|  |
| --- |
| First Coast Service Options, Inc.  JN Open Meeting |
| Thursday, April 28, 1 p.m.  Topics:  Proposed LCD DL36377– Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Treatment of Nails  Proposed LCD DL38227– Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) |
| CORPORATE PARTICIPANTS  Juan Schaening, MD – First Coast Service Options Executive Contractor Medical Director  Alicia Campbell, MD- First Coast Service Options Contractor Medical Director  Leslie Stevens, MD- Novitas Acting Executive Contractor Medical Director  Patrick Mann, MD - Novitas Contractor Medical Director  Suzanne Kim Doud Galli, MD, PhD - Novitas Contractor Medical Director  Bradley Davidson, MD - Novitas Contractor Medical Director  Jan Green, RN, MSN, CPC- Novitas Medical Policy Nurse  Nathalie Mohler, RN, BSN – First Coast Service Options Medical Policy Nurse  PRESENTERS  Mark S. Block, DPM – First Coast Service Options Podiatric Medicine and Surgery CAC member  Paul Rudolf, MD, JD- Arnold & Porter, LLP Senior Counsel  William Tettelbach, MD- MIMEDX Medical Director  Allan Staley- LifeNet Health- Vice President & GM Wound Management & Surgical Reconstruction  Eric Lullove, DPM- West Boca Center for Wound Healing Chief Medical Officer  Marcia Nusgart-Alliance of Wound Care Stakeholders Executive Director  Karen Ravitz- Coalition of Wound Care Manufacturers Healthcare Policy Advisor  Jaideep Banerjee-Smith & Nephew Medical Science Liaison and Clinical Strategy Senior Manager  Pedram Zendehrouh, MD, PhD, FACS-Healogics, LLC Associate Chief Medical Officer |
|  |

PRESENTATION

Operator

Good afternoon. My name is Mandy McGarvey, and I'll be your Webex host for today's open meeting. Before we get started, I want to take a moment to remind everyone that this meeting is being recorded. At this time I'm going to go ahead and turn things over to Contractor Medical Director of First Coast Dr. Juan Schaening, Dr. Schaening?

Dr. Juan Schaening

|  |
| --- |
| Good afternoon. I would like to welcome everyone to First Coast April Open Meeting. My name is Dr. Juan Schaening and the First Coast Executive Medical Director. On the phone with me today are my colleagues, Dr. Alicia Campbell, Natalie Mohler, and joining us from Novitas are Dr. Leslie Stevens, Dr. Patrick Mann, Dr. Susan Kim Doud Galli, and Dr. Bradley Davidson, and Jan Green. Please be aware that First Coast Service Options is recording this virtual open meeting to comply with the CMS guidelines. By remaining logged in and connected via telephone or webinar you acknowledge that you have been made aware that this virtual open meeting is being recorded and you are consenting to the recording. If you do not consent to being recorded please disconnect from this virtual open meeting. We are holding today's open meeting to discuss the review of the evidence and rationale for one local coverage determination provision and one local coverage determination consolidation. The proposed local coverage determinations topics for today's meeting are skin substitutes for treatment of diabetic foot ulcers and venous leg ulcers. And the other topic is gastrointestinal pathogens panels utilizing multiplex nucleic acid amplification techniques. During today's meeting, interested parties will make presentations of information related to the proposed local coverage determinations. Please remember, today's call is being recorded and we request that all formal comments be submitted in writing before the end of the comment period on May 28, 2022. At this time, I would like to turn it over to Jan Green to provide a brief overview of the proposed local coverage determination for skin substitutes for treatment of diabetic foot ulcers and venous leg ulcers. Please Jan, proceed.  Mandy McGarvey  Jan, are you still with us or are you on mute?  [silence]  Mandy McGarvey  Jan are you with us?  [silence]  Dr. Juan Schaening  Janice, can you speak? Then since Janice Green is having some technical issues, I'm going to proceed for time's sake and read the brief LCD review. This LCD has been revised to create a uniform LCD with other MAC jurisdictions. Once this revision to the LCD becomes effective, the current First Coast LCD, L36377 application as skin substitute grafts for treatment of diabetic foot ulcers and venous ulcer of the lower extremity and the relating billing and coding article, A57680 will be replaced with the revised policy. This LCD addresses the medical reasonable and necessary threshold for coverage of skin replacement surgery for application of skin substitute graft for chronic diabetic foot ulcers, and venous leg ulcers that have failed to respond to conservative wound care measures for greater than four weeks with documented compliance. The skin substitutes must be used in accordance with the FDA intended use. Coverage will be provided for products in the associated billing and coding guide that guideline meeting the necessary FDA regulatory requirements as of publication, each product has specific designation approved usage. New products will be considered for coverage if meeting the regulatory requirements and criteria. So now we're going to go to our first presenter, and our first presenter is our steam Florida CAC member, Dr. Mark Block. Please, Dr. Block, proceed with your presentation first stating any conflicts of interest and we greatly appreciate your participation. Thank you.  Dr. Mark Block  Good afternoon. Thank you. Can you hear me?  Dr. Juan Schaening  I can hear you well Dr. Block.  Dr. Mark Block  Great. So for full disclosure, I'm the CAC representative for podiatric medicine. I've been a CAC representative for more years and I can remember I've enjoyed working with the carrier. And I think we've had a very constructive relationship and the end results has been very positive. Again, I appreciate the opportunity to speak on this. My comments are based on my clinical experience and understanding and I will get into a brief discussion of some of the items or the items that I feel are of significance and as alluded to any additional information that I feel I may need to add, I will send in as comments. I also would like to say appreciate the hard work and effort that First Coast and staff, as well as Novitas have put in forward in trying to update this policy. I know it's a very arduous process and very challenging to try to come up with something that's equitable and works best for everybody. I also understand that in the end we want the best policy that affects a positive result for our patients, the highest standard of care available. At the same time, we also want to be mindful of any over utilization and potential abuses. We also want to keep the trust fund intact. And with that, I think I'll move forward and go through the items that I submitted. So I believe you all should have a copy of my talking points. I'm going to refer to page 2 of 20, which starts on coverage guidance. And then my first comment starts on page 3 of 20. I'll read the area of significance, and then my comment. It starts off, it is the expectation that its specific skin substitute graft product will be used for episodes of skin replacement surgery for wound care defined as 12 weeks from the first application of skin substitute graft. Assuming its use is not in conflict with the FDA assessments, for example, indications, contraindications have supplied and directions for use, etc. And then we'll jump onto the part that states repeat application of a skin substitute graft within the 12-week episode of skin replacement surgery for wound care may be appropriate for the package insert base on wound artery reassessment and must be supported in the medical record documentation for that encounter. My comment on this is the statement provides guidelines to justify reapplication. It does not state or justify a reason for a maximum of two within 12 weeks. So several of my other comments relate to the two applications, and I'll try to clarify that further as we discussed. But I believe that this needs to be clarified in this policy because there was a little bit of confusion. On one hand, it states a maximum of two in the policy, and on the other hand, it says that it should be predicated based upon the actual product approval, etc. So that I think needs to be clarified because there is some areas for confusion. Then on to covered indications 4 of 20. The area that I commented on skin substitute grafts utilize for the approval FDA intended use. Again, this statement again can support an argument that limitation of two applications in a 12-week episode may contradict quote, approved FDA intended use, end of quote. So again, that goes back to my argument on the two applications. Page 4 of 20, it was written in the draft the expectation is treatment will consist of the fewest repeat applications, that amount of product to heal the wound. It is expected that products are used per the labeling. It is not expected that every ulcer and every patient will require the maximum number of applications listed on the product label. This utilization pattern may subject to focus medical review.  And my comment on this is, again, this is another statement indicating guidance and application which is a little confusing, additionally it does not place a limit of two applications, so again, I think that needs to be clarified on page eight of seven-- eight through 17.  There were citations again, I'm not going to go through each one of them. There was one by Barbara, Carzel, Driver, Levry, Sanders, Zellin, and Carzel.  None of these trials appear to indicate limitations on a maximum number of application of skin substitutes. So if the intent was to use these citations to support that argument, I don't think it was successful in doing that perhaps the intention was for other purposes and maybe I missed something but perhaps that needs to be clarified if there's an intended point to be made with those. Page 3 of 15 on the article. Under article guidance, application codes billed must use the appropriate modifier example right or left to identify the location where the skin substitute was applied or the service will be denied. My comment is this appears to be an error the CPT codes address size and have appropriate codes available. Assigning right and left would add confusion and inappropriate adjudication of claims. The current CPT codes are assigned based on the total amount of barrier regardless of right or left. So I think that needs to be revisited before this policy is finalized. Under utilization parameters, application frequency must follow the product labeling a maximum of two skins substitute grafts. Product applications for wounds will be allowed for the episode of skin replacement surgery for wound care. To find this at 12 weeks from the first application of skin substitute grafts for those products recommended for the labeling to require a second application again we're seeing this language pop up again. And I think this is a little confusing the maximum of two as noted above this as I state is confusing if recommended labeling provides for greater than two applications, given it appropriate clinical presentation and requirements, there should not be this-- the limitation may be in conflict with intended use. And on page 12 of 15, L97.5, non-pressure chronic ulcer a foot, this is not included in the actual policy, where the draft-- perhaps it was an oversight, but this would address the appropriate ICD-10 codes for the four foot or toes. One closing statement I would like to make is, looking through the literature, unfortunately, the two weeks that I had when I was given the heads up on this-- I would've liked to had a little bit more time, so I that I could research that literature a little more. I'm still in the process of researching literature, so there may be some articles that would help substantiate or clarify some of these issues on the two applications, et cetera. But as alluded to, the present literature that I have available and I believe that your staff has don’t clearly delineate, in my opinion, a maximum or a minimum. And I think that being the case we need to really differ back to the clinical experience. I feel putting a limitation is a little too restrictive. I would agree in some cases one application may be more than enough, in some applications two-- in some instances, two would be enough. But there are instances and I can tell you from clinical experience were more than are appropriate. And I also believe in the policy as is written. There are mechanisms to deal with overutilization or inappropriate utilization. And I feel that the policy should differ to that rather than putting on a limitation of two. Unless we can substantiate one way or the other that in fact there are specific limitations or maximum utilization parameters. Again, I want to thank everybody for putting a lot of time and effort into this. I know it's very challenging. I know you all trying to do the best you can to make it equitable for all parties involved. I just like to say I remain available if I can assist in any way with this policy as I have in the past with other policies. So feel free to reach out to me and I will be more than happy to assist as needed. Again, thank you for your time and if there are no questions for me that would conclude my presentation.  Dr. Juan Schaening  Thank you, Dr. Block, we greatly appreciate your comments and you providing us your comments in advancing writing any additional comments that you want to do, the end of the comment period is up to May 28th. So any additional comments that you can provide us in the spirit of improving the policy and providing the best coverage to our beneficiaries, it will be greatly appreciated. So as always thank you for your participation and your commitment to the Medicare program. It's greatly noted and appreciated.  Dr. Mark Block  Great. Thank you for the hard work as well.  Dr. Juan Schaening  Okay, Thank you. So now let's go to our second presenter. Our second presenter is Dr. Paul Rudolf with Arnold and Porter. Please Dr. Rudolf, go ahead and stating any conflicts of interest. Thank you.  Dr. Paul Rudolf  I will Dr. Schaening and thank you very much for the privilege of being able to make a presentation. Can everybody hear me?  Dr. Juan Schaening  I can hear you loud and clear. Thank you.  Dr. Paul Rudolf  Okay, well thank you Dr. Schaening, and everybody from Novitas and First Coast. Can you please go to the second slide? I have a short slide deck that I'm going to be presenting. So this is who I am. I'm Paul Rudolph, I'm a physician, I'm a former contractor medical director and former policy person at CMS for a number of years. And now I practice law at Arnold and Porter and an outside counsel to Organogenesis. Next slide, please. And that's how I put it. So first, Organogenesis, we do appreciate the need to have a consolidation of LCDs and have consistent LCDs across jurisdictions. So we do appreciate that. And we also appreciate the need for documentation to demonstrate that wounds are responding to skin substitutes or not responding to skin substitutes. So we do appreciate those aspects of the LCDs. And we're continuing, by the way, to review the LCD, to review literature because we may want to raise additional points of agreement or disagreement in our comment letter that we will be submitting before the end of the comment period. All that said, today I want to present on behalf of Organogenesis on three items. The first, as a disagreement with the limitation to two applications of the skin substitute per an episode of care. the second is the proposed prohibition on switching from one skin substitute to another during an episode of care. And the third is what we believe is an oversight or an improper assignment of the PuraPly products to the group three list of non-covered codes in the accompanying article. Next slide, please. So first, quoting from the proposed LCD says that greater than two applications of a specific skin substitute graft product within the episode of skin replacement surgery for wound care, define as 12 weeks from the first application of a skin substitute graft. Then it says the expectation of this treatment will consist of the fewest repeat applications and amount of product to heal a wound. It's expected that products are used per the labeling. It's not expected that every ulcer in every patient will require the maximum number of applications listed on the product label. This utilization pattern may be subject to focused medical review. And this is from page six. The next slide, please. So, as a general matter, in terms of the discrepancy, we agree with the previous presenter. Is that there seems to be inconsistency in three parts of the previous statement. One, the limitation to two. The second, to apply product in accordance with the label. And then the third is to say but even though the product could be applied according to the label, we don't really think that all the label applications are appropriate. So first, we did not find any clinical guidelines that support a limitation on skin substitute applications. We know that in the tech assessment that First Coast had reviewed some clinical guidelines, but we were not able to find any guidelines, including the ones that were reviewed by First Coast that supported a limitation. So more specifically, guidelines for both venous leg ulcers and diabetic foot ulcers focused on the evaluation intervals and assessment of any intervention, including standard treatment, use of skin substitutes, or any other modality. The guidelines are silent on the frequency and timing of skin substitute applications. Apply skin substitutes three or more times is within the guidelines if the wound meets guideline criteria for improvement. Right below that we have guidelines on venous leg ulcers from the wound healing society. We cite this specific one, it says selectively use adjuvant agents, topical device and or systemic after evaluating individual patient slash ulcer characteristics and when there's a lack of healing progress in response to more traditional therapies. If significant wound improvement does not occur within three to six weeks of initiating a treatment plan, then re-evaluation of the patient and consideration of other treatment options should be considered. So again focus on selective use of adjuvant therapies after evaluating the patient. Next slide, please. These are the DFU guidelines. Again, same theme from the Wound Healing Society. There should be ongoing consistent documentation of wound history recurrence and characteristics the rate of wound healing should be evaluated to determine whether treatment is optimal. The principle is that ongoing evaluations are necessary. If the wound is not healing at the expected rate, intervention for wound bed preparation needs to be reassessed. The next guideline, I won't read the whole thing because folks can read this on the screen, patients who fail to show reduction in ulcer size by 50% or more after four weeks, should be reevaluated, other treatments should be considered. Then the Society of Vascular Surgery, the APMA, and Society for Vascular Medicine, again, their recommendations focus on evaluation at one to four week intervals, with measurements of the wound. And that the-- By measuring wounds at one to four week intervals, the clinician documents healing progress and identifies the basis for treatment modification. Next slide, please. So it's the view of Organogenesis that the only basis for limiting the number of skin substitute applications should be medical necessity. Physicians should be allowed to apply skin substitutes when medically necessary, to achieve wound healing. We have not found any clinical basis in the guidelines or in the literature that was reviewed by First Coast, or in other literature that we've been looking at to limit the number of applications to two or any other number, and in fact we, again site that Novitas and First Coast both agree that skin substitutes should be used according to their FDA labels. Now with that in mind, we would like to point out that most labels don't mention anything about the number of applications. And I think that's something that needs to be addressed in the final LCD that if there's no limit in the FDA label then it's our view that the only limitation should be based on medical necessity. And again we've rearranged what I have gone over with professional society guidelines that we have not found any literature either cited or not cited by First Coast to support a limitation. And we also want to point out that there is a huge variety of DFUs and VLUs in terms of size, depth, and all of that and it's very important that physicians be able to use the skin substitutes of their choice. Next slide, please. So with respect to switching in a 12-week period, the proposed LCD says switching skin substitute graft products in a 12-week episode of skin replacement surgery for wound care. Exceptions prohibit switching-- I'm sorry. Exceptions should be rare and may be considered on appeal when a medical necessity of the change is clearly documented in the record. We disagree with that limitation. We do not believe that switching from one skin substitute to another should be denied and then have to be appealed. A patient's lack of clinical response to one product may require switching to a different product, especially to a product that's technologically different. In fact, switching could actually result in fewer overall skin substitute applications. And in this connection, I just want to point as a general matter, that there are living skin-- living cell skin products that are a lot of meshes and there are a lot of human tissue products. so there are a lot of products with a huge variety of technological differences. Next slide, please. so with regard of the last item, so it's argued that the PuraPly products were improperly signed to group three. In the draft LCD, Novitas and First Coast both stated coverage will be provided for products in the associated billing and coding guideline, meeting the necessary FDA regulatory requirements as a publication. So this was the only criterion for assignment to group two or group three that we could find in the LCD, however, there are skin substitutes listed in group three that meet this criterion that I just stated and they should be reassigned to group two in the final LCD. Specifically, PuraPly, PuraPly AM, and PuraPly XT, are products that should be resigned to group two. PuraPly as products are cleared by the FDA under 510 Ks, they were cleared under the name of FortaDerm. And that name was changed to PuraPly after commercialization. And here we list the 510 K numbers with the original name and it's possible that the name may have been confusing to Novitas and First Coast and so, we hope that this is a helpful point of information. Next slide please. So we also want to note that all three of these products PuraPly, PuraPly AM, and PuraPly XT are indicated for use in patients with diabetic foot ulcers and venous stasis ulcers and are legally marketed for these indications. We further want to point out that PuraPly AM, and PuraPly XT are the only skin substitutes containing polyhexamethylene biguanide hydrochloride (PHMB), which provides an effective anti-microbial barrier and helps prevent microbes from getting into the wound. The predicate by the way for PuraPly was Oasis which is Q4102. And PuraPly’s FortaDerm was listed as a predicate for Integra Q4104 and Integra Q4108. Oasis Integra, Integra BMWD, and Integra are appropriately marketed as skin substitutes and are assigned to group two. So in other words, the predicates that we use for PuraPly Oasis and the predicate that Integra used for its BMWD product, I'm sorry I'm mumbling here, the integrity products are both appropriately in group two. The PuraPly product should also be in group II because the predicates that we used are in group II. And Integra using one of our products as a predicate, and then Integra being group two means that our products should all be in group two as well. I believe that's the last slide, is that correct? Yes. So with that, I'll end my presentation. Again, we really appreciate the work that you've done. We hope that you will follow the recommendations that we've made in this presentation and we will be filing a complete comment later before the deadline. Thank you very much.  Dr. Juan Schaening  Thank you Dr. Rudolf. We greatly appreciate your presentation. Does any of the other medical directors have any question for Dr. Rudolf or Dr. Block? |

[silence]

Dr. Juan Schaening

Hearing none, let's continue with our presenters. Our third presenter is Dr. William Tettelbach. With Mimedx please go ahead, stating any conflicts of interest, and before you do so, any presenter which I mispronounced their last name is welcome to correct me, and I apologize -- if I had mispronounced the name of anyone. So go ahead, Dr William.

Dr. William Tettelbach

So, I want to thank you and don't worry about the pronunciation. If you have a name that's hard to pronounce, you grow up with that, and that's what you live with. So I really do appreciate the introduction. So, I myself, I just want to give a little background and present any conflicts. One of the conflicts of interest here is the fact that, I am the Principal Medical Officer here at Mimedx over Medical Affairs, but also, been in this game clinically for over 20-plus years. I still practice clinically before I came to Mimedx I was PI on a lot of skin substitute type research nationally. I also was the executive director over the wound and hyperbaric program at Intermountain and was program director over the hyperbaric fellowship and wound fellowship with Duke University. I currently, medical director at several hospitals here in Salt Lake City and see patients in the outpatient and I'm an active Noridian CAC member and was actually involved in the development of the wound care LCD that was released last year, beginning of the year, last year. And I-- really excited to see the adoption of some of the documentation things that Novitas is integrating into the LCD in fact-- it is really appreciated putting further clarification into the LCD on what is needed to be evaluated. And as was mentioned before wound bed preparation and patient preparation is a big part of making these skin substitutes successful. We also noted the fact that these skin substitutes can be quite expensive or costly for the payer system. And we recently actually published two health economic and outcome papers one last July one just recent in March. One was a label the observed impact of skin substitutes and lower extremity diabetic ulcers lessons from the Medicare database from 2015 and 18, and just recently cost effectiveness of dehydrated amnion corium membrane allografts and lower extremity diabetic ulcer treatment. These papers actually show as the first one is an unbranded paper looking at the Medicare data, which is the real world claims data and demonstrating that you have improved outcomes in the sense of lower amputation rates, readmission rates, less ed visits of those patients being treated with skin substitutes, all high bundle product routes is defined by CMS. So the next step was to look at the cost impact. And so there is clearly a cost impact that kind of turns this paradigm on its head, that there is a significant cost saving, so the patient in the healthcare system. When these products are used and they're used appropriately. No one here is advocating inappropriate misuse or overutilization. And we need to somehow define that and address that within the LCDs that get develop. And we are currently actually waiting to start develop a new new skin LCD on the Noridian side. What I also want to note, there are comments that I submitted, and we'll be expanding those within the time that I have is really the fact that there is really no standard training in wound care. It's a multi-specialty specialty and not every product that we have works with the patient. There's no one product that works well. It's just like if you're in infectious diseases and you're told that there's certain susceptibilities and, there maybe underlying bioavailability issues that you have to change midstream to change to a different antibiotic or even treating hypertension, not this, there's not just one ACE inhibitor, there's many ACE inhibitors, and you have to find the one that works best for that patient because there's underlying comorbidities as well as genetics that come into play. So I totally agree that there should not be this limitation on switching to a different skin substitute midstream because there may be the realization that something else is needed and because the one currently being used does not work and why continue to use something that doesn't work? The most expensive treatment is really the one that's not working. So that's just as a minor point. But we're always driven by evidence-based medicine. So when I was overseeing all the wound care within the large institution, we didn't really use anything based just on cost, it had to have evidence behind it. And the payer market drives the same thing. So now you have evidence really looking at your own data - this was actually given to Larry Clarke and Gary Oates. But looking at your own data that how effective these are and how cost-effective they can be.

But the fact is, there are a lot of products out there that don't have evidence and we shouldn't really be necessarily using products based on evidence, not just the fact that they make the criteria for the FDA. Because it's noted in the LCD that not all those that meet the FDA criteria actually meet the criteria of a definition of a skin substitute. So that needs to re-evaluated. There's a lot of products out there that we should really be driving use of those that show efficacy. And right now, level one evidence is the best evidence that we have, we're trying more and more to get real-world evidence, but even registry databases reflect a variation in practice habits. And a lot of those clinicians who have come in later in life or part time, do not necessarily have the training to be utilizing these well, so really using a protocolized approach is what everyone should be doing. And even managed healthcare uses protocolized approaches to make sure that at least the basics are being done right. So I that's one thing I think needs to be addressed. It's not fully addressed in this, where there's a very broad coverage and I think we should have reevaluate that and allow folks to come in as the data becomes available. Now, the next is really what everyone I think is addressing here, is really the confusion on two applications within say a 12 week period. Again, there are some studies out there that have used, I say one initial and then followed up with a second, but these are looking at a much different category that, that most of these wounds don't get treated. One would be looking at a dermal matrix decellularized dermal matrix with folks with exposed bone. Well, first of all, the dermal matrix is a very small percentage of the market. When you look at the most used products from 2015 to 19, over 60% of those is really just three products in the game. And 12% of that is really combination therapy. So people are using combination therapy, I think at times, they don't have a real deep dive on that to find the product that actually works. So the thing is the Medicare data shows the average applications are well beyond two applications. So I think you need-- I think taking a look at that, and looking at other level one studies, and how many were used-- but the fact is, even when you get, say, in a VLU, 60% closure rates-- And then maybe you're going up to 70%. There's a significant percentage of those who may need to go longer. And the Lavery data clearly shows that the longer these chronic wounds, especially diabetic wounds, stay open the higher the percentage, or the risk, of infection. For these folks with chronic diabetic wounds are 4.7 times more likely to become infected. Once they become infected, they're 55 times more likely to be hospitalized, and they're 155 times more likely to be-- to undergo an amputation. So really, what needs to be done with these folks is to get these patients closed. And there's no study of folks with very good high level 1 multi-center prospective trials, where two applications showed any efficacy. There maybe had been granulation, but the wounds are not necessarily closed by that time. So I think this definitely needs to be further evaluated. And using the evidence that's out there to determine that - and again, I totally agree with past presenters - that you should not stop this application as long as there is evidence that the wound is improving every time and then there should be a benchmark just like the Wound Healing Society noted and I think we agree on that. If there is evidence at, say,three to six weeks that you're not getting the closure rates that are expected, maybe even using the sheehan data to help with that, then you need to reevaluate or go back and restudy what may have been missed; was there a perfusion issue there, was there an underlying vasculitis or is it autoimmune disease that wasn't diagnosed? It doesn't mean that the product won't work, it just means that a comorbidity probably hasn't been addressed. So I think that is an issue that needs to be reevaluated and I think you'll hear it more during this discussion because that is, I think, sent some ripples into the providers out there who are on the front-lines. Now, a couple of other things we're going to put comments in on this, but I want to note the smoking. The patient has to be smoking or not smoking. In the wound LCD at Noridian, you just have to document like we always do and should be doing that smoking cessation has been part of the conversation and you are trying to get these folks to stop smoking, but most of these studies, large studies, have not excluded smokers, or the mimetics studies surely did not, and those smokers that were in the treatment group actually had those went on to heal. In fact, it may be the only thing that gets those smokers. As long as they actually reduce the amount of packs a day, or the number they're doing. That's a win. It's very hard to get these folks up, and you have to sometimes start other medications to give them the advantage to do that. And again, the longer you wait for these wounds to stay open, the bigger the risk of amputation. And once they get amputated, then their five-year mortality rate goes up 56.6%. So we're not doing a service by limiting the number of applications. We really have to find out a way to have the appropriate number or the appropriate time to instigate it - which the Medicare data shows 30 days from the initial claim, 30 to 45 days - or sheehan data showing 30-- less than 50% closure at four weeks. Where then you know the rate of probably continuing the same guideline of treatments or course of treatment, your only gonna have a 9% chance of healing at 12 weeks.

The other is actually the A1C. We're gonna put a comment on that but the A1C, having an elevated A1C, does not inhibit wound closure. It may delay it. In fact, Utah Medicaid at one point would not allow hyperbaric therapy on patients with an A1C greater than eight. And we had our fellows, in the fellowship program that I was overseeing do a Meta Analysis on all the diabetic studies that were done with A1Cs and low and behold, even though those folks had elevated A1Cs they went on to heal. It's just that there's a delay healing. It's really more of their offsetting or dysfunction of the immune system, not the ability of the wound to heal. So, obviously, re-establishing or lowering, re-establishing a normal A1C or getting it lowered is always going to benefit the patient and will help with the outcomes and the complications that can occur. But again, delaying treatment because of an elevated A1C or the time needed to get that A1C down is not in favor of a patient with a chronically exposed wound that needs to get it closed because of all the risk factors of the exposed wound alone. So, that really I think touches on a little more than what's been stated so far today. I'd be happy to provide those papers that I indicated the titles to that have been published in a peer-review journal. We will put further comments based on all of these talking points. So, I really appreciate it, given the time to express the concerns and actually maybe help drive more evidence-based medicine within First Coast. If there are any questions, I'd be happy to take them or even if you can direct comments in my direction afterwards, I'd be happy to respond.

Dr. Juan Schaening

Thank you a lot for your comments doctor do any of the other CMDs have any questions?

[crosstalk]

Go ahead.

Dr. William Tettelbach

One thing I do want to note, I didn't state that but the Utah Medicaid reversed their decision and took the A1C off of the criteria as an exclusion because of the meta-analysis, which is a public page, is published, that we did, so just that's, evidence sort of driving medicine always good.

Dr. Juan Schaening

And that's our intent. And that's our intent. So the papers that you feel that will help us support an evidence-based approach are certainly welcome as well as any additional comments that you can provide us before the end of the comment period. So I think that we have the same goal. So we certainly appreciate your comments on behalf of evidence-based approach. So any and to all the presenters any papers to support your positions that you can provide to the contractor are certainly welcome. Any other questions for the presenter? Okay, he didn't none. I want to thank him again and then move to our fourth presenter. That is Allan Staley, with LifeNet Health. Please go ahead stating any conflicts of interests?

[silence]

Dr. Staley, you're on mute.

Unmuted.

There you go. Thank you so much. Go ahead with your presentations and statement of conflict of interest. Thank you.

Yeah, my name is Allan Staley. I'm the vice president and general manager for wound management and surgical reconstruction for LifeMed Health. LifeMed Health is a not-for-profit provider of organs and tissues. I'm currently the manufacturer distributor of two CTPs for advanced wound care in the US domestic market, and those are DermACELL and Matrion. And there was I think previous speakers that's referenced cited published clinical evidence, and DermACELL is the CTP associated with two of your cited published clinical evidence provided in your LCD. Our comments today will be in question form. Whether there's any interaction - obviously that it is up to the panel - with the objective to learn more about the genesis in tenants or visions of your graft LCD article. A question center around two topics. The limitation of two applications of CTPs and two, the criteria used to list Qcode CTPs in reference group two. The covered products versus group three, non covered products. I'll just state all four questions and is there any questions back or interest in commenting, we would certainly appreciate any feedback. Are questions are, one, to the extent of any, it's First Coast review and consult with commercial air policies in formulating each draft LCDs; Two, to what extent, if any, did the FDA regulatory status of skin substitute products affect it's placement in group two covered products versus group three, non covered products; Three, third question, does First Coast consider the literature search results provided in the draft LCDs to be generalizable to the Medicare beneficiary population and typical outpatient sites and service; And our question and final question, four, what process will First Coast implement to address cases of Medicare beneficiaries with documented clinical need for additional applications of CTPs beyond the proposed limitations too. And we will be providing a full set of comments with supporting materials for First Coast consideration before the May deadline. That concludes our comments. If there are any questions, I'm happy to answer.

Dr. Juan Schaening

So, thank you for your presentation and your questions. Your questions will be formally addressed on our comment response document. At this part of the meeting, I'm going to do certain comments that will address some of your questions. But for time's sake and since there has been recurring subject matters on the commenters that I will be addressing with my comments at the end. I think that I will defer my comments for after the last presenter. But we certainly appreciate your questions. They will certainly be addressed on the comment response document. Now I open it for the other Contractor Medical Directors you have any questions for Dr. Staley?

[silence] okay hearing none I want to thank him again. I will then move to our fifth presenter. That is Dr. Eric Lullove with West Boca Center for Wound Healing. Please go ahead and state any conflicts of interest. Thank you.

Dr. Eric Lullove

Thank you, Dr. Schaening. Can everybody hear me?

Dr. Juan Schaening

Yes. I can hear you loud and clear.

Dr. Eric Lullove

Thank you. I'd like to thank the-- I'd like to thank the medical directors and the contractor for giving us the opportunity to address you in this forum. I am Dr. Eric Lullove. I am the chief medical officer for the West Focus Center for Wound Healing. I am also acting in capacity as a representative of the Wound Healing Society on this call. My other conflicts of interest have been submitted to First Coast and Novitas in the documentation part of the meeting. Just to give everybody some background, the Wound Healing Society was formed in 1989, and we are the premier scientific organization focused on wound healing. We're a nonprofit organization composed of clinical and basic scientists and wound care specialists. And the mission of the Wound Healing Society is to improve wound healing outcomes through science, professional education, and communication. We are currently over 500 members and representing both academic and clinical specialties across the United States and internationalists. So thank you for allowing me to address you guys this morning-- oh right, excuse me, this afternoon So I have a few points I would like to make. The first one is basically on the nomenclature that the continued use of the term skin substitutes is not accurate at this time. We have been working very closely with the ASTM to change the nomenclature of these tissues and these products and at a time years ago, when these tissues were placed in clinical procedures, they were initially used as substitutes for skin grafts, but as we've moved and progressed into chronic wound healing these tissues have been more used as weekly temporary coverage and the term cellular and or tissue based products for wounds is a more accurate description. So I'd like to make sure that that is put into the record, please.

Moving on, I'd like to cover something into covered indications. The third item in my list that I had submitted as a bullet point was that the venous clinical severity score that you have placed into the policy was actually as a recommendation for measurement for venous leg ulcer disease, was actually created as an inadequacy of the CEAP classification.

And it's confusing as a provider and I am in private clinical practice as well, that the contractor in this case you guys need to be very specific as to which specific measurement you want to the clinical record. Because it's confusing the providers to have two separate venous leg ulcer documentation systems to have coverage approved for products. So I would recommend that you either stay with this CEAP classification and keep it simplified, or convert everything to VCSS which is a little bit more specific and disease appropriate. I would also like to thank the other presenters that have come before me that have brought the two application limitation, and that's going to be my next point.

It's a huge issue as a private clinical provider. Again, I don't need to address the FDA clinical indications for these. The others speakers have done that. My issue is in the literature review and in the wound healing societies guidelines. That there is no limitation on the number of applications for any specific product. None of the sources have ever limited, in any clinical capacity, any number of applications in the studies that you have cited in this document. And as a stakeholder, as a resident, and a practicing provider in the state of Florida this is not only very concerning, but also very disrespectful for the years of work that we have put in to heal patients. To make sure that they stay out of the hospital. To make sure that they maintain some level of healing in an outpatient setting. What you are asking for is a big problem. You're asking for these patients to be readmitted back to the hospital. You're asking them to have increased outpatient surgery for rotational flaps and free flaps, and all other advanced surgeries that they may not be really indicated for. But out of necessity are going to have to have it. You're asking them to increase the use of outpatient IV antibiotic therapy, which is going to increase the rate of possible nosocomial resistance to bacteria because we're going to have to give patients more antibiotics. And, you're going to actually increase the cost of specialist interventions because these patients are going to wind up in the hospital. So as result of limiting the number of applications you are, you are setting up a domino effect of actually increasing the cost of care across the board for every single one of these patients, whether they have a DFU or VLU. The other thing too is in that same policy, you've talked about wastage, and in many hospital systems, the provider does not have the responsibility of deciding which products are placed on the shelf. Sometimes they are, they are held beholden to the medical directors of the facilities, to the merchant, to the, to the contracts that the hospital systems are governed under. And they don't have a choice as to which products are stocked in which sizes, so it's not always feasible to use the smallest size for every potential wound because of the number of SKUs available from every company and not every product maybe have multiple SKUs to change the excessive wastage issues that you placed into this policy. So I would suggest that you remove that portion from the policy. At least take the burden off the provider because it's not -- a lot providers work hospital outpatient departments and their employed physicians and don't have the ability to make that clinical decision at least from a materials management perspective. My next point is moving into the summary of the evidence which is where I really feel that the contractor here has failed the stakeholders. In paragraph three under "Evidence-based Guidelines for Standard of Care," you've listed the ABI is below 0.9 yet have provided no reference in the citations outside of a guideline from the Society for Vascular Surgery. But, you did not cite why 0.9 was an appropriate number and you have not gone into any effect and discussion on most diabetic patients are not below .9, they're actually above 1.1 because they've got calcific sclerosis of the arteries. And there's been no other conversation in this document on making sure that these patients have an appropriate vascular assessment beyond an ABI. You've got in that may require skin perfusion pressure, may require TCOM, toe pressures. So my question to the contractor is as a supplement, when is it going to be appropriate on a case-by-case basis where the contractor decides that in this particular patient, patient one, it's okay for them to just have an ABI but in patient two, you're requiring more additional vascular documentation without any background information on the patient? it seems too arbitrary in the comments in the actual policy that says, "May." And that's problematic because it's not specific, and it leaves too many doors open for interpretation on a case-by-case basis on the contractor level. It's not trusting the clinical providers to make the proper medical necessity decisions that we are charged with with our beneficiaries. I'd like to thank Dr.Tettelbach for bringing up the HbA1c issues in paragraph seven under evidence-based guidelines because there are-- I have provided three sources of references for the contractor on-- there is recent data and research that shows that Medicare beneficiaries, particularly over the age of 65, who are diabetic, who are type 2, with A1c levels below 7.5%, have an increased mortality rate. The source of LeRoith , Biessels and Braithwaite in treatment of diabetes in older adults, which was a clinical practice guideline by the Endocrine Society, literally stated that you want these patients, A1cs, above 7.5% to keep them from having an event that could cause mortality. So the use of A1c below 7% in the policy is not clinically accurate, nor is it medically prudent in some of our patient populations. And then, in the third source I listed in my comments that I submitted the study by Riddle and Gerstein that "The hemoglobin glycation index identifies subpopulations with harms or benefits from intensive treatment in the ACCORD trial". And that was in Diabetes Care in 2015. I think the contractor needs to look at that study very specifically because the ACCORD trials was very elaborative in the mortality rate of patients with really low A1C levels that were type two diabetics. And the final point I'd like to make to close out my comments for the afternoon is in the technology assessment that you've created here in this policy. It has been very painfully clear that the contractor did not use real world evidence or even look at the 21st Century Cures Act in their utilization in this technology assessment and literature review. There is no evidence that you used any time of registry data, real world data, or even claims data in your analysis that you've published. All the studies of RCT design and I thought it was very interesting that every clinical study that you have referenced it was "industry sponsored studies. As a multi-specialty specialty, we do not have the benefit on a grand scale of NIH grants, of grants from the federal government to run high-level RCT studies. We just don't have that ability. So unfortunately it has fallen a lot on industry to sponsor a lot of the RCT designs that we have created. Now we do our best jobs as researchers to minimize bias, to try and be as inclusive in the inclusion criteria and to account for the patient populations that we are going to be treating. Unfortunately, this is the only route that we have for clinical research sometimes. And out of that clinical research that you made available, you only utilize three systemic reviews in 22 RCTs of 16 products and you have ignored RCTs that have recently been published, that show efficacy in use in non-progressive diabetic foot ulcers, specifically with some new Omega3 products that are on the market and other products that have shown level of efficacy above the standard of care. That had no minimums or limitations on coverage. It's to me having done this for a number of years as a stakeholder and trying to work with First Coast on issues. It's that I do believe that the contractor has biased its own policy at this point by negating the use of the 21st Century Cures Act. The other thing that I wanna address is a closing discussion is that I don't really think that the contractor really understands the wound healing paradigm and the providers that service the beneficiaries that are in question here. I know that as a-- and I appreciate all the work that Dr. Block does on behalf of the Florida Podiatric Medical Association. But I, again, as a leading wound care researcher in clinical specialist in the state of Florida, I've never been reached out to, from First Coast to help craft the policy, to help guide the contractor, to write a sensible policy. Instead, what you've delivered to us is a document that's rife of errors. That's factually inaccurate and very provocative in nature. And as this policy currently stands, it will detrimentally harm patients of these populations and will lead to an increase of care. So I would like to caution the contractor very carefully that this policy, as it's currently written, is not helping patients. It's not helping the beneficiaries that you have charged us to take care of. And like my other speakers before me, I am available to the contractor to help formulate a policy to answer questions to be a part of this process to make this sensible and to make it worthwhile for these beneficiaries to get the proper care. So I'd like to thank everybody for their time this afternoon, and I'll be available for questions and comments. And the Wound Healing Society will be submitting our own individual comments, as well. And, again, thank you very much.

Dr. Juan Schaening

Thank you that we appreciate your comments. And we will address them on our comments response document. Any supporting literature, as I spoke to other presenters is certainly welcome. Any questions from the other CMDs?

Dr. William Tettelbach

Are you allowed to ask a question?

Dr. Juan Schaening

Yeah well, yes, go ahead.

Dr. William Tettelbach

So one question I had you mentioned about the the ABI, would you agree that the ABI number or getting an ABI really is for the purpose of understanding you may need to get evaluated for a intervention, but not necessarily. That not using a product that has bio activity that could cause local changes, say angiogenic changes that may be the only hope for a patient who is not a candidate for say a angioplasty or endarterectomy or something like that. And that’s to Eric.

Dr. Eric Lullove

I'm sorry. Who asked the question?

Dr. William Tettelbach

Oh, this is Bill Tettelbach, I'm sorry.

Dr. Eric Lullove

No, I'm not saying that the ABI should be the only reference point and if patients are or , have say severe enough PAD where they have a diabetic foot ulcer or a mixed disease venous leg ulcer, then that is the only product available to them and they can't have an-- they can't undergo an intervention or surgical bypass, or, if that is the only route that they have, they should be entitled to get that procedure. They should be entitled to that procedure and that tissue product. Absolutely.

Dr. Juan Schaening

Thank you. Any other questions?

Dr. William Tettelbach

Yeah. Thank you.

Dr. Juan Schaening

Go ahead. Sorry to interrupt.

Dr. William Tettelbach

No, no, I said thank you. That's all I was saying.

Okay. Thank you so much. I appreciate your question. Thank you. So let's move forward then to our next presenter. Our six presenter is Marcia Nusgart with the Alliance of Wound Care Stakeholders. Please go ahead stating any conflicts of interest. Thank you.

Good afternoon. yes, this is Marcia Nusgart with the Alliance of Wound Care Stakeholders. I am it's executive director, the only conflict of interest would be that those members of the Alliance do pay a membership fee. So we appreciate the opportunity to provide our comments on the skin substitute LCD, and the accompanying LCA. The Alliance is a nonprofit multi-disciplinary trade association of physician and medical specialty societies, clinical associations and patient associations who missioned is to support 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. We have a number of different comments today, and obviously we will have very detailed written comments mailed to you before the deadline approaches. As Dr. Lullove had mentioned that one area that the Alliance is concerned about, before we get into the regular detailed issues with the LCD and LCA is really the use of the term, "skin substitute," quote unquote. This term is not a technically accurate item, doesn't really describe the technology that's either currently or will be in the marketplace for products that contain living cells or constitute tissue based products intended for use in the management, treatment, or healing of chronic ulcers. Historically these products have been referred to as quote, unquote, "skin substitutes" in reference to their initial use as substitutes for skin grafts in clinical procedure. However, over time, the usage of these products shifted towards chronic ulcers where skin grafts are infrequently used and not standards of care. Moreover, newer products in this category look nothing like skin and indeed have not been designed to function as skin replacements. Thus there's a need to define terminology in the context of chronic nonhealing ulcers as opposed to skin grafting procedures. As such, we would recommend that First Coast adopt the term cellular and/or tissue-based products for skin wounds. Otherwise known as CTPs which does accurately describe and is broadly inclusive of both current and future technology. Would respectfully point out that other organizations, contractors, and the wound care clinical community have adopted this verbiage and to underscore the importance of this nomenclature, the ASTM had created an actual unique standard guide for CTPs and has recently updated this.

So let's go to the revisions contained in this draft. We have many concerns with the draft LCD as it currently is written and many of the speakers before me have mentioned many of them. But for the purposes of the public meeting, I've narrowed our concerns down to four. First, many of the statements limitations in the policy do not seem to have the scientific evidence to support them. We have great concerns that a thorough evaluation has not been done since First Coast is not only omitted known published evidence but old evidence was cited and often evidence cited contradicts statements in the LCD that the evidence was used to support. Number two, utilization parameters that have been provided in the draft LCD seem arbitrary will negatively impact patient care or not supported by the evidence provided by First Coast. Number three, there's conflicting, confusing, and or incorrect information contained in the draft LCD which is not only problematic but at times also clinically incorrect. And finally, we have some significant clinical procedural issues with the release of the draft LCD. So I'll take just a few minutes to elaborate briefly on each of these points. Number one is the evidence. We'll provide a more detailed discussion on evidence in our written comments but again many of the speakers before me had talked about the confusion in this policy regarding the number of applications of a CTP permitted under this draft. Where the draft policy permits two applications of a CTP, however in the literature cited in the policy directly contradicts the limitation. Rather the evidence cited in the policies depending on the product being utilized and the number of applications ranges from 1 - 8.9 based on the studies cited in the policy. We couldn't find any evidence supporting two applications as being clinically justified and would appreciate First Coast advising us as to where the evidence is located. And as you're aware, 21st Century Cures does require evidence to be utilized to support the positions taken in an LCD. We have not found any to justify this change in the policy language and believe that allowing only two applications is not clinically appropriate. So number two along those lines is utilization. The limitation of two applications in an episode defined as 12 weeks being not medically reasonable necessary is not only contradictory to other statements in the draft policy that products should be used based on their labeling instructions. It's not supported literature as noted above. The FDA labeling for some products requires re-application every seven days while the FDA labeling for other products requires re-application every two to three weeks. So it's very likely that if a product requirement is to apply the product five times every three weeks, the clinician will be over the number of applications under this policy, all while following the FDA labeling for product usage. Moreover, if the LCD limits treatment to 12 weeks, some of these products will not be able to be used since some of them, according to their labeling require multiple treatments and a span of time that would exceed 12 weeks. The alliance is concerned that clinicians would always have to justify utilizing the product chosen to treat their patients, even though they're following the FDA labeling for the products covered under this policy. This in itself is problematic. However, even more, troubling is that the two application limitations are not founded on any evidence in the literature as I just mentioned. We're in disagreement with the two application limitation. We urge first case to simply include a statement that the product should be applied in accordance with the FDA labeling of the product, which places the responsibility on the physician or clinician to apply the product correctly and document in the files so that it would be sufficient to show that the physician, clinicians was following guidelines for the product being utilized. Number three, there's many examples of incorrect and inconsistent or confusing language contained throughout this LCD. One of them was examples that Dr. Lullove and others mentioned about the hemoglobin A1C. I won't belabor this point. I think that Dr. Lullove addressed this very accurately just to say that we disagree with the statement where they talk about adequate glycemic control of hemoglobin A1C defined by this policy as less than 7% is recommended to reduce the incidence of D abuse and infection. So we disagree with this. Clinically, we're going to stay evidence from the American Diabetes Association and their standards of care, and we believe that this section should be revised. Also, there's very inconsistent language throughout the LCD on what's a chronic non-healing wound? In some places the LCD defines this as a wound that's not healed from one to three months. Other places, it says greater than four weeks. And yet, in other places there are other measurements of time define a chronic non-healing wound as a wound that does not respond to standard wound treatment. Four weeks is more consistent with the literature and with other LCDs and NCDs related to wound products, therapies, and devices. The Alliance recommends that First Coast utilize the standard by which all policies have been written, and use the 30-day or four-week timeframe, and not the one to three month measure of a chronic non-healing wound which was stated in the policy. The range is too long, and it creates ambiguity. The literature supports the 30-day or four-week timeframe, and it's the standard which all clinicians follow prior to proving it in the advanced therapy to their patients. Now, what's interesting is the title of the LCD is Skin Substitutes for the Treatment of DFUs and VLUs. So why does this policy consistently or constantly refer to the pressure ulcers which have completely different etiology and other types of wounds? There's no reason for this, and it causes confusion, given the limited nature of this policy. We request that First Coast only refer in its LCD the types of chronic ulcers that are subject to the policy and delete reference to any other wound or ulcer type as well as the term "Wound" as DFUs and VLUs are chronic non-healing ulcers. The last issue is procedural. It may be one of the most important of all. As Dr. Lullove also mentioned that we're disappointed that First Coast did not engage any stakeholders, or at least it seems that way, including convening a meeting of it's CAC to create questions and discuss the evidence for this draft LCD. Many of the clinical errors in this policy, as well as the incorrect use of the evidence may have been caught prior to this draft being released. We would recommend in the future that the Alliance could serve as a resource for the First Coast Medical Directors, since we serve as an unbiased multi-disciplinary knowledgeable clinical resource for information and as a collaborator. We can address any would care related subject matters. As we mentioned before, we consist of physicians, surgeons, podiatrists, physical therapists, nurses, and dieticians. We can help you with technical questions, create educational seminars for your staff, or convene an education seminar on CTPs as we've done with CMS staff in the past and we probably will in the future. We hope that you will utilize our expertise to help engage and insure that this policy is well-balanced and clinically accurate. We really do appreciate your time in having this public meeting today. Thank you so much. We're happy to answer any questions for you.

Dr. Juan Schaening

Thank you. We appreciate your presentation. Do any of the Contractor Medical Directors have a questions for the presenter? So we appreciate your presentation. We will welcome, as stated, the more written comments and more literature for the contractor. Hearing no more questions, we will move forward to the next presenter. Our seventh presenter is Karen Ravitz with the Coalition of Wound Care Manufacturers. Please go ahead, stating any conflicts of interest. Thank you.

Karen Ravitz

Thank you so much and I hope you can hear me. Good afternoon. My name is Karen Ravitz and I am the health care policy adviser for the Coalition of Wound Care Manufacturers. I do not have any conflicts of interest other than our members do pay a membership fee to participate in our organization. Thank you again for the opportunity to provide the Coalition's comments on the draft LCD and the accompanying LCA. Founded in 2000, the Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. Our members manufacture cellular and or tissue based products for skin wounds or CTPs, which I know you've been hearing this nomenclature now with several speakers. It is the nomenclature that is replacing the term skin substitutes. We do have a best interest in ensuring that this policy is clinically sound and based on evidence. The coalition has major concerns with this proposed LCD. Unfortunately, evidence has been omitted from this policy review and the evidence that has been utilized is either not the most current evidence available or is used in such a way that is contradictory to the points First Coast is trying to make. Furthermore, the policy is fraught with clinical inaccuracies that ultimately will be detrimental to patient care.

The coalition recommends that First Coast pull this draft policy, work with stakeholders, and the CAC to create a more accurate and well-balanced policy. And before getting into a couple of problematic areas in detail I would like to list some of our preliminary concerns with this policy. And they include, again you've heard this from previous speakers. The use of the clinically inaccurate term skin substitutes, rather than cellular and/or tissue based products for skin wounds or CTPs. Throughout my presentation I will refer to these products as CTPs and not skin substitutes. The lack of a consistent and accurate definition of what is a chronic non-healing wound is also problematic. It should be 30 days or four weeks, as is already standardized and used by CMS and other A/B MACs rather than the range of one to three months, greater than four weeks, no less than four weeks or other ranges of time lines that have been cited in this policy. Also, there is some incorrect terminology describing the application of CTPs as an adjunct therapy rather than an advanced therapy. There are admitted coverage of products in the LCA including many sheath products, which has been referred to by previous speakers as well. There is inappropriate use of the term wound throughout the policy, given the fact that the title of this LCD and LCA is for DFUs and VLUs only. And similarly, the use of the terms pressure ulcer, decubitus ulcer, burns, and trauma throughout this policy which, again, specifically states it only addresses DFUs and VLUs. There's also an omission of a significant number of IC10 codes from the LCA that should have been included. As just one example, it is concerning that First Coast only identified codes with the .621 suffix, which is for the foot only, and has excluded any patient with a diabetic ulcer, even when just above the ankle. The increase in the smoking cessation timeframe prior to the use of a CTP to six weeks is not only problematic, it is not based on any evidence cited by First Coast in this policy. And furthermore, the number used for the measurement of the hemoglobin A1C is too low for for this this patient population, and I know others have addressed that concern as well. There's also no reference for the ABI of 0.9 provided by First Coast. And as a result, there's a level of uncertainty as to where that number came from, because there's no citation. The inability to switch products or use additional applications when medically necessary is problematic and it has been addressed by other speakers as well. And also there's a lot of inconsistency in the policy where First Coast has stated that something is recommended and then later it's being required. And that's problematic. Is it recommended or is it required? And one example of that is a venous clinical severity score or a VCSS. In one part of the policy, it says it's recommended and later is required. First Coast also provided reference to the tissue reference group or TRG. TRG is used for coding and not coverage, and a provider should not be required to provide a TRG letter in order to use any given product. Providers will not have those letters and not all CTPs require a TRG in order to obtain a code. The reference to synthetic occlusive dressings throughout the policy is confusing because a synthetic CTP is not a dressing. Synthetic products should be treated like all other CTPs and not singled ruled out as CMS has included them in the definition of what is the skin substitute in recent rulemaking. And finally, the requirement, and this has been brought up by a previous speaker that clinicians utilize the smallest package size available for purchase from the manufacturer. I think Dr. Lullove actually addressed this, it's not appropriate. The clinician does not control what is purchased whereas on hand at their facilities, they simply use the best product to treat their patients that is either on their formulary or on the shelf at their clinic at the time of treatment for their patients. All of the issues I just mentioned are just a sample of areas of coalition concern. And we will be providing significant written comments on these issues. And therefore I'm not going obviously into any detail on them, but I did want to highlight a couple of specific areas that I would like to get into a little bit of detail that we are extremely concerned about, and believes First Coast could have benefited from CAC and stakeholder involvement. They include but certainly are not limited to, the first issue being the limitation section in the LCD, where First Coast allowed only two applications for a specific product, we submit as have others that have spoken before me that this is an arbitrary application limitation that is not based on the evidence in general nor is it based on any evidence cited in the policy itself. In fact, the evidence cited in the policy either shows the number of applications to be higher than the two permitted under this draft policy, or is very clear that the number of applications should be based on the labeling instructions for the specific product being used. And so basically if the clinician follows the product labels and then they're going to be over, potentially, the number of applications under this policy, while following the labeling instructions for the CTP being used to treat their patients. Or they're going to be required to stop treatment midstream, prior to the wound being healed, in order to comply with the requirements of this draft LCD and this seems counterintuitive, is clinically detrimental to patient care. Furthermore, the two applications limitation is also contrary to several provisions stated in the policy in which First Coast specifically states that the labeling instructions need to be followed. So, as a result, the coalition just recommends that First Coast eliminate any specific limitation and rather simply state that the number of applications need to adhere to the product labeling instructions. The second issue that I wanted to speak about, a little bit more in detail is with respect to CTPs being defined as surgical supplies. Specifically, the language used in this draft states that all though skin substitutes have attributes of both biologicals and devices, the current position is that these products are best characterized as surgical supplies or devices because of their required surgical application and their similarity to other surgical supplies. In fact, this isn't a current position, this language was used in the draft-- in this draft policy was taken directly from the calendar year 2015 hospital outpatient PPS proposed rule. In which CMS was trying to justify moving the pass through application process for skin substitute from the drug and biological process to the device process. There were legal reasons why they should not have taken place, but the agency moved ahead to finalize it as written since CMS wanted to limit the number of products granted pass-through status at that time. And this being said, that statement was used for a specific purpose with respect to pass-through status but has no place in this draft, LCD. CTPs are not surgical supplies. They should not be referred to as surgical supplies. This reference is simply clinically incorrect. As CTP promotes wound healing by interacting directly or indirectly with the body tissues, there is direct biological effect in the wound bed as a result. The role of CTPs is not to cover and protect wounds like a surgical dressing, but rather to stimulate endogenous healing. Although whether or not an individual CTP is capable of exerting effects on wound healing must be determined by adequate evidence.

Furthermore, CTPs are distinct from surgical dressings and specifically, the AMA-crafted application codes for them in the surgical section of the CPT book, because they require specific wound bed preparation. These codes apply to the surgical application, no matter whether they're done in a physician's office or provider-based department. And they apply to all CTPs and must be applied by a physician or nurse practitioner, not by a nurse or physical therapy, and they must be fixated. A CTPs is simply not a supply of any kind. Now a wound or surgical dressing is a covering and considered a supply. It's a material that's utilized for covering and protecting a wound, helping to maintain optimal wound environments and shield the wound against the environment without exerting direct effect in the wound bed. And often surgical dressings are chosen based on whether they help with exudate or mechanical protection, shearing, or friction. As such, it's completely inappropriate to refer to CTPs as surgical supplies, and that language should be stripped from the policy.

And finally, the coalition is concerned that this policy is not based on evidence as is required under the 21st Century Cures Law. We recognize their studies and literatures that have been cited in this policy that were supposed to substantiate First Coast positions, but after review of the literature, it's clear that the evidence cited does not substantiate the significant changes that First Coast is attempting to make. And as such, the coalition once again requests that First Coast work with the CAC and stakeholders to ensure that the policy language is based on evidence and will not negatively impact patient care. And with that I thank you, and I'm happy to answer any questions you may have.

Dr. Juan Schaening

Thank you. I greatly appreciate your presentation. Do any of the CMDs has any questions for the presenter? Hearing none we will address your comments and questions on our comment response document and we will move forward to our next presenter. Our seventh presenter is, sorry, our eighth presenter is Jaideep Banerjee with Smith and Nephew, please go ahead stating any conflicts of interest. Thank you.

Jaideep Banerjee

Thank you very much, just making sure you can hear me?

Dr. Juan Schaening

Yes, we can hear you. Thank you.

Jaideep Banerjee

Perfect. Thank you much. My conflict of interest is that I am an employer of Smith & Nephew, this is a company which manufactures and distributes some of the CTPs, that are affected by this proposed LCD.

I lead the clinical R&D strategy for biotherapeutics at Smith & Nephew, and also the medical science liaison team for wounds. So there are comments that I've already submitted, but I'll narrow it down to three major concerns that I want to, touch upon in my time, and as has been repeatedly mentioned by a lot of the panelists today, I think the top concern is defining a maximum or minimum number of applications for some of these CTPs. In fact, the proposed LCD recommends using a CTP or a skin substitute as per the product IFU. But as far as I'm aware, there is no product where-- or, no CTP which has an IFU which defines or which limits the number of applications. I believe Dr. Block and Nusgart they mentioned that-- I agree to that that I looked at literature, and I was not able to find any literature which justifies this number of applications, restricting the number of applications to two. And WHS and SAWC guidelines also does not mention any limitations of application of these skin substitutes.

So I'm going to point-- and some of these clinical evidences have been mentioned before by the previous speakers, but I'm also going to point to some of this evidence which actually suggest the contrary to restricting to these two applications.

So if you look at real-world evidence-- and I'm going to start off with Dr. Armstrong's study which was published in 2021. I believe Dr. Tettlebach had mentioned this study already. If you look at that-- and that paper looked at Medicare patients from 2015 to 2018, and the average number of applications for skin substitutes-- and this is, indeed, a unrendered paper, so includes all the different kinds of skin substitutes, right? So the average number of applications that's reported in that paper is 3.7, which is again much higher than the two applications that is being proposed in the sensitive. Then if you look at Level one studies for DFUs as well as VLUs, almost pretty much all of these studies have at least an average number of applications for the wounds that have closed in the range of about four to six. And there is, I could not find any Level one study which says that the mean number of applications for the ones that have closed is two or less.

So Level one study, as well as real world evidence, suggest that the number of mean of applications is actually higher than what has been proposed to. Now, I think we need to keep in mind that every wound is not the same, right? Every person is different, and the physiology is different. And so every wound is different. So how many applications is really needed for a particular wound to close? It really depends on the initial wound size, the wound depth. The core morbidities that the patients have. If the patient is radiated, radiated wounds and troubles , they don't tend to heal in a specific amount of time. You need much more help for those wounds. Patients with high A1Cs. So I mean, all the RCTs and real world evidence point to the fact that in a similar patient population it was do see the same number of application, it really doesn't vary from product to product. If you look at any product RCT will still see the 4 to 6 applications. It really depends on who the patient is and how bad the wound is. And so I think this decision should be left under the clinician to assess the wound and then decide if this wound needs more number of applications or not, rather than restricting that number of applications and actually affecting the patient, yeah. Another paper I think I like to point out is recent paper which is published by Dr. Dobson, the ones published in 2022, and this was, they had validated patients medical history from 2013 to 2017. And so both this paper as well as Dr. Armstrong paper, both of them suggest that not only should we be concerned about the wounds that are being closed, but for the wounds that are not being closed in that specific amount of time, and repeated application can still lead to the probability of, an improved probability of wound closure, reduction in wound size or reduction in application or ED, hospital readmission, cost of care. So ulcer records will tell you is all of these parameters which you see, you see those clinical benefits showing up as you keep on applying some of these products. In fact, if you look at the Kaplan-Meier curve in a lot of these publications and if you see many of these products are weekly applications, right? So if you're restricted to two applications, that means you are pretty much looking at that two-week data. If you look at there, there's almost no difference between when you're applying a product, as opposed to when you're applying no product so there is a big chance. So there is a big chance and the benefits that we achieve from a lot of these CTPs, this is a very mental process. So there is a big chance that if you are restricting it to the two applications, you are losing the progress that you are making in that two applications and you may end up actually wasting the entire money that you spend on those two applications because the wound will just revert back to it chronic phase and you may not be able to bring the wound out from that and lead to closure. So, I mean, even if you look at the previous LCD or the CMS LCD 35 or 41, I believe this was the previous one, they even mentioned skin substitute, grafts and quo from there, skin substitute grafts would be allowed for the episode of wound care in compliance with FDA guidelines for the specific product, not quick, see 10 applications of treatments. So even 10 applications probably make sense, but two applications really does not make sense. And our fear is, it will actually be of no benefit. It will be a total waste of money if you're just restricted to applications. But along with saying that there's not been a maximum, I think it's also important to keep in mind that we want to avoid abuse and avoid overuse. So again, I'm going to record this from the previous LCD because this is something that we also need to keep in mind. That repeat or alternative applications of skin substitute brush should not be considered medically reasonable and necessary when the previous full course of applications was unsuccessful. And so what is defined by an unsuccessful treatment, it's basically meaning that an unsuccessful treatment is defined as increase in size or depth of an ulcer, or no change in baseline size of depth, and no sign of improvement or indication that improvement is likely to define the granulation entity realization or progress towards closing for a period of four weeks pass start of therapy. And I think these four weeks primarily comes from Dr. Peter Sheehan's paper, I think this was also mentioned before in this conversation. A four-week improvement is a good indicator of whether a DFU will close the club of time, right? So at least we need to give that amount of time to evaluate if a treatment is successful or not. And I mean without doing that, it would be very unreasonable to say that this product will be non-medically reasonable. And then I think I also agree with Dr. Rudolf and Dr. Tettelbach they mentioned about switching [off-skin?] substitutes in the treatment. I truly agree with that because not only are different products of different compositions, but wounds have different anatomy [inaudible], and by anatomy I mean the surface area of the wound may not be like a flat surface, right? Some wounds

are deeper, some need something to be packed. So depending on what kind of wound we are looking at, how deep that wound is, it may be beneficial to start off with something which is more of a [inaudible], something that can go deeper, something that has a larger mass. And then as the wound progresses, as you're getting more [inaudible], [maybe?] switch to a different product which might be more cost-effective, or something that can be applied more superficially, something you don't need to suture. So depending on what wound you are starting with, and how the wound looks to you, some wounds-- as you are treating a wound, some wounds might just get infected or some might just get [inaudible] and need another so changing to a different skin substitute as a clinician is observing the wound progressing in the wound closure, I think is a good idea. And I think Dr. Tettelbach mentioned this may actually end up using less amount of skin substitute because you're now using logical judgment to evaluate the wound every day and apply what is needed. And then, finally, I think we had another place where I think a little bit of more clarification would be useful, I think it was mentioned about the smallest size of these CDPs that should be used. I think this needs to be clarified that this does not necessarily mean smallest size to fit any wound size. Right. So it should mean the smallest in proportion of the size of wound to achieve the maximum increment of closure between applications. And it should be really following the clinician's judgment and as directed by the previous LCD, CMS/LCD 3541, it states where multiple sizes of a specific product is available, the size that best fits the wound with the least amount of wastage should be utilized and I think that's a really good statement that should still be followed. And my last comment I think both and can relate both of them mentioned that while this is specifically being considered for diabetic foot ulcers and venous leg ulcers, should it really be called as a lower extremity chronic ulcers? Because there are ulcers which are above the ankle, or even the ankle, I think, is not considered as a DFU. So should this be considered as a lower extremity chronic ulcer, as opposed to something like limiting it to just DFU or real use?

So, I mean, as with the nephew, we really appreciate the effort that is being made to update this policy. I think all of our goals is to maximize the clinical efficacy, but at the same time, avoid overutilization and abuse. But we really want to be aligned with CMS's mission statement of establishing better coordination and communication between CMS, the contractors, and the healthcare providers. And honestly, also the manufacturers and industry. And so we really appreciate this opportunity for comments from all the healthcare providers and industry on this panel to make this LCD better. So with that, I'll be happy to take questions, or any questions that can be directed to me later on. I'd be happy to answer that.

Dr. Juan Schaening

Thank you for your presentation and your comments. Are there any questions from the other medical directors? Okay. So moving forward then, our last presenter is Dr. Pedram Zendehrouh with Healogics. Please go ahead stating any conflict of interest. Thank you.

Dr. Pedram Zendehrouh

Yes. Thank you. I do not have any conflicts to disclose. First I'd like to thank you for all the hard work that was done on this LCD and the large effort to review the literature. And I also appreciate the opportunity to be allowed to make comments to the proposed LCD. I am the associate chief medical office for Healogics. At Healogics we have over 600 hospital wound care clinics in the United States, including the First Coast jurisdiction. We treat over 300,000 patients per year accounting for more than 3 million wound care encounters. I also practice in a wound clinic in the First Coast jurisdiction. We recently published our outcomes, which revealed that of the 620,000 wounds. Approximately 36% of them are secondary diabetes and 23% of them are venous leg ulcers. Therefore, nearly 60% of all patients treated in our wound centers might be it's for skin substitute products. The proposed LCD provides a detailed review of the literature to support an evidence-based approach to the coverage determinants. It is for this reason, we were surprised by the limitation of two applications of a specific skin substitute, particularly since most of the quoted articles described more than two applications were needed to achieve one healing. For instance, the LCD cited the article by Babul et al. This is a retrospective mask cohort study to establish the efficacy of a cryopreserved human bioactive split-thickness skin Aloe graft, plus standard of care when contrasted to standard of care alone for the treatment of diabetic ulcers. The data for this study was obtained from an initial pool of more than 650,000 diabetic ulcers. The study demonstrated that healing rates were greater in the treatment group compared to standard of care. And the most substantial improvement was in the worst diabetic wounds. There was also a substantial reduction in recurrence at three months, six months, and one year. The punchline here is that the overall mean number of Allografts required to achieve closure was in excess of two applications. I do not believe this was specified in the LCD. Additionally, the LCD is cited Lavery et al in a prospective multicenter, randomized single-blinded study to contrast the effectiveness of a human viable wound matrix to standard wound care and treating chronic diabetic foot ulcers. Patients in the active treatment group received an application of skin substitute once a week for up to 84 days. Which is once per week for 12 weeks, compared to a control group receiving standard of care. The percentage of patients who had attained complete wound closure was substantially higher in the active treatment group compared to the control group. Now, these are just two studies described in the LCD where more than two applications were utilized. There are other studies in the LCD for both diabetic foot wounds and venous leg ulcers that required more than two applications. And additionally there are also a myriad of other articles in the general literature that supported the use of more than two applications. So in summary, we believe placing a cap of two applications on this advanced wound healing modality is overly restrictive, and limits access to care. It appears that the LCD has taken a narrow view of the number of applications in the articles cited on the preponderance of literature utilize more applications in their treatment groups with positive results compared to standard of care. We believe the number and frequency of applications should remain at the discretion of the clinician understanding the indication requirements, as well as conducting utilization review. As a physician myself, seeing and caring for these patients with challenging wounds and comorbidities, access to every tool in the toolbox is necessary to achieve favorable outcomes. With that, we hope you take these considerations into account, and thank you again for the opportunity to present.

Dr. Juan Schaening

Thank you doctor. We appreciate your presentation. We certainly are going to take all comments and presentations and written presentations into account. Are there any questions from the other medical directors?

Dr. Leslie Stevens

Questions Dr. Schaening. This is Dr. Stevens from Novitas. And I look forward to tomorrow where I know many of you will be presenting the same material, and we appreciate it. And we will be reviewing all the comments in great interest and with great detail. Thank you.

Dr. Juan Schaening

Okay. So thank you. So before moving forward with the, I'm going to make some comments. First, I greatly appreciate all the input and presentations on skin substitutes for the treatment of diabetic foot ulcers and venous ulcers We will address all written comments on our common response document. Even though contractors write reasonably and necessary coverage on LCD with the intent of developing reasonable and necessary coverage for services paid by the Medicare program. On this LCD, we want to address products that aren’t payable with the CPT codes for applications of skin substitute graft codes. So, therefore, products that have FDA approvals as wound covering or dressings should provide evidence that their products provide wound treatment by providing scaffolding for tissue growth. I also want to make note that CMS stated on the 2022 Physician Fee Schedule final rule that manufacturers of human cell tissue products, it should consult with the FDA tissue reference group, or obtain a determination through a request for the designation, on whether the human cell tissue products are appropriately regulated solely on the Section 361. Therefore, manufacturers claiming to be regulated on the Section 361 should submit to First Coast evidence from FDA that the product for its intended use is appropriately regulated under Section 361. In this set, I want -- to, again, give my thanks to all the presenters and all evidence documentation that can be provided to the contractor to make this policy better and to achieve the best treatment of our beneficiaries is certainly welcome. So now we are going to continue with our meeting. So since there are no additional presenters for this proposed LCD, at this time I would like to turn it onto Natalie Mohler to provide a brief overview of the proposed LCD for gastrointestinal pathogen panels utilizing multiplex nucleic acid amplification techniques. Natalie, just go ahead.

Nathalie Mohler

Thank you, Dr. Schaening, and good afternoon, everyone. First Coast's current LCD provides coverage for gastrointestinal pathogen GIP panels utilizing multiplex nucleic acid amplification techniques, NAATS, for patients experiencing acute or persistent diarrhea of at least seven days' duration and patients with paralytic ileus who are experiencing persistent abdominal pain with fever or nausea and vomiting. Currently, services that are considered not medically reasonable and necessary are any of the following. Testing a symptomatic patient. Testing for evaluation of chronic diarrhea. Repeat testing utilizing the same or different GIP panel within seven days during the same episode of diarrhea. Performance of more than one GIP panel on the same date of service. Ongoing data analysis identified an increase in the utilization of GIP panels utilizing NAATs of 12 or greater targets placing the utilization above the national average.

In response to the data analysis, the LCD was revised to provide limited coverage for outpatient testing of GIP panels utilizing multiplex NAATs or Medicare beneficiaries with acute or persistent diarrhea with signs or risk factors for severe, excuse me, for severe disease. And for Medicare beneficiaries that have an immunocompromising medical condition with acute or persistent diarrhea. The proposed LCD provides coverage for GIP panels utilizing NAATS of 11 or fewer targets for patients experiencing acute diarrhea of at least 7 days duration, and for patients with persistent diarrhea of 14 to 30 days duration. Also, there is coverage for GIP panels utilizing multiplex NAATS of 12 or more targets for immunocompromised patients experiencing acute or persistent diarrhea. Of note, the coverage for patients with paralytic ileus has been removed. The services that are considered not medically reasonable and unnecessary, are any of the following testing asymptomatic patients, testing for the evaluation of chronic diarrhea, repeat testing utilizing the same or different GIP panel within 7 days during the same episode of diarrhea or performance of more than one GIP panel on the same date of service by the same or a different provider. Thank you.

Conclusion

Dr. Juan Schaening

Thank you, Natalie, for your presentation. Since they're no presenters for this LCD, I would like to thank everyone for their participation in today's open meeting and remind you to submit comments in writing before the end of the commons period on May 28, 2022. This meeting is adjourned. Thank you for your participation.