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Moderator: Marc Duerden, M.D.

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2:00 p.m. CT

Coordinator: Welcome, and thank you for standing by. At this time, all participants are in a listen-only mode until the public comment session of today's conference. I would like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Dr. Mark Duerden. Thank you. You may begin.

Dr. Mark Duerden: Thank you. Welcome to the National Government Services Jurisdiction 6 and Jurisdiction K Open Meeting, which is being held by teleconference on 5/16/2024. As set forth in the Medicare Program Integrity Manual, Chapter 13, Section 2.4.4, after a proposed LCD has been made public, the MACs hold open meetings to discuss and review the evidence and rationale for the proposed LCD with our stakeholders that are in our jurisdiction. And that's what we're going to be doing today.

We welcome you, and we're very interested in your comments and your opinions regarding this LCD. As the operator pointed out, this call is being recorded and will be transcribed. The transcription will then be placed on our website for your review.

Go to the next slide. I'm joined today by my fellow Medical Directors at National Government Services, and that includes Dr. Awodele, Dr. Mullen, Dr. McKinney, and Dr. Noel. Each of these physicians may also join us verbally if they have questions or comments to make during this

teleconference.

Go to the next slide. The only agenda item that we have for this current open meeting is the draft LCD 39828, which is about skin substitute grafts, cellular and tissue-based products for the treatment of diabetic foot ulcers and venous stasis ulcers.

Next slide. This draft LCD is a collaborative policy between CGS, National Government Services, Palmetto, Noridian, Novitas, First Coast, and WPS Medicare Administrative Contractors. This open meeting is only part of the official comment period, and the total comment period has been in place and is going to continue and has been in place since 4/25/2024, and will continue until 6/8/2024. We would like to remind all presenters that their oral comments that they're going to be making today in presentation will need to still be submitted as all formal comments must be submitted in writing.

So, the next slide, this LCD is going to address the issue of skin substitute grafts and cellular tissue-based products for diabetic foot ulcers and venous stasis ulcers. Wounds due to other diagnoses are not addressed in this LCD, and the coverage determination can be made for those types of wounds based on individual MAC discretion. Medicare coverage for an item or service must be reasonable and necessary, and it's based on the Program Integrity Manual, Chapter 13, Section 5.4, which discusses how medical reasonable and necessary is determined.

Next slide. This local coverage determination was developed to create a policy consistent with the current medical evidence. In substitute grafts and cellular-based, tissue-based products may be one of the several types of treatments that can be used for diabetic foot ulcers or venous stasis ulcers. Treatment effectiveness is currently an area of active investigation in the medical literature. Stakeholders' input for this proposed LCD was strongly considered in the development for this proposed LCD, and as I pointed out previously, we've had a comment period which has been continuing since April.

Next slide. This open meeting is, as I described initially, is to review the evidence and the rationale for the proposed LCD with the stakeholders in our jurisdiction. This meeting is going to be able to provide you an opportunity as a stakeholder to recommend changes, submit additional evidence for consideration, and to present concerns you may have regarding this proposed policy. This policy was developed based on a systematic and predicable review of the medical literature that was done with a specific systematic grading system.

Go ahead to the next slide. The FDA classification and indication for skin-based or skin-substitute products is not the sole determinant for designation as a skin-substitute graft or a cellular tissue-based product, And they do not provide the sole basis for determining what is reasonable and necessary criteria for Medicare coverage. The policy does not limit consideration for Medicare coverage to any specific study design. The reason that this policy was designed this way was to allow investigators multiple options and in future options to treat and develop the clinical studies that are necessary to show that an item is no longer investigational and also is reasonable when necessary.

Next slide. An episode of skin replacement therapy is defined in the policy as 12 weeks from the first application of a skin substitute graft or cellular tissue-based product. While the policy does limit the frequency of skin substitute grafts and cellular tissue-based products to four applications, there is also a clear pathway for additional applications or time for that application when it is medically necessary.

Next slide. This LCD is based on societal guidelines which are summarized in the societal input section of the proposed LCD. This LCD aligns with four of the five societal guidelines detailed in the policy and as explained in the societal input section on the proposed LCD, it was based on the quality and the methodology of the studies that were used in the assessment of those studies. This is an evidence-based policy, and all future evidence must be submitted through the LCD development

process.

Next slide. The presenters at this meeting should introduce themselves at the beginning and cite any potential conflicts of interest prior to their presentation. We'd also like to remind presenters that any pertinent literature from peer-reviewed journals which are not cited in the current draft LCD may be submitted to National Government Services along with comments during the current comment period that will continue until 6/8/2024.

Next slide. We want you to know that everyone who has requested to be a presenter today, as well as anyone who is going to also submit formal comments, is that we want to express our appreciation in the beginning for your time and efforts in looking at this topic and helping us as a contractor for the Medicare program, we really appreciate and respect your opinions, and we encourage your opinions to be based on the medical literature.

Due to the presentations that we have today and the many presenters that we have today, we do have a limited amount of time and some time constraints. So, we would encourage all presenters to give comprehensive, but concise, scientific informational presentations.

I would also like to inform that as the moderator, I will take moderator preference and I request that all these presentations be conducted in a professional interaction. And if I have to interject, it's not because I want to cut you off. It is simply that I'm trying to facilitate this meeting and within the time constraints of the meeting. Next slide. So, to begin this presentation, I would like to turn the time over to Ms. Meenakshi Datta for our first presentation. Ms. Datta, are you there?

Meenakshi Datta: Yes, can you hear me?

Dr. Mark Duerden: Yes.

Meenakshi Datta: Oh, terrific. Glad that worked. Thank you. May I have the floor?

Dr. Mark Duerden: You do.

Meenakshi Datta: Thank you. Well, good afternoon, and thank you for the opportunity to speak today regarding the draft LCD. My name is Meena Datta. I am a partner at Sidley Austin, and I represent Organogenesis. And we wanted to begin our comments by applauding the MAC for the evidence-based approach reflected in the draft LCD. We will have more to say about that in our comment letter, but in our time today, we wanted to focus on five recommended changes to the draft LCD.

And these recommended changes are important to strengthen the draft LCD's evidence-based approach and provide safeguards for appropriate patient access to medically necessary care. So, our first key point is that any final LCD should recognize that favorable real-world evidence, or RWE, constitutes quality data demonstrating a product's safety, efficacy, and positive clinical outcomes. FDA, NIH, and a significant body of medical literature recognize that RWE constitutes quality supporting evidence.

And importantly, RWE addresses health disparities as it demonstrates efficacy and patient outcomes and populations that are often underrepresented in randomized controlled trials, or RCTs. RWE captures how care is administered to patients, which is often missing from the highly controlled environment of an RCT. RWE includes data from registries, health records, and other sources, and leverages claims data to evaluate the impact of treatments in clinical practice. Accordingly, any final LCD should cover products that have sufficient RWE support.

Moving to my second point, any final LCD should specify clear criteria regarding the data and evidence required for a product to be covered under the LCD. A lack of clear criteria creates confusion. And consistent with our first recommendation, the criteria in any final LCD should specify that the evidence supports coverage when sufficient RCT data or RWE is

available.

Moving to my third point. Any final LCD must expressly provide a process to ensure timely review of additional data and prompt implementation of coverage within 30 days following submission to the MAC of evidence sufficient for coverage. Right now, the draft LCD does not address whether and how coverage updates will occur. Failure to do so is problematic, as it would create significant patient access issues and undue delays.

Moving to my fourth point, the number of permitted applications should be increased under any final LCD to ensure appropriate and medically necessary care for all patients, including those with large or complex wounds who are among the sickest and most vulnerable patients in our healthcare system. Failure to do so would result in denying medically necessary care to patients and exacerbating harmful health disparities in this space. Notably the draft LCD itself recognizes the significant problem of health disparities that already exist in the area of wound care. Any final LCD should take steps to mitigate this problem, not aggravate it.

Moving to my fifth and last key point, appropriate implementation timing is critically important to address any final LCD's impact on patient access. Any final LCD should have a notice period of one year to ensure patients and providers can adjust to coverage changes. The proposed LCD would eliminate coverage for over 90% of the products currently covered in the skin substitutes market, which could significantly affect capacity and supply, as well as patient access to needed care.

A one-year notice period would help ensure an appropriate amount of time for provider education and for manufacturers of covered products to ramp up production to meet patient needs. With those five key points in mind, we look forward to following up further with our comment letter. Thank you again for the opportunity to speak today.

Dr. Marc Duerden: Thank you, Ms. Datta, for your thoughtful comments and really appreciate

you staying within the timeframe as well. Moving to our next speaker, Dr. MacEwan, are you there?

Dr. Matthew MacEwan: I am. Can you hear me okay?

Dr. Marc Duerden: Yes, doctor. You've got the floor.

Dr. Matthew MacEwan: Wonderful. Thank you so much for the opportunity to speak today. My name is Dr. Matthew MacEwan, and I am the Chief Science Officer at Acera Surgical, manufacturer of the Restrata wound matrix.

Next slide, please. Here are my disclosures and conflicts of interest. Next slide. Today, I'm here to provide a comment on the proposed LCD on behalf of Acera Surgical. Overall, Acera Surgical agrees with the intent of the draft ELCD, which is to provide support for products with high-quality clinical evidence. But today, I want to make the specific point that the analysis of available clinical evidence that was performed did not include a key, peer-reviewed, published, level-one prospective randomized control trial that specifically evaluated the use of our product Restrata Wound Matrix in the treatment of chronic diabetic foot ulcers.

This study that was published in early 2024 by (Hussain Et Al.) demonstrated a level one clinical evidence similar to that of other products that are categorized as covered under Group 2. As a result, Acera Surgical would like to request that Restrata be similarly categorized as covered in Group 2, as again, it is supported by high-quality Level 1 clinical evidence.

Next slide, please. Very briefly, our product, Restrata Wound Matrix, is very unique. It's a synthetic skin substitute that is engineered to mimic the structure and architecture of native extracellular matrix. Restrata was originally cleared by the FDA in April of 2017. It was granted a C code, C1849, in 2020, and a unique product code, A2007, in 2022.

Next slide, please. Restrata is very unique in that it's engineered rather than harvested. It's created using a technology called Electrospinning,

which allows us to create a material that mimics the subcellular structure and architecture of native extracellular matrix and native human tissue.

Next slide, please. Because of its unique synthetic and engineered design, Restrata has a number of properties that are different from harvested human and animal skin substitute products. It has a unique mechanism of action. It supports cell in-growth, new tissue formation, and wound healing. It is supported by Level 1 clinical evidence, which we'll talk about here in just one moment. And because it is synthetic in design, it is useful in specifically in patient populations who are sensitive to the use of harvested animal or tissue products.

Next slide, please. So, specifically, the clinical analysis that was performed and missed a key publication by (Hussain et al) that came out in foot and ankle surgery in January of 2024. This prospective, randomized, blinded, controlled trial evaluated the comparative efficacy of Restrata as compared to standard of care in the treatment of chronic diabetic foot ulcers. It was properly powered based on a prior prospective multi-sensor study that was completed in 2021 by (Avek et al), which demonstrated complete closure of 75% of diabetic foot ulcers in a 12-week period.

Based on this study design, 60 subjects were screened in this study with diabetic foot ulcers ranging from 1 to 30 square centimeters. And eventually, 46 of these subjects were enrolled and randomized one-to-one to receive either Restrata or standard of care over - up to a 12-week period. And what's unique about this study is only two subjects were lost to follow-up, and so the clinical evidence of all enrolled subjects were available in this study.

Next slide, please. The outcomes of this study demonstrate comparable clinical efficacy of Restrata to other products that are covered under Group 2. Specifically, these results demonstrated that Restrata was

statistically superior to achieving complete wound closure of diabetic foot ulcers as compared to standard of care. Our Restrata achieved closure of 74% of chronic DFUs as compared to 33% in the standard of care group. This study also demonstrated that Restrata was statistically superior in persistence of wound closure and time to complete wound healing. Again, overall, the results of this our Level 1 clinical.

Dr. Marc Duerden: Time warning

Dr. Matthew MacEwan: Yes.

Dr. Marc Duerden: Time warning.

Dr. Matthew MacEwan: Thank you. So, overall, this study demonstrated comparable clinical efficacy to other products in Group 2. Next slide, please. So, overall, we believe that this Level 1 clinical evidence shows all of the necessary characteristics as described in the analysis of other clinical evidence products covered under Group 2.

Next slide, please. So, in conclusion, Acera Surgical request that Restrata similarly be categorized as covered under Group 2 as it is supported by Level 1 clinical evidence that was missed in the analysis of available clinical publications. Additionally, a therapeutical would urge that non-coverage of a synthetic skin substitute like Restrata would discriminate against patients with religious, cultural, and ethical objections to human and animal products.

With that, I'd like to thank you all for your time and for the opportunity to comment and would be glad to take any questions that you might have.

Dr. Marc Duerden: I don't have any questions. I thank you for your presentation.

Dr. Matthew MacEwan: Thank you very much.

Dr. Marc Duerden: Thank you, sir. Next slide. Next presenter is Mr. Eric Smith. Is Mr. Smith

here with us?

Eric Smith: Can you hear me?

Dr. Marc Duerden: Yes, sir.

Eric Smith: Oh, great. Well, first of all, thank you for the time. If we can get to the next slide, that'd be great. Next slide, please. So, Eric Smith, I'll be presenting today. I'm the Senior Vice President of Reimbursement and Health Policy, as well as a few other functions within MiMedx, and I look forward to walking through these slides and comments with you. And again, I appreciate the time today. Thank you.

Next slide, please. So, I think it's great, and when we reviewed the LCDs, there's been some progress. We're very supportive of evidence-based medicine, and also, I think that there is a pathway for treatments that was not there when these LCDs came out about a year ago. With that said, we do believe there's still some opportunities for improvement and some concerns. One is the process was not described as to kind of what the - for future products, what would the criteria be for clinical trials, as well as the process.

We do believe that four applications leave the significant patient population at risk. The KX modifier, you know, we just want that to be used appropriately and not be a surrogate for prepayment review. The diagnosis codes, as listed, appear to be incomplete and could put patients at risk. And then just making sure that there's clarity between the evidence that's generated versus the cover list. In some instances, there are products that have DFU evidence, but not VLU, but they're all covered, and making sure that the providers will have clarity on that.

Next slide, please. So, again, we're really supportive of evidence-based requirements. The company's invested a lot of time and resources in doing that, and I think that's a great step forward. With that said, as we discussed, there were no explicit requirements. And we really request that there would be clarity around the requirements for those studies. And

then second to that is really focusing in on, well, what will that process look like? And reconsiderations, if done at a MAC-by-MAC level, will be extraordinarily time-consuming. So, having some sort of consistent process that's efficient is something that we would like to see in any revisions going forward.

Next slide, please. So, we have some real-world evidence that's out there. We've seen somewhere 30% to 40% of patients are not healed at four applications. This is something that we do believe should be increased. We've seen that in our study that four applications was an average, but moving, like, one standard deviation beyond that might be more acceptable, something that starts to look more like seven, but certainly, there's a large population that could be put at risk here and could create a potential documentation challenge for those patients as we go forward in providers.

Next slide, please. KX modifiers, I mean, overall support for them if they're used as an informational modifier. With that said, it could be challenging if it's really used as a surrogate for prior authorization process, or if it generates significant additional documentation requirements, we really want to make sure that, you know, this is not something that really puts a challenge to the providers in treating these patients. And if you look at that within the context of a poor application limit, I think that becomes even more concerning.

Next slide, please. I won't spend a lot of time here, but it is just, again, getting clarity between some of the - if you look at the evidence summary that's included in the LCD, certain products have studies for DFUs, and certain products have studies for VLUs. But the covered list, I think, theoretically covers both. So, we just want to make sure there's clarity for the providers as well as Medicare Advantage plans.

Next slide, please. So, when you look at the diagnosis codes, there's some concerns here as well. As written, it would simply intend to cover, really, just diabetic foot ulcers versus lower extremity ulcers. At this point,

again, as written, there'd be no coverage for DFUs, even as high as the ankle. Similar concerns with the L97 codes, patients with deeper ulcers can benefit from skin substitutes. We have some evidence that supports that, so we really want to make sure that these patients that can benefit from these products have access to that.

Next slide, please. I'll go through these next few slides very quick. We always want to remember that this is a challenging patient population with significant mortality rates. Next slide, please.

Dr. Marc Duerden: Time warning

Eric Smith: I'm sorry?

Dr. Marc Duerden: Time warning.

Eric Smith: Okay. Great. Yes, I've got two more slides. Again, we're dealing with a sick patient population. Next slide, please. And just a reminder that, when you use these products appropriately, readmissions, admissions, ED visits, and whether it be for low extremity ulcers or, next slide, venous leg ulcers, you're going to see improvements of that, which is good for patients and good for overall healthcare economics as well.

And then that last slide is just in conclusion. Again, it's great to see the progress. Thank you for the time. And then there's just some concerns as we've addressed here. And looking forward to seeing, you know, the next steps here. Thank you.

Dr. Marc Duerden: Thank you, Mr. Smith. Our next presenter is Dr. Gunasekaran. We can turn the time over to you.

Alicia Barling: Dr. Duerden, I don't know if this speaker is present on the meeting at this time.

Dr. Marc Duerden: Okay. We will go to the next slide. Next speaker is (Sophie Hafley). Ms.

(Hafley), are you on the phone? Can one of the staff check and make sure on the panelist list or the participant list that Ms. (Hafley) is or is not present? Hearing - not hearing anything from Ms. (Hafley). We will go to the next presenter, which is Ms. Carrie Hartill. Ms. Hartill, are you present?

Carrie Hartill: I am. Can you hear me okay?

Dr. Marc Duerden: I can hear you. I turn the time over to you.

Carrie Hartill: Thank you very much. So, thank you very much for allowing me to speak on behalf of Geistlich at today's open meeting. My name, as you heard, is Carrie Hartill, and I am an Executive Director at Geistlich. I have on my second slide. Next slide, a conflict of interest statement to clarify that I am an employee of Geistlich Pharma Ag which is a company based in Switzerland.

Next slide. Today, I'd like to request specifically reconsideration for coverage of Geistlich Derma-Gide, HCPCS Code Q4203, in the proposed LCD DL39760 for skin substitutes, grafts, cellular, and tissue-based products for the treatment of diabetic foot ulcers and venous leg ulcers.

In the draft LCD, the Geistlich Derma-Gide was listed in table two as a non-covered product with no literature identified. This reconsideration request is based on the publication of Level 1 clinical evidence in a 105 patient prospective randomized control trial.

In the specific publication, the Geistlich Derma-Gide was actually referred to from its scientific name or descriptor as PRBM or Purified Reconstituted Bilayer Membrane, which is the generic descriptor of the product technology. As you can see in the screenshot from the publication on the right that PRBM is branded in the U.S. as Geistlich Derma-Gide and processed by Geistlich Pharma Ag here in Switzerland.

Next slide. The clinical study team for this 105-patient RCT includes Dr. David Armstrong, Dr. (Charles Dellon), and others as listed here. Next slide. The results of this prospective randomized control trial demonstrate that Derma-Gide is highly effective in the treatment of chronic diabetic prognosis, showing an 85% to 90% closure rate at 12 weeks, with a percentage area reduction of 93.6%. This is compared to the standard of care alone, with 45% to 67% closure rate at 12 weeks.

Slide 6. So, next slide please. In addition to the statistically significant improvement in Geistlich, the Derma-Gide also demonstrated favorable health economic outcomes as compared to similarly published data on other technologies that are covered by CMS. The mean graft cost of closure showed the lowest cost of comparable technologies, those with cost data that is published.

Next slide. In addition to our 105-patient RCT, there are additional prior publications including a 40-patient interim analysis of the overall prospective RCT, a ten-patient observational theory, a ten-patient retrospective series including deep and difficult-to-treat wounds, and the Material Characterization manuscripts demonstrating the mechanism of action of the Geistlich Derma-Gide.

Next slide. In summary, Geistlich's requests reconsideration for coverage of Derma-Gide in the proposed LCD for skin substitutes, grafts, solvents, and tissue-based products for the treatment of diabetic foot ulcers and venous leg ulcers based on the publication of the Level 1 clinical evidence, formally described, in a prospective randomized clinical trial.

We agree that prioritizing our clinical evidence to support technologies is important. We are fully committed to this and pleased to see that solid outcomes and improved wound healing for patients suffering from chronic diabetic foot ulcers is a priority in your consideration. Thank you for your time today.

Dr. Marc Duerden: And thank you for your presentation. Our next presenter will be Dr.

Johansson. Dr. Johansson, are you with us? Dr. Johansson, I don't hear you, I'll just give you another moment to see if you can get off mute.

Dr. Awodele: I do see him on the call.

Dr. Gunnar Johansson: Hello, do you hear me?

Dr. Marc Duerden: Yes, Dr. Johansson.

Dr. Gunnar Johansson: Hello.

Dr. Marc Duerden: I turn the floor over to you.

Dr. Gunnar Johansson: Hello.

Dr. Marc Duerden: Yes, sir. We can hear you.

Dr. Gunnar Johansson: Do you hear me. All right. Thank you all. My name is Gunnar Johansson, Medical Director at Kerecis. Just one more second, what the other speakers have said, that we highly praise the MACs for their focus on evidence-based medicine, and also thank you for the improvements in a lot of the clarifications of the application criteria and having processes in place for additional applications and a longer treatment of care. What I want to focus on here is some care's specific materials regarding our evidence and coverage decision.

We are part of the Alliance of Wound Care Stakeholders, and we support their messages on the clinical application aspects. Next slide, please. Yes, this - I'm an accelerated employee of Kerecis, but I have no other financial interest to disclose. Thank you. Next slide.

Very quick update. Want you to know that Kerecis was the first skin substitute worldwide that is from intact fish skin, and we have two products that are from the same material with different configurations. Next slide. And our key point in this comment period is the Kerecis data that was reviewed was older data on the Kerecis products. It was an interim study on our diabetic foot ulcer trial that was

reported in acute wound studies. But unfortunately, our landmark last test 2023 study on diabetic foot ulcers that had over for 102 patients and seems to fulfill all the clinical evidence criteria and the search criteria, which was not included in the review. The full study publication with full ultimate data is published.

Next slide. It is peer-reviewed and has a PubMed ID. And to summarize the key findings, this is a randomized controlled trial comparing fish skin grafts to standard of care in diabetic foot ulcer patients. It has that large sample size and a multi-centered design, has well-defined and clinically relevant inclusion-exclusion criteria, has an appropriate standard of care comparator.

It has a rigorous statistical analysis with both intent to treat and protocol populations, a robust randomized controlled design, independent blind data that justification of healing outcomes. It has a 12-week outcomes, but also what was highlighted as a miss in many of the studies for long-term follow-up. It has 12-month follow-up on both short and long-term advocacy.

And we believe this is clinical, meaningful, and statistically significant improvement in healing outcomes that puts the priority on the beneficiary and their clinical outcomes. Furthermore, the long-term follow-ups shows the reasonable safety profile with no product-related serious adverse events. And this is a very recent publication and ensures the data is highly relevant to clinical practice.

Next slide, please. Just to summarize the criteria, we believe Kerecis fulfills all the three main criteria, both the product characteristics, the clinical evidence, and the product form. Next slide, please. And just to review how the Kerecis study compares to some of the other studies that were included on the covered list, there are many good studies there, but many of them have smaller patient populations or have identified a higher risk of bias, but were still covered in the OCD policy. And based on that baseline, we believe that the Kerecis, the study on the diabetic foot

ulcers with Kerecis should exceed the coverage requirements that were listed.

Next slide, please. So, the impact of including it, we believe this, including the (Lante) study would strengthen the evidence-based for fish skin graft and diabetic foot ulcer treatment. It provides additional context, and it supports the coverage decision. And omitting this study, we believe, would limit access to patients to newly published evidence-based treatments and limit options of patients that might not want human take or cow source products for cultural or religious reasons.

So, we just strongly urge you to consider the study, and we will be submitting the manuscript in our written comments. And that concludes my comments. Just thanks again for a clear process and wish that you consider our evidence.

Dr. Marc Duerden: We appreciate your comments, sir, and thank you for your time in looking at this. Our next presenter will be Marcia Nusgart. Ms. Nusgart, are you there?

Marcia Nusgart: Yes, I am, sir.

Dr. Marc Duerden: I turn the time over to you.

Marcia Nusgart: Thank you. As we just said, my name is Marcia Nusgart. I am the CEO of Alliance of Wound Care Stakeholders. So, we appreciate the opportunity to provide the Alliance's concerns related to the release of the Skin Substitute CTP-LCD and the accompanying LCA. So, the Alliance is a nonprofit multidisciplinary trade association of physician specialty societies and clinical associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas.

So, this oral statement was written with the advice of our clinical specialty societies and organizations who not only possess expert knowledge in

complex chronic wounds, but also in wound care research. And we will certainly submit written statements, you know, by the deadline in June. We do have several concerns with the current draft and areas we identify which need further clarification that we'll address, as I mentioned, in our written comments.

However, today, I just have three issues I'd like to discuss briefly. First of all, the proposed policy continues to permit only four applications of CTPs in a 12-week period of time, as opposed to previous drafts and GSA's permitting additional applications and an extension of the 12-week period of time when medically necessary and documented in the patient file.

The Alliance fully supports the proposed LCD language permitting additional applications or an extension of the 12-week period of time based on medical necessity with documentation provided in the patient's medical record. It's important that the patient be able to receive more applications when medically necessary, especially when their wounds are progressing.

So, the Alliance appreciates and supports this clinically, necessary and appropriate change from previous drafts. Secondly, the Alliance also supports coverage based on evidence. We've always been on the record supporting evidence-based medicine. However, we're concerned that NGS eliminated coverage for a significant majority of products in the market currently, many having evidence to support their use.

As such, we believe that NGS needs to be clear as to the evidentiary bar as we believe that studies for products that were eliminated from coverage that should not have been. We're also aware of products that have evidence that were not yet identified in your list of product evidence that was reviewed.

So, what is the process for a manufacturer to submit evidence that does not appear to have been reviewed? More information on the evidentiary bar and any recourse that the manufacturer has with respect to evidence

review should be provided. Finally, we'd like to urge NGS that once this policy becomes finalized, given the limitation on the number of products that are currently on the proposed list of covered products, there should be ample time to implement this policy. Patients will be in the midst of treatment plans on products that may not be covered any longer.

Their treatment plans are 12-weeks, and any changes to these treatment plans can negatively impact them. Furthermore, facilities who do not use products on the proposed list of coverage products will need to go through a formulary review process of the products that are covered to determine what they should add to their formulae.

Please recognize that this process can take upwards to eight months. As such, we encourage NGS to ensure that there's enough time to implement the provisions of this LCD once finalized so as not to negatively impact patient care. Thank you so much for your time. We appreciate it.

Dr. Marc Duerden: Thank you, Ms. Nusghart. I appreciate your comments, I really do. Our next speaker will be Dr. Rader. Dr. Rader, are you there?

Dr. Andrew Rader: Yes.

Dr. Marc Duerden: Turning the time over to you, sir.

Dr. Andrew Rader: Hello.

Dr. Marc Duerden: Yes. All right. The time is yours.

Dr. Andrew Rader: Good afternoon. My name is Andrew Rader. I'm the Doctor of Podiatric Medicine, and I serve as Medical Director at Memorial Hospital's Wound Center in Huntingburg, Indiana, where we specialize in the treatment of non-healing wounds, including diabetic foot ulcers and venous leg ulcers. We also provide this care to our private offices due to the rural nature of our practice.

And I appreciate the opportunity to share my views on the proposed local coverage decision limiting Medicare coverage of skin substitutes used in the treatment of venous leg ulcers and diabetic foot ulcers. I'm somewhat surprised and concerned to see the proposed LCD that would so dramatically truncate options for both providers and their patients in the use of skin substitute products. I do not think that a cutoff of Medicare coverage of skin substitutes to only include a little more than a dozen older products with RCT evidence acceptable to NGS is wise or justified.

This potentially sets a dangerous precedent for requiring RCT evidence for any approved skin substitute, effectively quashing further innovation that's in response to scientific discovery. This would be akin to only approving surgeries with RCT evidence where to date only a small fraction of surgeries performed have this level of evidence to support their use. Appendectomies, for example, do not have this level of evidence, yet save countless lives every month.

It's an extremely serious decision to limit the skin substitute in this way. It would prevent me from using the products that based on science, I believe are best for my patients. I'm certain that it will place many other professionals who struggle with these wounds in a similar situation. I think that significantly more input from providers, patients, and experts should have been sought before introducing this proposal.

For example, in my practice, I use InnovaMatrix. This device is unique, and it utilizes porcine placental tissue and a process that effectively cleanses residual cellular material to create a medium that is very - that very importantly mitigates the immune response while supporting the effective tissue growth.

This has been successful where other products have failed for my patients. This device is predicated on an earlier four sign-derived product that has at least six clinical trials demonstrating effectiveness, but it would now be excluded because it does not have its own trial. Excluding products such as this with clear, real-world evidence and a sound basis

for FDA approval is not in the best interest of my patients. In addition to stifling continued medical innovation, this will likely extend the course of treatment for many patients.

The consequences of this is more complications, including amputation, in the Medicare population suffering from diabetes. This population is disproportionately individuals from under-resourced communities challenged by a myriad of social risk factors. It ignores many other sources of information that demonstrate efficacy, including real-world evidence found in retrospective studies as well as peer-reviewed scientific literature.

This includes a very large study using Medicare data from 2015 through 2018, showing that effectiveness and reductions in amputations and readmissions. With regard to limitations on the number of applications in a 12-week episode period, I do appreciate that the proposed LCD moves away from the hard stop at four that was previously proposed. That is more in alignment with the published research, and I do appreciate the need to articulate some limits on applications.

As now written, the LCD allows four exceptional cases in which four applications did not result in adequate healing. In such situations, additional applications would be considered with documentation of progress on wound closure and the medical necessity of additional applications.

Needed here for providers and patients is more specifically as to what documentation would be required, what amount of progress should be expected to justify additional applications and how the size of the wounds would be taken into consideration. Without this guidance, providers such as myself would be proceeding in an information vacuum. Thank you again for the opportunity to present.

Dr. Marc Duerden: And thank you, Dr. Rader, for taking the time to present.

Dr. Andrew Rader: You're welcome.

Dr. Marc Duerden: Our next presenter is Karen Ravitz. Ms. Ravitz, are you there?

Karen Ravitz: I am. Can you hear me?

Dr. Marc Duerden: Yes. You have the floor.

Karen Ravitz: Wonderful. Thank you so much. Good afternoon. As said, I'm Karen Ravitz. I'm the Health Policy Advisor for the Coalition of Wound Care Manufacturers. Founded in 2000, the coalition represents leading manufacturers of wound care products used by Medicare and commercially insured beneficiaries for the treatment of wounds, including cellular and or tissue-based products for skin wounds or CTPs that are the subject of this policy. Thank you again for the opportunity to provide our feedback on this proposed LCD and accompanying LCA.

The coalition appreciates that the MACs adopted many of the changes recommended by the coalition in our previously submitted comments, including, but certainly not limited to the ability for patients to obtain additional applications when medically necessary and documented.

There are many areas in which we believe clarification is necessary, but we'll provide those issues in our written comments, as well as more substantive comments on provisions that are also contained in the draft policy. For the hearing today, I'm focusing on three issues.

First, while we fully support evidence-based policies, more clarity is needed to better understand the evidentiary bar. For example, it appears that the MACs are only providing coverage for products with RCT studies. There are several products that have RCT studies which are not covered. It also appears that the only RCT studies that the MAC is accepting is for products that have applications within the policy parameters.

The MAC has also indicated the coverage will be provided for CTPs

having peer-reviewed published evidence, and yet there are products that have peer-reviewed evidence that are also not covered. There's no consistency in the evidence that's being accepted by the MAC, nor is there any transparency as to what metrics were utilized to review the evidence. Although, there were things that were published in terms of AHRQ and other documents, there are still no tables or any metrics that were published, so that the public can see where the MACs came out with this information.

We would request the MAC be more transparent in its criteria for product coverage and publish what is considered an adequate trial design and outcome to gain coverage. Second, we would also like to better understand the timeframe and process a manufacturer will need to undertake when submitting evidence for consideration.

Does the manufacturer need to submit a reconsideration request in order for the MAC to review evidence for consideration of being placed on the Group 2 list? Or since changes can usually be made to the LCA without going through notice and comment, which is why the LCAs were established in the first place. A manufacturer can simply submit their evidence for consideration and the MAC will review and place the product on the Group 2 covered list if the MAC deems the evidence to be satisfactory without going through the notice and comment period.

If the latter, then how long will it take for the MAC to review and make a decision for inclusion? Will the decision include the rationale for either not placing or placing the product on the group two covered list? We raised this issue as in previous drafts we've been told inconsistent messages and would appreciate clarity being provided. We would also like to know, excuse me, when NGS reviewed evidence for this policy, what was the cutoff date, as there seems to be some recent studies that do not seem to be included in the evidentiary review for this draft policy.

And finally, we would like to ensure that all of the 15 codes and corresponding products listed in the Group 2 covered product list are

available for coverage and reimbursement for both DFU and VLUs, and I'm curious to know if the medical directors on this call would be willing to confirm this during this call today.

As mentioned, the coalition will be submitting comments with additional issues being addressed, and we appreciate the opportunity to speak today. Thank you.

Dr. Marc Duerden: Thank you, Ms. Ravitz. I don't have the ability to confirm that information at this time, as you requested. But we do really appreciate your thoughtful ideas, and actually some of the questions that you raised. So, we will work on those during this comment period, as we look at the comments from everyone else as well.

Having said so, our next presenter is Dr. Thomas Serena. Dr. Serena, are you there? Dr. Serena, we're going to give you a moment to get off mute. All right, hearing no comments at this point. We'll move to Dr. Pontarelli. Dr. Pontarelli, are you there? Not hearing from Dr. Pontarelli, we'll move to Dr. Wuesthoff. Dr. Wuesthoff, are you there?

Dr. Wuesthoff: Hello, can you hear me?

Dr. Marc Duerden: Yes.

Dr. Wuesthoff: Fabulous. Good afternoon. Thank you so much for this opportunity to present. Here I'll briefly outline how our device, the device from the company I represent, can be a part of supporting the implementation of the draft LCD while helping all stakeholders involved.

If you go to the next slide. So, the medical technology company I represent produces and commercializes a handheld imaging device called MolecuLight. We have a unique platform that is used across the U.S. and it enhances wound care, including the application of skin substitutes. We wanted to be part of this conversation, because our

device supports and improves upon the documentation requirements that are outlined in this draft LCD.

If you go to the next slide. A good example is the documentation of a failure to respond to four weeks of standard of care treatment of these VLUs and DFU's. The next slide. Our device enables an unbiased documentation of the appropriately performed wound bed preparation and infection control needed prior to the application of the CTPs.

Next slide, please. MolecuLight is also supporting adequate patient selection by avoiding placing CTPs on actively infected or heavily colonized wounds. And it also supports more accurate wound sizing, that will lead to appropriate CTP site selection and its use.

Next slide, please. And how it does so, well, MolecuLight is an FDA-cleared Class II device. It has two distinct functions. One of them is bedside bacterial detection feature. It has been demonstrated that it has four times greater sensitivity than the standard of care detection of infected wounds. And it also has a digital wound measurement component that has an over 95% accuracy.

The bacterial detection component is accomplished through a non-invasive, non-contrast, and non-contact fluorescence imaging technology, which means that this is a completely safe procedure for patients. The images you see here on this slide is what a provider or clinician would see when using the device. On the left-hand side, you see a classic, what we call cyan signal at the very top of that wound shining very brightly. And that is specifically indicating the presence of pseudomonas.

On the right-hand side, you see a diabetic foot ulcer with a very bright red signal coming from the center of the wound. And that is representative of a mixture of different bacterial species at concentrations that would cause healing delay and infection. So, being able to identify and locate bacteria enables the removal, its removal effectively and objectively.

Next slide, please. So, the information from those features is

collected, and it's stored in a cyber-secure, HIPAA compliance manner. And you can revisit this information at any point in time. So, both the wound's clinical evolution, as well as their size can be tracked over time, objectively, in standardized ways. And it's really a visual, undisputable document.

Next slide. So, it's very important also to highlight that our technology works perfectly well across all skin tones and all races, something that is not universal for all skin diagnostics. And so in this way, we're supporting the CMS's initiative to provide more equitable care.

Next slide. Thanks for time, also next slide, please. So, the molecular imaging device can present a solution for the multiple stakeholders that are involved or impacted by the proposed LCD. We believe that we support the 28-day medical necessity documentation versus standard of care prior to the application of CTPs. We support the medical necessity verification and sequencing of allowed CTPs.

The device demonstrates the adequacy of chosen treatments and wound preparation ahead of a CTP application by providing visual testimony, pre and post treatment and other treatments of the bacterial presence. The providers can use MolecuLight to achieve better and more thorough wound bed preparation, ensuring that the CTPs they are placed in are given the greatest chance of success. And our digital wound measurement feature is providing a standardized visual record for the payers that the wound size is reasonably corresponding to the chosen CTP.

If you go to our last slide, please. So, in summary, our technology is enhancing documentation and appropriate CTP usage, allowing providers to objectively demonstrate medical necessity to the payers and supporting required documentation in an efficient way, satisfying the payers' expectations and reassuring them that their work will be adequately reimbursed.

We would like to request respectfully further dialog to discuss the inclusion of fluorescence imaging and the digital wound measurement from the MolecuLight as the only device that can provide those two simultaneous features in the draft LCD. Thank you very much for this opportunity.

Dr. Marc Duerden: Thank you, doctor, for your comments. What I'd like to now do is circle back and see if Dr. Gunasekaran is available and has joined us. He is a Research Scientist from EnColl Corporation. Doctor, are you on the phone?

Dr. Gunasekaran: Yes, I'm on the phone. Are you able to - yes, I'm sorry. I'm holding that up. Can you hear me?

Dr. Marc Duerden: Yes, sir. Go ahead. Time is yours.

Dr. Gunasekaran: Yes. My name is Subramanian Gunasekaran. I'm the President, CTO of EnColl Corporation in California. I hold a PhD degree in biological sciences, and I'm also affiliated with the Society for Biomaterials for 40 years as an active member. In this scientific organization, I currently serve as a Liaison, as well as the program chair for the SIG, namely biomaterials, medical products, commercialization.

Based on my interest and expertise in the field of biomaterials, during the mid-'90s, I have been involved with FDA authorities to evaluate the collagen-based biomaterials for the safety and effectiveness in device applications. As an example, I had the opportunity to inform FDA team about the technical impossibilities of producing a Type 1 Collagen using recombinant methods. They also played a significant role in establishing the ASTM for Surgical-Grade Type-I Collagen.

In - further, I have collaborated with Dr. Grace Picciolo, PhD from FDA in the industry and regulatory groups meeting focusing on tissue engineered products. I have also worked along with Dr. Eric Sussman in FDA through

the Society for Biomaterials. Together, we have organized webinars to shed light on the evaluating a medical device based on the scientific relevance of the bio - chemical composition of the biomaterials.

Moreover, I have also been instrumental in organizing a few panel discussions emphasizing the commercialization hurdles of biomaterial-based regenerative medical products to address challenges in the field. With all this expertise, I'm here to provide my perspective on the recent LCD proposal. I do admit that I have a personal interest as a commercial product developer in understanding the scientific and technical relevance of the current proposed LCD.

It is very interesting to note that CMS and MACs have recently seen to promote amniotic and placenta-based products as skin substitutes. The role of FDA to monitor the safety and efficacy of such medical devices is highly impaired compared to the routine market clearance of your medical device using 510(k) or PMA pass.

During the last LCD proposal by Novitas, First Coast and CVS-MAC, it was decided to call for a TRG letter from the FDA to properly recognize the HCT products. This decision was strongly objected by the certain group who argued that such decisions would dramatically affect patient care, leading to the cancellation of the whole proposal.

Now, there is another proposal by CGS. I don't want to include all the ELCD numbers, but CVS, Novitas, Palmetto, WPS totally removed the need for a TRG letter, however, it included only certain products based on the clinical study data. Unfortunately, such clinical study evaluation is not adequately guided by CMS. Please see the observations and possible solutions.

One, disparities in clinical outcome. Manufacturer sponsored studies may not be relevant to access. Several covered products, clinical outcomes have been assessed under high risk category. Please see the issued

proposal. FDA involvement in the assessment of safety and efficacy should be mandated. The proposed LCD contains controversial statements that need to be clarified. No proper pre-announcement of the need and guidance of clinical studies provided to the manufacturers.

Conclusion, in order to provide suggestive solutions, CMS should give responsibility of assessing the safety and efficacy of each product to FDA authorities. Until such a progress gets implemented, forcefully thrusting the proposed LCD would have a major setback on the commercial usage of most of the skin substitute products currently available in the market. Thank you.

Dr. Marc Duerden: And thank you, Doctor.

Dr. Gunasekaran: You're welcome.

Dr. Marc Duerden: The next speaker, I'd like to turn it over to is Ms. Hafley. Ms. Hafley, are you available?

Sophie Hafley: Yes. Can you hear me?

Dr. Marc Duerden: I can. I turn the time over to you.

Sophie Hafley: Thanks so much. Good afternoon. My name is Sophie Hafley, and I represent the Medicare Access to Skin Substitutes Coalition. The MASS Coalition is a group of skin substitute companies that are dedicated to ensuring access to critical wound care products. We are seriously concerned about the coverage policy set forth by the MASS in this draft LCD. It is arbitrary and capricious, sets unclear standards, is inconsistent with the FDA regulatory framework for skin-substitute products, and is bad for patient care.

Next slide, please. First, it is important to recognize that the CGS, Meridian, and First Coast MASS issued very similar final LCDs in the summer of 2023. After the MASS Coalition and other stakeholders voiced

their concerns with the policy in those LCDs to both the MASS and CMS, the MASS rescinded those final LCDs before they became effective.

Here, not only did this MAC issue a draft LCD very similar to the ones that were rescinded, but all of the MACs throughout the country followed suit, effectively issuing a national coverage policy. Even after rescinding the final LCDs last year, the MASS did not obtain stakeholder input with regard to the new draft LCDs.

No contractor advisory committee and no public meetings to obtain input on how to formulate a policy that works for the benefit of Medicare patients with chronic wounds were held. Instead, we have the same substantive policy that was rescinded last year, just packaged a bit differently.

Next slide, please. The MASS coalition products are HACCPs under Section 361 of the Public Health Service Act. It's important to note that FDA would not consider HACCPs for amniotic or placental tissue products to be indicated for any purpose other than serving as a wound cover or barrier. FDA would not consider an HACCP to be appropriately described as functioning like a skin scaffold.

Next slide, please. But the draft LCD adopts a definition of skin substitute that requires the product to be, quote, scaffolding for skin growth. This requirement is inconsistent with how FDA views HACCP. Again, the FDA TRG would not issue a letter stating that an HACCP should function like a skin scaffold. The MASS cites the AMA codebook, but there is no clear rationale in the draft LCD regarding why the skin scaffold definition in the CPT codebook is relevant to a Medicare coverage determination.

Next slide, please. The draft LCD proposes coverage for only 15 skin substitute products and puts over 200 products in the non-covered category. The reason why a product was put into a particular category is unclear. The proposed standard for clinical data is not clearly defined,

and the skin scaffolding requirement is also not clearly defined.

The distinction between covered and non-covered products is also arbitrary and capricious. For example, there are products in the covered category that arguably provide scaffolding for skin growth and other products that do not.

Next slide, please. Regarding the four application utilization limitation, this was widely challenged in the final LCDs that were rescinded last year. Yet, for some reason, the MACs have proposed it again. Clinical experience shows that most large and complex wounds require more than four applications to completely heal.

There is clinical data that is relied upon by the MACs to support coverage for certain products that use more than four applications to heal wounds. The authors of the primary study relied upon by the MACs to support the four-application limit have stated that the MACs misinterpreted their study.

Next slide, please. If this draft LCD is finalized as proposed, Medicare beneficiaries will suffer. It is unreasonable to expect that only 15 products can serve the entire Medicare population. Treatment of wounds will be delayed if treated at all. Medicare beneficiaries in vulnerable populations, rural, underserved, minority populations will be disproportionately affected.

Next slide, please. In summary, the draft LCD is legally defective and bad policy. The MAC should not finalize the draft LCD. Instead, the MAC should take steps to obtain input from a wide variety of stakeholders before proceeding with a new coverage policy.

Unlike this draft LCD, the new coverage policy should be well-reasoned and based on established data and clinical experience, establish clear and attainable parameters for coverage that are consistent with FDA's regulatory framework, and it should promote effective wound care for Medicare beneficiaries. Thank you for your time.

Dr. Marc Duerden: Thank you, Ms. Hafley. Circling back, we'll continue with another presenter who was not able to join us in the queue, but is Dr. Serena here?

Dr. Thomas Serena: Yes, I'm here.

Dr. Mark Durden: Sir, I've turned the time to you.

Dr. Thomas Serena: All right. Thank you. I got disconnected just as we started last time. So, thank you for allowing me to speak. Today I'm speaking on behalf of SimLabs, on behalf of my group, which is the Serena Group Research Organization, a physician-owned contract research organization, my patients, and my Type 1 diabetic son.

So, I don't have any conflicts. I accept that I do research for a lot of the companies that make skin substitutes. You know, my basically - my life now is really randomized controlled clinical trials. So, let me start off by saying I applaud the MACs for making this an evidence-based program. I think following the evidence is just exactly the way it should be done. I do have some comments, however.

First, we don't have any guidance on what - you know, what is the right kind of clinical trial that you need to obtain reimbursement. We don't really know what the bar is. And we publish all of our protocols. We put them on clinicaltrials.gov. We publish to be - you know, we go through the process of publishing them in peer-reviewed journals.

So, they are available, and I'm going to send some of them to you in the written section so that you can look and see how we do them, and hopefully many other people will agree. I think most people follow a general framework for doing RCT.

In addition, there are some new RCT designs that have come out of the pandemic, such as platform designs and other master trial designs that

are really ideally suited for this market, and SimLabs has embarked on one of these platform designs.

And I would encourage you to take a look at this design and makeup because it really allows for the gathering a large amount of evidence in for these particular types of skin substitutes. Also, I think it's really important that the clinical trials aren't just to get approval for the various products that we've heard all about today, and that's great, but it's also important for advancing the science of, you know, diabetic - treatment of diabetic foot ulcers. For example, SimLab has given us a grant along with Dexcom for us to study continuous glucose monitoring in the next clinical trial.

And that's something that's never been done in a DFU clinical trial. And does time and range predict microvascular complications like it does in retinopathy and nephropathy? Does it work on healing diabetic foot ulcers? We'll find out, and we'll find out because they're doing this clinical trial and really applaud them for allowing us to add these things to clinical trials.

Also, the SimLabs trial, particularly the complex platform design, has been in the works for three months. And next week we will be at the IRB, and we expect that we will get approval for the trial. But it's going to take us time to gather all this information and get it published in the peer-reviewed journal.

So, I would request that you consider getting a grace period to those companies that have taken the time and effort to have submitted a protocol to an IRB and registered on clinicaltrials.gov. And I think if you meet those criteria by certain - a certain date, then you should be granted a grace period in order to gather that information. And I would really strongly ask you to consider that.

Also, one other thing I would have, and others have mentioned this, the four applications, that's really not how we have done it in the clinical trials. The clinical trials have looked at 10 applications or 12 applications, and

that's how we've studied it. So, we don't really know what four applications does. I can tell you that in some patients with complex wounds and lots of comorbidities, you put on four applications and the wound just stalls when you stop applying it.

Now, I don't put ten on every patient I see in the clinic, but I'd like to have that option. How do I do it in practice? The way I do it with our nurse practitioners and my partners and our practice is, we apply four applications. If the wound hasn't healed by 40% with four applications, we stop at that point, because the skin substitute has not done what I wanted it to do. It's not accelerated the wound closure. We go back and reassess the patient. Is it perfusion? Is it too much bacteria presence?

So, we're looking for other things that might go on. But we stop, we don't just go on to ten. I would encourage you to look at that as a possibility. You know, say, okay, if you apply four applications of a skin substitute and it's not working, then you stop. And I think that is a more practical way to do it. Now, at the other possibility - the other thing I just want to mention about, giving the grace period is we've talked a lot about removing a large amount of products and then decreasing patient access.

If you give the people that have clinical trials in progress now a grace period, you solve that access problem because a lot more products will have - will be available to our patients. And I want to thank you very much and again applaud you for taking an evidence-based approach.

Dr. Marc Duerden: Thank you, doctor, for your comments. I would like to continue to look through the queue and see if Dr. Pontarelli is with us. Dr. Pontarelli? Okay, Dr. Pontarelli was representing BioTissue. What I would like to do is turn the time over to the operator to see if there are any other commenters that would like to present a brief comment for this LCD.

I will, again, continue to moderate the time to make sure things will flow, but I do really want to have an opportunity to hear from anyone else that

would like to make a presentation or have comments or recommendations for this LCD. So, operator, can you tell me if anyone there is raising their hand or would like to get into the queue for presentation.

Coordinator: Thank you. As a reminder, if you would like to make a comment, please press Star 1. If you need to remove yourself from the queue, press Star 2. Again, to make a comment, press Star 1. I'm showing no comments at this time.

Dr. Marc Duerden: Thank you, operator. I would like to give Dr. Pontarelli one more opportunity to join us if he's on the line. Doctor, are you available? And since Dr. Pontarelli is not available, what I'll do is turn the time back over one more time to the operator to see if there's any other presentations.

Coordinator: I'm showing no comments at this time. Oh, we have a comment from Susan Walsh. Your line is open.

Susan Walsh: Hello?

Dr. Marc Duerden: Ms. Walsh, I'll turn the time over to you.

Susan Walsh: Hi, this is Susan Walsh on behalf of the American Podiatric Medical Association. Thank you for the opportunity to comment.

Dr. Marc Duerden: Ms. Walsh, hold for just a second.

Susan Walsh: Sure.

Dr. Marc Duerden: You're breaking up, and we're only getting bits and pieces. Are you on a cell phone?

Susan Walsh: Let me try for a better spot, and if not, I will. How's that? Is that any better?

Dr. Marc Duerden: Why don't you start your presentation again, and I'll see if it holds steady

for us.

Susan Walsh: Thank you. Again, Susan Walsh for the American Podiatric Medical Association. We will be submitting written comments. One thing I did want to comment, which I think I may have only briefly heard today, is - if the LCD will include or identify or explain other diagnoses, whether or not they are included in the LCD such as burn wounds, trauma wounds, any other kind of wound that's specifically in details, VLUs and DFUs, but some of these products are being used now on other diagnoses and so what will be the status of that? Thank you.

Dr. Marc Duerden: Thank you, Ms. Walsh.

Susan Walsh: Thank you very much.

Dr. Marc Duerden: And we have to - able to hear everything. So, you got to go with position. Anything else? Thank you.

Coordinator: Our next comment comes from Dr. Rashad Sayeed. Your line is open.

Dr. Rashad Sayeed: I just want to piggyback on Dr. Walsh. Including trauma and burn, a lot of people are using it for sacral ulcers. So, some guidance on that would be appreciated. The other thing is, is this recording being publicly available to us to review afterwards?

Dr. Thomas Serena: Yes, it is.

Dr. Rashad Sayeed: Okay. Perfect. Thank you.

Dr. Mark Durden: Thank you, sir. Operator, anyone else in the queue?

Coordinator: Our next comment comes from Heather King.

Dr. Mark Durden: Heather, do you have the floor?

Dr. Thomas Serena: We can't hear you.

Dr. Marc Duerden: Ms. King, are you on the phone?

Heather King: Hello, Dr. Pontarelli is on the line. I think he's having trouble connecting. Shall he just press Star 1?

Dr. Mark Durden: Oh, excellent. We'll have the operator look into that. Did you want to have an opportunity to make a comment?

Heather King: That was the only comment I have. I don't have slides in front of me.

Dr. Marc Duerden: That's fine. We'll see if we can get Dr.Pontarelli on.

Heather King: Wonderful. Thank you.

Dr. Mark Durden: While we wait for Dr.Pontarelli, we'll also have the operator looking for anyone else that may be in queue. And we'll wait for just a second.

Coordinator: I have no further comments in queue. Dr. Pontarelli, your line is open.

Dr. Pontarelli: Oh, hello. Can you hear me now?

Dr. Marc Duerden: Welcome, Dr. Pontarelli, you're on.

Dr. Pontarelli: Okay. Oh, good. Great. So, just talking here representing BioTissue and speaking on their behalf based on my experience. So, I mean, I have some slides here, but basically I'd rather just speak about my own personal experience with it. I have a very busy podiatry practice, deal with a lot of diabetic ulcers and venous basis ulcers, and you just notice that, you know, this product has been getting people better quicker with less applications.

And I'm sure - I haven't heard any of the other speakers. I was in surgery, but I heard - I'm sure that everybody pretty much was on the same page with this, talking about how beneficial it is and how it should be considered for coverage.

Dr. Marc Duerden: Well, Dr. (Pontarelli), thank you for taking the time out of your busy clinical practice to join us. Were there any additional comments or any other final statements you'd like to make at this point?

Dr. Pontarelli: Yes, one. Yes, on the slides, I mean, there's studies that can be referred to, however, you know, I just think that in real life, on my practice, I've treated dozens and dozens of ulcers with this product, and it's - it really worked quite well.

Dr. Marc Duerden: Thank you, Dr. Pontarelli, for bringing us also some of that clinical input, we appreciate that.

Dr. Pontarelli: Okay.

Dr. Marc Duerden: Operator, is there anyone else in queue?

Coordinator: I'm showing no further comments at this time.

Dr. Marc Duerden: Seeing no additional comments, what I'd like to do is bring this open meeting to a close regarding the proposed LCD on skin substitutes and cellular tissue-based products. The comment period for this proposed LCD will continue until 6/8/2024.

On this slide, you'll see how to make public comments on the proposed LCD. We encourage you to submit comments and opinions, and then also provide the basis for those opinions. And we particularly encourage the submission of peer-reviewed, robust clinical studies to substantiate and corroborate the opinions that you have may present.

Having no other comments at this time, I would like to leave just a moment for my colleagues, Dr. Awodele, Dr. Mullen, Dr. McKinney, and Dr. Noel, if they had any comments. Otherwise, we'll bring this meeting to a close.

Seeing no additional comments from my colleagues, we will again express our appreciation to those that took the time out of their very busy schedule to present to us, and we do recognize the time commitment that it does take to come and present, so we express our appreciation for those efforts.

We again will just reiterate that formal comments need to be submitted in

writing, and with that statement, we will bring this open meeting to a close, and I thank you for your attendance.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

END