10 years. Uh, it's here to stay and it has been a true, uh, enhancement of my clinical practice, uh, and many other clinicians are finding the benefit of near infrared spectroscopy and I'd like to walk you through why. Next slide, please.

Near infrared spectroscopy is essentially using the device to image hemoglobin in the tissue and we can differentiate by passing light through the tissue. Oxygen that is bound to hemoglobin and also hemoglobin that is unbound oxygen. We can then analyze those signals and come up with a display of tissue oxygenation using a colored image on the device. Next slide, please.

This is really basic. We're not going to spend a lot of time with the warmer colors. The reds, the oranges indicate higher StO<sub>2</sub>s, uh, whereas lower values, blues, greens are going to suggest decreased, uh, StO<sub>2</sub>s. And so with using the device to image tissues, you could very clearly and quickly, uh, determine the level of oxygenation of the tissue. Next slide.

When we're talking about vascular assessment, the parameters that are listed in this LCD really address macro vessels and all clinicians on this call know we don't use macro vessels to assess for wound healing. That comment has been made several times. We really have moved past TCOMs. That was, it's an antiquated therapy. I don't know of any clinicians that are really actively using TCOMs. I haven't personally used them in clinical management for about a decade and a half. There's a lot of problems with these evaluations of the macro vessels. We don't need, certainly we need to assess this as part of our overall management, but really what we are focused on with wound management are the micro vessels, the microvasculature. Next slide, please.

So we this has already been suggested by a few presenters. There are significant limitations in ABI, it's very poor guidance for wound healing. There is falsely elevated values and patients with arterial calcification, primarily our diabetics. There's very modest sensitivity for detecting disease, and it really gives no guidance doing an ABI as to what the TCOM or the, the tissue oxygen

saturation is in the wound, nor is it predictive of healing and that's been suggested by several speakers already today. Slide.

When you're using TCOMs, there are also significant problems. If you look at the upper 2 panels, the upper 2 pictures, that is RGB image with a TCOM lead and a similar image using spectroscopy and you can see where that TCOM lead is. It's over an area of tissue hypoxia. The area of interest distally is reasonable and so you're going to miss that using TCOM in this patient. Look at the other images, you can see how it would be impossible to get TCOMs on patients with this type of skin condition or disease states, giving TCOMs no relevance for for this LCD and using uh topical oxygen. Next slide, please.

What we really need to focus on with these patients is the microvasculature. That's where the wounds are located, in the subdermal plexus. And you don't measure that subdermal plexus by using macro vessel analysis. You look at the micro vessels and this is where near infrared spectroscopy really is useful because that's exactly where we're focused. Next slide.

If you look at this image, it's a picture of a wound with near infrared camera and I can see exactly what StO2 is in the wound as well as in the periwound. That was very, very helpful for looking at the oxygenation of the wound. And we use these images to look at tissue hypoxia and correlate that to tissue healing or compromised healing. And we use it to analyze the tissue perfusion because obviously you're not going to have a perfused wound or a perfused periwound without perfusion of the, the macro vessels. So that's why it's so important [inaudible] direct look of the wound. Next slide.

**Michael Hanna:** You're about 25 seconds left in your allotted time, sir.

**Jeffrey Niezgoda:** Okay. This is an image looking at how poorly [inaudible] recordings follow, where the images follow very quickly and this is an image. I'll close with this image. This is an image of my use of the NIRS camera in a patient receiving topical oxygen and successfully healed this patient by monitoring them closely with [inaudible]. So our ask is to include near infrared spectroscopy as one of the parameters in the LCD for vascular assessment. Thank you very much.

**Michael Hanna:** Thank you, sir. Appreciate it.

**David Dexter:** Hey- [inaudible], this is David Dexter and I'm on-[inaudible].

**Michael Hanna:** Good afternoon, Mr. Dexter. We moved on from your time slot. Would you be willing to hold on the line and we can add you in at the end. Is that acceptable?

**David Dexter:** [inaudible]

**Michael Hanna:** I'm sorry, I did not hear a response.

**David Dexter:** [inaudible]

**Michael Hanna:** It appears you're cutting in and out, sir. I'll check back with you momentarily.

**David Dexter:** [inaudible] I'm here and I'm happy to wait.

**Michael Hanna:** Okay. Thank you, appreciate that. Our next speaker is John Steinberg. John are you on the line, today?

**John Steinberg:** Yes, I'm here. Thank you.

**Michael Hanna:** Thank you. Go ahead, please, sir.

**John Steinberg:** Great. I [inaudible] have some slides if you could go ahead and advance to the first slide for me. Alright, and I'm not able to turn on video, we'll just stay on audio I guess.

**Michael Hanna:** I've got the slide up on the screen with your, uh, name and what you do, sir.

**John Steinberg:** Oh great. Okay. I was just trying to unmute my camera here but it won't let me. [Inaudible] says it's blocked, that's no problem. So good afternoon, everybody. Thank you so much for the opportunity to speak here. My name is John Steinberg, joining you from Washington, D.C. I'm a podiatrist and co-director of the Center for Wound Healing here at MedStar Georgetown University Hospital in Washington, D.C. and I'm also professor in our Department of Plastic Surgery at the Georgetown University School of Medicine. Go to the next slide.

No disclosures relevant to this presentation. Next.

So topical oxygen therapy, great presentations. I've enjoyed the, uh, hearing from, uh, the various, uh, uh, stakeholders here. It's been a very, uh, very educational, uh, session here to be online with everybody. I fully support, uh, our decision here by CMS to cover, uh, topical oxygen therapy for

nonhealing diabetic foot ulcerations. We have embraced this therapy, uh, in our clinic, uh, with a number of patients, uh, with diabetic foot ulceration and it has been a significant clinical tool for us in a lot of particularly no option patients, particularly those who we cannot revascularize any further and those patients with severe pain sometimes associated with some of their particular wounds or surgical sites. We do want to point out though, or I'd like to point out, the concern and, and that we'd like to advocate for some delineation between the types of topical oxygen therapy in particular. Our experience has been very favorable with the continuous oxygen therapy, but even more favorable with the intermittent compression that we can get with some of those cyclical pressurized devices that are out now. So the intermittent approach, as abbreviated here, the CPTWO cyclical pressurized topical oxygen seems to have some unique benefits and we have a paper that's coming out, under review now in the Journal of Wound Care, emphasizing that both we, we are able to facilitate their twelve week healing but then also able to facilitate their healing durability when looked at the 12 month range, because we know all of us on the call are challenged with the fact that these are not just challenging wounds when we face them, but they're challenging wounds that are highly recurrent and having a therapy that can help decrease recurrence and improve wound healing durability is a major benefit to our patient population. We can go to the next slide.

So emphasizing here in some of the published data that we know about topical oxygen and then looking at the bottom here where it's separated from the class as a cyclical pressurized topical oxygen, separating out those patients in that study data to show our improved healing in those patients and the durability that we're looking at for those patients. And this is what we're trying to demonstrate in our publication, again, that's been submitted for the Journal of Wound Care, just emphasizing that durability for these individuals and the fact that cyclical seems to have a improved ability, uh, to have longer lasting wound healing for this challenging patient population. Next slide.

So the additional point here in particular for this conversation, looking at the center, uh, portion of this bar graph, uh, with 2257 foot ulcers, uh, in this, uh, general vascular, uh, surgery, uh, publication looking at this patient registry, uh, and seeing that the wounds healed, uh, in less time than they had actually been open. So these wounds were, were healing at a decreased time period than the chronicity that they are already presenting with. Next slide.

And then, very importantly, looking back at many of these papers that have looked at topical oxygen therapy, in particular the cyclical topical oxygen therapy, uh, what we discovered and, and have now submitted for emphasis in publication uh, is that the recurrence rate in both diabetic foot ulceration, but also in venous leg ulceration wounds was, was significantly decreased, uh, in comparison. So we found that the, uh, recurrence rate, uh, for instance, in the Frykberg paper in those treated with topical oxygen was less than seven percent versus those in the comparator arm was 40 percent. Uh, in the Tawfik and Sulan paper, no recurrence rate in the topical oxygen treated versus 40 percent in the comparator arm. So continuing on down the line, these numbers are fairly significant and statistically relevant. Next slide.

So adjunctive use of cyclical pressurized, uh, topical wound oxygen, uh, looking at a particular case review. Next slide.

Just to give a clinical, uh, view on this, here's a patient with diabetes, uh, traumatic laceration to the lateral ankle. Many of these wounds, of course with diabetes, will start off with, uh, trauma or pressure and then, uh, become chronic uh, which is entering that uh difficult phase of wound healing where we need to assist them with some of these advanced modalities such as topical wound oxygen therapy. So this patient was receiving excellent serial debridements, appropriate local wound care, even had prior attempts within skin grafting uh and was remaining at a plateaued state with nonhealing as you can see displayed here. Next slide.

So our goal with topical oxygen therapy was to support the wound biology and support that wound environment in this stalled chronic wound. So as you can see here, uh wound therapy initiated uh, June 5th last year, with continuing the current topical wound care and baseline therapy with the wound measurement here you can see greater than four centimeters. Next slide.

Dramatic improvement, uh, rapid improvement in this patient with rapid epithelialization, uh, we were able to boost this wound through, uh, to a healing course. And you can see here after week one through week four, uh, dramatic improvement, rapid epithelialization, and improvement in area reduction. Next slide.

At week 6, the wound was declared healed and you can see here, uh, a healed, maybe not fully matured wound base but fully epithelialized wound at this point. We can go to the next slide.

And then final visit for this patient, uh, the initial area of the wound was 15 or 15 centimeters squared. The, uh, duration of therapy was six weeks. Uh, and you can see here this again

emphasizing that durability of healing, uh, is that we seem to find, uh, that with the cyclical pressurized oxygen therapy, uh, that we get an improved durability of healing, uh, in these patients. And you can see here, a follow up of 17 weeks shows excellent durability and maintained healing and improved overall wound contour for this patient. So a dramatic tool for us, we're, we're excited to see this, uh, potential added access that we're going to have for our patients, uh, that are in much need for this with the diabetic foot ulceration of limb threatening wounds, uh, and in a particular, uh, we've also found a significant role for this in the no option, critical limb ischemia patient with a diabetic foot ulceration where we're not only helping with their wound, but we're also helping in a lot of those critical limb ischemic patients where traditionally these are nonpainful neuropathic wounds. A lot of those patients are experiencing significant pain from their ischemia and were able to get significant relief not only for wound healing, wound durability but also not for their painful critical limb ischemia. Happy to help support and thank you for the opportunity to present this data today.

**Michael Hanna:** Thank you for the input. Our next speaker is Frank Aviles, are you on the phone today?

**Frank Aviles:** Yes. Can you hear me?

**Michael Hanna:** Yes, sir. Your audio is fine. Go ahead, please.

**Frank Aviles:** I did have a presentation.

**Michael Hanna:** It should be up now.

**Frank Aviles:** Thank you very much. Good afternoon and thank you for the opportunity to provide comments regarding this proposed local coverage determination especially for topical oxygen therapy. My name is Frank Aviles. I am a physical therapist and certified wound specialist, bringing more than 35 years of clinical experience. I'm also a lymphedema therapist dealing with edema and lymphedema and also been a hyperbaric technician also involved with the [inaudible] of Life Foundation organization. So my combination of experience that I bring to you helps me with my comments today because I have spent much of my career looking at chronic wounds from different perspective. But we look at the chronic wound itself, the role of oxygen and healing and also the role that edema and lymphatic dysfunction play in, in preventing healing. Now I do agree with a couple of the prior speakers, Mark from EO2, that this technology can also greatly help patients with VLU and I've seen that firsthand.

So before I finish today, I would like for the following four points to be remembered. One, that we understand the important role of oxygen that plays physiologically in the repair process of these chronic wounds. So we do want to consider intermittent topical oxygen therapy and continuous topical oxygen therapy valuable in treating the chronic wounds, but yet these two devices have different mechanism of action and because of my experience with edema, I'm going to talk about intermittent topical oxygen. Second of all, hypoxia remains one of the fundamentals barriers to chronic wound healing and edema is an important and often underappreciated contributor to the hypoxia that we deal with today. And third, there's also newer evidence regarding intermittent topical oxygen therapy that deserve consideration as is not cited in this LCD. And lastly, fourth, I will respectfully ask that the final coverage criteria be refined so appropriate Medicare beneficiaries are not unintentionally excluded nor treatment not follows is indicated for therapy that has proven research and also my personal witness in the real world environment. So let's start. Let's go ahead and do the next slide, please.

Let's begin with the distinction between, oh as disclosure I have spoken on topics regarding all devices and I've been a past consultant for AOTI. Next speaker.

Alright, so in addition to that, I've been concentrating on lymphedema in the wound care space, but why am I talking about this is because there's a distinction, edema is a big barrier as we discussed, but there's real world evidence showing that this device can help and also when patients can use this in rural settings as I was involved in Louisiana. It's also another avenue for these patients. Next slide.

So intermittent therapy, what we want to know is that this device is used 60 to 90 minutes per day, five days a week. The combination of oxygen and this noncontact cyclical compression addresses two of the huge barriers that we deal with in wound healing, which is wound hypoxia and edema. And as you can see there's RCTs listed and these RCTs what we talked about is that 40 percent of the patients that was one of the studies had moderate ischemia, which I'm saddened to hear that we have an ABI of .7 that's an exclusion because a lot of the patients that we treated that have micro and macrovascular that have been exhausted with vascular procedures and were facing amputation we were actually able to save the legs using the two mechanisms that I described. And as the other speaker said, I really like the ability to use technology like NIRS and low weight infrared thermography to look at the wound bed change [inaudible] it because if I can change

that wound environment, the patient will heal just like the patient that was facing amputation but continuous delivery of oxygen is also another important device. But let's talk more about intermittent therapy. Next slide.

So the next slide was a consensus and one of the speaker was involved with this and you can see what they decided and what they looked at was the two different devices and looking at what the efficiency of this. Next slide.

And so when we go back and talk about intermittent therapy, that distinction matters because we're, we're comparing different devices, delivery characteristics and propose- proposed mechanisms are very different. And so now let's step away from the patient for a little bit and I want to ask why do chronic wounds become chronic and obviously there's two main reasons and usually it's that hypoxia and edema, but also we have to consider vascular disease, neuropathy, infection, repeated trauma, inflammation, all these make these wounds obviously not make progress. But the common denominator is that we have wound hypoxia and so as a hyperbaric technician, I understand the importance of oxygen in wound repair but yet a lot of the wounds that we are dealing with usually have oxygen compromise and this is where I want to emphasize that I believe in, to making sure that we treat edema and having noncontact cyclical compression is usually key because when we start looking I have a device that actually can provide nonmedical grade and medical grade compression and tested to go all the way up to 37.5 millimeters of mercury. And that's why a lot of the patients that I've treated with this device has actually healed. And so when we look at these advanced products, okay, we have to address the physiological wound environment. We have to look at perfusion, oxygenation, edema, pressure, infection and all and inflammation because if we don't, we're going to be surprised because healing will stall. And that is why the mechanism of action, cyclical compression, is usually important when we're looking at intermittent topical oxygen. So it's not just putting oxygen in a wound, it's actually helping decrease the diffusion distance that we talked about and it's been studied that we can, that distance will increase from 64 microns all the way to 160, which compromises oxygen delivery. But the last thing I want to talk about is refining of the LCD. So I appreciate the proposed LCD recognizes topical oxygen as a potential [inaudible] for diabetic foot ulcers that have failed optimized treatment for four weeks. However, I respectfully ask the DME MACs to consider the following requirements. So number one, clarify specific coding to be used that is simply for the modalities; recognize that intermittent and continuous topical oxygen as distinct modalities. Second, [inaudible] the current skin subs CPT LCD to specify coverage based on RCT proven devices. And third, amend intermittent application frequency from four days, as it stands, to five days per week, which is consistent with the RCTs and manufacturing instruction for use. And lastly, something else another speaker brought up to reconsider whether a rigid month to month wound area reduction threshold should be the sole determinant of continued coverage. Sometimes a wound progresses from the inflammatory to the proliferative phase of healing and you'll see that decreased drainage, decreased depth, decreased undermining, decreased [inaudible] inflammation will happen prior to a percentage of area reduction. So wound healing, as everybody said, is not lineal. Finally, I encourage consideration of the growing evidence surrounding long-term outcomes and durability, not simple short-term closure.

If you go to the next slide, you'll see that there's four more studies that would, were recent and not considered in the prior LCD. When you look at those, we help our beneficiaries, not only make sure the wound stays closed, but also stay out of the hospital, prevent amputation and also know that we're improving the quality of life of our patients, especially if we save a leg, we're going to save a life. So as a clinician, it's not simply to close a wound on day 84, but durable healing, which we've seen when we look at topical oxygen. And so- [inaudible].

**Michael Hanna:** Your time has ended, sir.

**Frank Aviles:** Alright. with that I will close and thank you for your time.

**Michael Hanna:** Thank you. Our next speaker is Raghad Batarseh. Are you on the line this afternoon, please? And the final speaker, before we go back to some late entries, Matthew Garoufalidis. Are you on the line this afternoon, Matthew?

**Matthew Garoufalidis:** I am. I'm all set.

**Michael Hanna:** Thank you. You're ready to sp—.

**Matthew Garoufalidis:** Put up the first slide, please. My name is Doctor Matt Garoufalidis and I've been involved using all sorts of topical oxygen modalities for many, many years, especially when I was involved in the VA where we had access to these modalities. Next slide, please.

I've been an author on several papers, been involved in limb salvage and treating wounds for a long, long time. I am the chief medical officer for AOTI because I chose to take that role after using all the different modalities that this would be the best use of my resources. Next slide, please.

The evidence is amazing in topical oxygen. We have an RCT that was published in Diabetes Care in 2020. This is a very nicely organized, rigidly controlled RCT that has a perfect Cochran score that you don't typically see in wound care. And we have a real-world evidence studies that speaks to what a lot of folks have been talking about today – treating the worst of the worst, those patients that wouldn't qualify for any RCT. Next slide, please.

So the RCT is a very interesting study. We first presented the outline for this research to Medicare in 2017, at which point they were amazed at the way this RCT was constructed and were very eager to see the study be completed because they knew that if we could complete the study, we would have amazing outcomes. And indeed we do. We had two end points, which is very unlikely in wound care. But we have a 12 week outcome and a 12 month outcome. We were able to demonstrate that using this modality we were, we could heal wounds 12 times more likely, six times more likely in 12 weeks, and when we did a follow up in 12 months, we had six times lower reoccurrence. Next slide, please.

This is just an example of the two arms, the sham and the active arm, looking at the great difference in the study arms. This study used a group sequential design, it was study to go to 220 patients. It had a predetermined evaluation group with predetermined marks, stopping points, depending on how effective this therapy was. When we got to the first stopping point, which was at 73 patients, it was found that this modality was treating patients more effectively. More than 30 percent with greater efficiency than the sham. That caused us to stop the study at 73 patients because it was unethical to continue. We would be depriving those patients in the sham of an opportunity to heal their wounds. And we all know what happens with diabetic foot ulcers if we don't heal them, they end up losing their leg or worse. So this was a huge study to be able to show that great, great range in healing. The 12 month outcomes were also very important. Next slide, please.

In the 12 month outcomes, we were able to reestablish Armstrong's study that appeared in 2017 in the New England Journal of Medicine where he stated that diabetic ulcers re-ulcerate at a rate of 40 percent. Our sham arm in this study did just that, re-ulcerate at a rate of 40 percent, while the patients that received this TWO therapy, multimodality therapy, re-ulcerated at a rate of less than seven percent. Next slide, please.

This is considered a landmark study now and it received an award in the ninth International Symposium of the Diabetic Foot in 2023 as one of the top four studies in the past four years on the study of the diabetic foot ulcer. So quite an honor. Next slide.

So that was an RCT looking at Texas grade one and two wounds, however my patients in the VA, we were using this on everyone. We were using it on train wrecks, patients that would never be included in any RCT. And we decided to do a retrospective study looking at two, two points, hospitalizations and amputations. So we slipped in over 200 patients at two different VAs and look back at their care. One group received this therapy, the other group did not, and the difference was amazing. The group that received this therapy had an 88 percent reduction in hospitalizations, 71 percent reduction in amputations. Next slide, please.

And we took all comers. We took grades of wounds, we took the ischemic wounds with ABIs as low as .3. So I would recommend that we lower that bar a little bit more. We took patients with hemoglobin A1C's as high as 19, patients on dialysis and even two pack a day smokers. We were able to demonstrate in this study that we could heal wounds with moderate ischemia. Next slide, please.

We took a matched cohort to validate the outcomes of this study with similar outcomes and then looked at the risk so that we can now say if we have a patient with a diabetic foot ulcer and we do not use this multimodality approach, those patients have a risk nine times higher risk of hospitalization, five times higher risk of amputation. Next slide, please.

There have been multitudes of studies that are out. Some have been referenced already. This study was out in the Journal of Vascular Surgery looking at over 3000 veterans with different types of wounds, VLU's, diabetic foot ulcers, arterial ulcers, and also a mechanistic study that Doctor Regulski spoke about earlier. There's also been a study in Journal of Clinical Medicine looking at this TWO therapy as compared to other advanced treatment modalities that are paid for by Medicare and TWO therapy outperformed them. So this shows us that we also can reduce amputations and reduce hospitalization costs in a large, large cohort of patients. Next slide, please.

It's a unique modality that uses both pressurized topical oxygen and noncontact cyclical compression that works synergistically to help the patient heal better, faster and more durably so we don't have the reoccurrence of these wounds. So thank you for the opportunity to present this therapy. I think that we're going down the right road here. Thanks so much.

**Michael Hanna:** Thank you, sir. I'm going to pause sharing momentarily so we can reset the presentation to allow David Dexter to complete his portion of the presentation. So hold momentarily while we— [inaudible].

**Anahita Dua:** May I also say I'm on the call as well [inaudible].

**Michael Hanna:** I noticed that. I have you listed immediately after Mr. Dexter so once he finishes up you'll be ready to jump right in, okay?

**Anahita Dua:** Thank you very much.

**Michael Hanna:** Thank you, appreciate that. I'll be back just in a moment and we'll get started.

**Michael Hanna:** Alright. David Dexter, are you ready? I've got your section ready to begin.

**David Dexter:** [inaudible]

**Michael Hanna:** I've got your first [inaudible].

**David Dexter:** I am—I am here. Ready. Can you guys hear me?

**Michael Hanna:** You're cutting in and out but we do have some audio. I've got your introductory slide called up. Ready to go, sir.

**David Dexter:** Perfect for my introduction, I'm David Dexter. I'm the Chief of Vascular Surgery at Sentara Healthcare in Southeastern Virginia and also chief through our local medical school at Old Dominion University. In preparation for today, I actually have given a very similar lecture unfunded, unsponsored on behalf of multimodal oxygen therapy at the [inaudible] symposium in Manhattan, which is the largest vascular-involved meeting on the planet and it sort of shows the level of interest my group and I have had in finding advances in wound care in the practice. Next slide.

I have not been paid by any of the current available oxygen therapy devices nor do I plan to in the future. Next slide.

So just some background words here. For 15 years I've been in practice with one of the largest groups of vascular surgeons in the country and limb salvage has been a catastrophic problem, particularly in the southeast where diabetes, morbid obesity and renal failure are predominant and, unfortunately, some of the only growth we've seen in our practice over the last decade and a half is in amputation levels. So in an attempt to further our local science, we have followed oxygen therapy and delivery for the decade and a half I've been in practice, including the use of hyperbaric therapy, which is very limited in how we can apply it to patients. So following the research and contributing to the literature has been extraordinarily for— uh, important to me. So certainly excited that so many modalities have been approved by CMS in the past. The current coverage criteria proposal seems very reasonable. I do think we need to further who we can treat, how we treat, how we assess wound healing, and make sure we have good, validated tools. Next slide, please.

So there are two distinct proposals, as Frank said a few minutes ago, both intermittent and continuous. I have experience with both. My, my true heart lies with intermittent, probably because it offers such great multimodal therapy and I'll sort of go through that in the future. The AOTI device has been the device I spent the most amount of time working with and researching as of late. We'll show you some peer-reviewed papers. Next slide.

As a vascular surgeon, this is sort of the most telling single piece of data that I share with my team — that standard of care therapy for advanced peripheral arterial disease still leads to amputation rates that we know are exponentially too high. The number of wounds we're actually able to close is a very, very small amount compared to what we'd like to be able to close. The black line you see on the left is standard of care therapy with the addition of multimodal oxygen therapy. This one happens to have been delivered by AOTI. There are other papers, as we've heard about today from other manufacturers. This is not meant to be specific but you can see the curve separates out very early, very quickly with a P value of .009. This shows us how much more we can heal our wounds in immediate time periods. You can see how quickly these lines separate out, as early as in about a month. Next slide, please.

Let's go right to the next slide cause this, all of this slide says is that Doctor Lohr, Doctor Raffetto, and I have been doing active work reviewing the literature out that's out there on advanced oxygen therapy. Next slide, please, guys.

There we go. So this, this comes from a paper that Doctor Lohr, Doctor Raffetto, and I wrote looking at what causes chronic wounds. and it's a combination of factors, which is why multimodality therapy is so important and how important local tissue hypoxia really is. Lo— Local

tissue hypoxia, whether it's from lack of blood delivery to the wound or excessive edema at the wound restricting blood flow or oxygen to get in, really is the crux of the argument of why many of these wounds don't heal, and it's a very interconnected mechanism That drives chronic wounds and while the majority of them have an underlying arterial source, an underlying vascular source on the venous side is also equally important, which is why we publish this not just in the Journal of Vascular Surgery, but in the venous and lymphatic sub journal therein, which has a higher impact factor. Next slide, guys.

So-again I'll put this in the written comments in the next month as they become available because there's just too much to go over in the slide here, but you can see on the left what topical oxygen therapy does, and in the middle what cyclical compression does and really in our, in my world, what with the devices we currently choose to use, what combined therapy does in both cyclical compressions with topical oxygen therapy. And at the bottom you can sort of see why we get such better wound healing, Not just with the time that it heals but actually keeping these wounds healed over time. Next slide, please.

So this is one of my patients. This is probably the fifth or sixth patient I ever used this on and I've shown him in meetings with his permission and we can did crop his face out. This is a no option revascularization patient and he was given standard therapy of attempted revascularization and, unfortunately, as you can see, his forefoot became gangrenous. We had amputate it and the likelihood that his wound healed is somewhere below 30 percent. So this is an ideal patient for advanced multimodal, intermittent oxygen therapy. If you go to the right. Next slide.

So the healed picture is gone but we were able to heal him in about 120 days of total therapy. In our hospital system, utilizing topical oxygen, we've now identified that our ulcer rating— ulcer healing rates have gone up, our number of complete ulcers that have healed has gone up, our recurrence rate of arterial and venous ulcers has gone down and I think most importantly, from a system standpoint, we've decreased the number of people that need to be in the hospital for infected diabetic foot wounds and infected venous ulcers. We've also decreased our amputation rate. Next slide.

As I run into time, at any point you guys can cut me off, I felt it was important to show the differentiators between devices because I think ultimately having devices that do multimodal therapy are really important. The AOTI device, the reason I chose it as the device of record for me, is it offers not just topical oxygen therapy but offers intermittent compression and humidifies wounds. Both of which have been found to be critically important in wound healing. Next slide.

**Michael Hanna:** You have about one minute remaining, sir.

**David Dexter:** Perfect. Just can cut me off when that minute runs out and I'm fine with that. What you can see here is what happens when we increase supplemental oxygen to local wounds and you can see what happens both to fighting infection as well as increasing cell metabolism and creating collagen. This is why hyperbaric oxygen therapy is important, it's why local topical oxygen therapy is important. Keep going to the next slide.

I'll just finish right here. Compression is one of those things that is often left out as part of the multimodal therapy because the concern on fixed compression in arterial wounds is that it will inhibit arterial wound healing. This allows us to have an intermittent cycle of up to 40 millimeters of mercury pressure several times a minute to reduce edema, decrease the resistance of blood flow into and out of the leg and, ultimately, it's this combination of therapy we think that probably improves healing so well. And I'll leave you guys with that. I appreciate your time and thank you for letting me speak today.

**Michael Hanna:** Thank you for your input. [inaudible] Luckily, we move to the next section. Anahita Dua, you were able to join us. Are you available now?

**Anahita Dua:** Yes. Thank you very much.

**Michael Hanna:** Perfect. You're ready to begin at your convenience.

**Anahita Dua:** Thank you. So my name is Anahita Dua. I'm a vascular surgeon at the Mass General Hospital in Boston and associate professor of surgery at Harvard Medical School. I'm the associate director of our wound care center, the director of our limb salvage center, um, and the clinical director of research and um, I have—have a lot of experience using the topical oxygen essentially and, and really am pleased we're able to have this conversation today. I will skip over parts that we've already discussed, but I do want to focus on, on some new literature that we've just had come out that we weren't able to initially show when we were doing the LCD because of the complication timing, but I think it's important to show because it's really real-world data. So next slide.

I, of course, am a member of the TOT CAC and, most importantly no financial disclosures and no connection to any of these companies, just love the product. Next slide.

So there's a special place in hell for people who read off slides, so I'll not be doing that to you. What I really just want to say here, which is important and I want to put in black and white, is that I really do fully endorse the coverage for TOT, especially for the diabetic foot ulcers. Diabetic foot ulcers are one of the most expensive things that we take care of in the United States, primarily because we pay for hospitalizations and we pay for nursing care. The longer these patients have those wounds, the longer they end up having those nurses, and that's where all that money actually goes. We all know that, and in an environment where we really need to be saving money and re-ensure that these patients can get back to working and functioning, having something that has kind of been a breakthrough in healing these wounds has been incredible, and

it's important that our government support things like this so that we can ensure our public can get back to working. I do think that the LCD has been extremely well thought out, especially in terms of the coverage criteria, and overall does reflect what we know about TOT, but as I mentioned, I do want to point out an article that I'll show you in a moment. I do, support the scoring aspect of things, and the fact that, like, we are focusing on durability. Historically, when we used to talk about wound healing, we would talk about wound healing. The wound is healed, yay, everything is great. That's actually not the way we do things anymore, and it shouldn't be the way we do things because durability and functionality after the wound heals is actually everything. I don't care if the wound heals today, if the whole thing breaks down in a month, and I'm doing the same process over again. Patients hate that, I hate that. So something that's come out, which is, of course, our oxygen therapy, the topical oxygen therapy that is shown clearly that once the wound heals, the collagen that makes up that wound is almost as strong as the regular skin that initially was part of the patient, allows for the patient to have a really long-term healing effect, where we're not seeing them again and again with repeat breakdown of the wounds and that is the crux of why this is such an amazing technology. And as I mentioned earlier, I do want to highlight this pretty large study that I was a senior author on. Over 3,000 patients looking at all different types of wounds but as I mentioned, I'm a vascular surgeon, so venous wounds and arterial wounds are really the big guns and showing how well not only the wounds healed, but most importantly, how durable the wounds were in terms of their maintenance of their healing overall. Next slide. So again, we've gone through a lot of presentations. I'm not going to belabor the point, but I think the important thing to bring up here is why is this different? We all know, like, topical oxygen works nicely. What's the deal with topical oxygen and the cyclical compression? The compression therapy combined with the topical oxygen, and I think something that we need to mention also is the ease of which we're able to use this. This is not something that a patient needs to go anywhere to do. This is something that can be done in the comfort of their own home. It's something that's easily and readily applied without any pain, and it can also penetrate through bandages. I mean, it's like a wonder solution because those are all the barriers that prevent patients from getting therapy in terms of coming to a hospital, taking down their dressings, and of course, the time and effect that it would have on a patient. A patient could literally be working in their job, at their computer, at their—in the comfort of their own home, and be able to apply this therapy easily and get the benefits of it. So I think that's incredible because not only is it a benefit, but it also takes away some of those barriers to wound care that we face. Next slide. Now, this is the study that I wanted to mention. So we published this in the Journal of Vascular Surgery, Vascular Insights. It was a retrospective review of over 3,000 patients who had chronic lower extremity wounds, but they were different types of wounds. So as you can see up here in the left-hand corner, you have the diabetic foot wounds of course, you had venous wounds, you had arterial wounds, and then atypical wounds are just wounds that are kind of combined. The point of this is that across the board, regardless of the type of wound, the topical oxygen was highly beneficial, not only in healing the wound, but also maintaining the new material that comes on top of the wound to heal it. And there is science behind this that has to do with the fibroblasts, the way in which they're brought into the area, so it's not just voodoo. There's a real reason why this occurs, but again, from a clinical perspective, the point is, especially in the diabetic foot wounds and in the venous ulceration wounds which have a tendency to repeatedly break down the patients repeatedly come back. In those patients, this is really a wonder therapy. Next slide. We've again talked a lot about the diabetic foot wound, but I think it's important to bring up because in the, let's say I see 100 wounds, 50 percent of them will be diabetic foot wounds. The problem with the diabetic foot wound is because you have the diabetes in the background, not only do you have the skin ulcerations and the wound itself but if you leave this thing open, ultimately you are going to infect the bone underneath and get osteomyelitis. So even if you have good blood flow, you ultimately get amputated. So speed, speed to healing the wound is fundamentally important, because the faster you can get that tissue to regenerate, the lower your chance of getting the bone infected, the lower your chance of getting amputated. So any therapy, specifically this one, with the cyclical topical oxygen that allows that to happen in a fast fashion, in a durable fashion, is really something

that we should be violently supporting. Next slide. So overall, I know we again had a number of presentations. I just want to add some specific points. My big thing again, again, again is the durable healing and the low complication rates from getting this type of therapy. It really takes nothing for the patient to put it on. We've got a number of patients that have used it had incredible success. And, again, with that durability aspect of it, looking at a year out, still having a wound that is nicely healed, and then walking on it and using it, and of course, no risk of amputation. The healing rates are clearly indicated in multiple studies at this point. This is not even a question anymore that when you use this therapy, you get better healing rates, and then if you couple that with the fact that it's easy to use and the durability, you really have something wonderful. The other phenomenal thing is I— just like Dr. Dexter, I'm also a vascular surgeon. A lot of the wound healing material that has come out historically has told you, CMS, that, hey, if you use this thing,

we're going to heal faster. The argument against that is, well, if you're going to heal faster, who cares if you take another month to heal, I still save the money and the patient still gets healed, so why would we spend the money. In this particular case, with vascular patients, they don't heal. That's the whole point of them. And the majority of our patients today are patients that have what we call lower ABIs, or decreased blood flow. So if you don't have an adjunct, like this, to heal these patients, they're not just going to heal if you take more time. So this is different from the wound healing products that have previously come to the CMS, where we're not just going to end up with a situation where they heal regardless. And thank you very much for your time. I really appreciate the opportunity to speak.

**Michael Hanna:** Thank you for the information. I'm going to pause sharing again for a moment. It's my understanding that one of our speakers who was unavailable during our regular session or portion of that is now available. Raghad Batarseh. Are you now available and on the call, please?

**Raghad Batarseh:** Yes, I am.

**Michael Hanna:** Perfect. Please go ahead and begin your session or your portion of the session and I will move the slides forward behind the scene.

**Raghad Batarseh:** Okay, thank you. Well, thank you for allowing me to attend the meeting and be part of advancing wound therapy to be able to heal our patients. Introducing myself, Raghad Batarseh, I'm a nurse practitioner at wound clinic Spark Wound Healing Center in Arizona and I cover wound clinic and Boswell West Wound Clinic in Boswell Hospital [inaudible] Wound Banner Boswell Hospital Wound Clinic. With my experience, I'm not a vascular, however, from a wound perspective, where we have to send our patients to a vascular specialist until they clear our patients, especially in the wounds in the legs and foot, it takes time. And that's one of the main things I, like, when I got approached and I found about the topical oxygen helped my patients to start the healing process while we are working on their vascular to get diagnosed and to get all the surgeries and everything that they need to start healing the wound. And that's one of the main things I, like, really liked the process. So, when we apply the topical oxygen, I have been working with a company NATROX. I also don't I did not say before that I do not have any conflict with this. I don't get paid for that. It's just because I'm amazed with the outcomes that we have at our wounded clinic with using the topical oxygen therapy. So I don't want to go through all the studies that is going to say why oxygen is important as the previous vasculars, I think, addressed that very good. So I want to talk about why I see this as working with my patients. The NATROX topical oxygen, it comes with a small waffle that gets the humidity up to all the time, 24 hours, to the patient's wounds. And the idea of having the oxygen delivered to these wounds earlier, before even starting working with them on their vascular, it shows a lot of healing and healed the patients faster. One of my patients, he was going through his surgical interventions for vascular, where it took him, like, four or five months to get these things done, and going between these appointments, his wound was healing to some point and degree before we started the oxygen. When we start having the oxygen on that patient it was, like, his wound heals, I would say, two to three times faster than what we used to see beforehand. The other thing is the waffle is easy to apply in any areas. So even in the toe, I have a patient before we be able to get him the oxygen therapy, he had a wound to his greater toe from a vascular, arterial issue and we saw him for eight months. [Inaudible] he's elder, he does not want to go through the surgical interventions for vascular. Once we applied for him, the oxygen within two months, his wound was healed. So there is a lot of ways where we want, like, the oxygen is helping and my point is, if we heal the wounds and we're providing oxygen, we're decreasing the pain the patient has, infection, the hospitalization, amputation, and we're improving their quality of life. I work with my patients to save them limbs, so especially with these patients with DFU, once we, they, they come to me maybe after they already tried many other providers And because with the way we approach them with advanced treatments and applying the oxygen on their wounds, I see where Doctor Anahita was talking of the collagen that gets like the skin that we don't, I don't even see a scar on these patients. So they really come back, like, the skin heals and have a good cushioning that prevents

these wounds to come back, and I don't have any one of my patients that we applied oxygen on their wounds opened back up, even within six months. After that, I can totally, like, I don't know, but even within six months, their wounds were not open up and there is studies that I rely on, which is the independent meta-analysis published in 2021, 2022, and 2023 were constantly confirmed that topical oxygen therapy there were significantly increasing the healing rate. The ratio was from 1.6 to 1.9 and there is a significant reduction in the wound area. And one second, let me go through my notes if I forgot anything. So also with NATROX because the wound get the oxygen all the time so I am able, as a wound specialist, to be able to reassess the wound more often if I need to, or also if the patient's having drainage, then I don't have to wait like other materials where, like, you needed to have a foam, so that required me to wait until 72 hours to be able to change on the wound. However, with this waffle, it was easy that we change on the wound more often, or home health can change on the wound, or the patients be able to change on their wound if they have more drainage, so it's not soaked with the wound and it does not need 72 hours. The oxygen delivered immediately to the patient, immediately when we start on the, putting the oxygen waffle on the wound and it's an easy used machine. It's a small one. It's like a mobile device and patients having no hard time were changing the battery on and off every day. But otherwise it's really helping the patients in reduction of the amount of the time they need to close the wound, and also from, like, for me, I want to save the money for the admissions and infections and putting patients on antibiotics and all of that.

So I saw once I start using the device, the oxygen, I start having a lot of reduction on readmissions using even like needing infections where I have to put my patients again on antibiotics and so on, or even finding infectious disease to look at these wounds and adjust this medication is a big hassle in Arizona. We need, like, these patients need to wait about two to three months to be able to get with anyone of infectious disease. And so it's an like it's an economic argument, but at the same time, it's the best to save these patients' limb. So restricting the access to this, it will not reduce cost. Actually, it's increasing them because we have longer wound durations, we have more clinic visits, more emergency encounters, more hospitalization, and amputation. So, the more every week the wound remains open, we add more cost and risk, and instead we are saving money from that perspective. And again, I respectfully argue that medical to, for this proposal, the LCD to preserve medical care coverage for this topical oxygen therapy, including continuous use oxygen devices, such as NATROX for the benefit, the beneficiary and the qualifying, for qualifying wound, chronic wounds, that have failed the standard of care and even with acute wounds. I have been seeing, like, elder patients with acute wounds when it's hard for elder patients with laceration or acute wounds to be able to heal or hematomas. Once we start applying these oxygens on, they will be able to heal faster. So my [inaudible].

**Michael Hanna:** Unfortunately, your time is up. We appreciate the input and we will move on to the next portion of this afternoon's call.

**Raghad Batarseh:** Thank you.

**Michael Hanna:** We're at the section of this open meeting where we will bring back Doctor Ballyamanda with some closing remarks and instructions for comments. So, Doctor Ballyamanda, turning it back over to you, ma'am.

**Dr. Smitha Ballyamanda:** Thank you, Michael. We want to thank, we excuse me, give me one second here. Can you guys hear me? I just want to do a quick audio check.

**Michael Hanna:** Yes. Your audio is fine, Doctor Ballyamanda.

**Dr. Smitha Ballyamanda:** Okay, great. We want to thank everyone for your thoughtful comments today. Once again, please remember to send your comments in writing to the appropriate email address as displayed and mentioned previously. Thank you, Michael. So as displayed on this slide, please send your comments to that e-mail. As another reminder the comment period will end on Saturday, September 5th, 2026. Once we have considered and collated all of the comments received during the open comment period, we'll consider any changes necessary as a result of the comments received, and then follow up with the PIM Chapter 13 process to determine a possible final LCD, along with the response to comments document and article. The final LCD will take effect at a, effect in a minimum 45 days following the posting of the final LCD. So for any updates, please refer to the DME MAC websites. And again, I want to thank everyone for participating today, and we will formally adjourn this meeting now. Thank you.