# Open Meeting:
# Pneumatic Compression Devices

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| **Meeting Date & Time:** | November 3, 2021, 12:00 p.m. ET |
| **Facilitator:** | Belinda Yandell |
| **Location:** | Virtual Meeting |

**Belinda Yandell (0:02):** Good afternoon. My name is Belinda Yandell.

I'm a Senior Analyst with Provider Outreach and Education here at CGS, and I'll be moderating the meeting today.

For those of you that are scheduled to present your comments, please make sure you have entered your audio PIN into your telephone keypad.

If you can hear my voice but you have not entered your audio pin, you must hit the pound key, enter your audio PIN, and then hit the pound key once more.

Again, just as a note, the audio PIN is located in the audio pane.

That is to the right of the screen on the GoToWebinar app.

It is imperative that you do this so we can unmute your line when it's your turn to speak.

Now I'm going to turn the meeting over to Doctor Peter Gurk.

**Dr. Peter Gurk (0:50):** Good afternoon and welcome to our virtual open meeting today.

Our purpose for the meeting today is to solicit comments on the proposed LCD for pneumatic compression devices.

I'm Dr. Gurk, the DME MAC Jurisdiction D Medical Director with Noridian Healthcare Solutions, and one of the four DME MAC Directors on our call today.

With me today, also from CGS is Dr. Stacey Brennan with Jurisdiction B and Dr. Robert Hoover from Jurisdiction C. We also have Dr. Smitha Ballyamanda from Jurisdiction A, who is also with Noridian Healthcare Solutions.

We look forward to hearing your comments today regarding the Pneumatic Compression Devices LCD.

Please put these comments in writing and send them to us via the e-mail at PCDRecon@Noridian.com.

It's capital P, capital C, capital D capital R- Recon and Noridian dot com. Details for submitting comments are also available on the DME MAC website.

Please remember that we can only respond to written comments.

These comments are due by the close of business on Saturday, November 13th.

We have three speakers who have pre-registered to make presentations today.

We're only permitting registered speakers for today's meeting, but anyone can submit written comments to the e-mail address I mentioned—I mentioned above.

First, a few words on the background about the proposed LCD.

The proposed LCD was created in response to receiving a formal LCD reconsideration request, to include Medicare coverage for intermittent pneumatic compression treatment for interoperable chronic limb ischemia. We, the medical—the DME MACs conducted an extensive review and analysis of the clinical literature. Based on our review, the proposed LCD has criteria remaining as not reasonable and necessary.

We'll now open the lines for your comments.

**Belinda Yandell (3:14):** Our first commenter today is Daphne Denham.

Ms. Denham, I have unmuted your line. You may start with your comments at this time.

I see that Ms. Denham has not signed into the meeting, so we're going to move forward to our next speaker.

Our next, Dr. Oscar Alvarez. Dr. Alvarez, I have unmuted your line.

Please let me know when you'd like the slides to advance.

**Dr. Oscar Alvarez (3:45):** Thank you very much, Belinda. Good morning. It's a great pleasure for me to introduce and work through this work that I've done in the past, and to support the reimbursement of high pressure, intermittent pneumatic compression for CLI patients without a surgical option. This is work that we've done that's taken us quite a bit of time to do. But it's a clinical trial that really concentrates on clinical and patient-centric outcomes.

Next slide.

Approximately 18 million Americans suffer peripheral arterial disease and, of these, two million suffer from critical limb ischemia, the most severe and deadly of this disease. CLI is associated with significant mortality. You see amputations, diminished health, and a very poor quality of life.

We propose that this high pressure, intermittent pneumatic compression, is a viable non-pharmacologic therapy for patients with a PAD and CLI who are not candidates for revascularization.

Next slide please.

This work has been published and is reported here, as well as in other abstracts before this, but this really is the summary of the work.

You know or may not know, high intermittent—high pressure, intermittent pneumatic compression has a great deal of evidence in the treatment of PAD and critical limb ischemia.

Next slide, please.

We did a study between 2009 and 2013, screened 64, only randomized 34. This is a tough study to do among these patients because, as you know, they're severely compromised with many comorbidities. There were 18 patients randomized to the HPIPC group, and the exercise group, which was walking on a treadmill unsupervised for 20 minutes twice a day, were 16 in that group. The HPIPC treatment was 60 minutes twice a day. Major evaluations occurred at week four—at week four, week eight, and week 16. The evaluations were peak walking time, the amount of time you can walk that distance without pain, wound surface area, we looked at radial ABIs—ankle brachial index, we looked at pain both index and relief, we looked at quality of life and adverse events, of course. The endpoints were increased function in peak—by peak walking time and pain relief and we also looked for wound improvement.

Next slide.

The IP—the HPIPC device we used here, shown here, is a BioArterial Plus. We did contact, other manufacturers, Arjo Huntleigh and ArtAssist, is to provide us with the pumps, but we only received inquiry and interest from BioArterial Compression. So we used this pump, this is 510(k) pump which predicate was the Arterial Assist Pump. The cycle time provided here are shown in this, right on the right-side panel of the slide. The pressures are high, up to 120 millimeters of mercury. The sequential compression is for about three seconds and a resting period of—of 17 seconds, resulting in a 20 second three cycles per minute interval. And the dosaging was 60 minutes twice a day for 16 weeks.

Next slide.

This is a color flow duplex image evaluation of blood flow with—of the popliteal artery at rest, which is the panel on your left, and during high pressure, intermittent pneumatic compression, the panel on your right. As you can see by the flow and the actual image here, you can see that the flow curves is about three times the amount of blood flow going through that artery when the HPIPC device is attached and working.

Next slide, please.

The parameters that we used to look at patient centered outcome are the Wong Baker Face Pain Scale for measuring pain relief, and VAS regular analog scale to use and measure pain index.

Next slide.

We used a Short Form-36 health survey questionnaire to evaluate quality of life. And this was done at week eight at baseline of course, before the start of the treatments at week eight and at week 16.

As you know, the SF-36 measures—measures physical functional, role in physical activity, bodily pain, and general health. Also does mental health, role in emotional, social function, as well as vitality as both physical and mental components to this questionnaire. And it has been clinically validated and used previously in quite a few studies.

Next slide, please.

This is the result associated with the mean, peak walking times at four, eight, and 16 weeks, between the group that received a high pressure intermittent pneumatic compression, and the group that was controlled with exercise. And, as you can see here, at week eight you start to see a difference and at week 16 the difference was statistically significant.

HPIPC patients actually had quite a bit longer peak walking time, so they were able to ambulate and function without pain for longer periods.

Next slide.

This is a diagram showing leg pain results at baseline and after treatment. Pain index is on the left at the VAS scale, and the pain relief or Face Scale is on the right. And as you can see, differences were starting to be seen at week eight. By week 16, the differences were statistically significant in pain relief, in favor of the high pressure, intermittent pneumatic compression group.

Next slide.

This is the results associated with the quality of life survey questionnaire. And as you can see, from here, both physical function and bodily pain were significantly improved with HPIPC. Also, general health and vitality were, as well. That was not statistically significant.

Next slide, please.

The mean ankle brachial index and the FSCTI is a foot to chest skin temperature index, is the bottom panel of the slide, and you can see that is the mean r-ABIs do not change remarkably; however, the temperature does—the skin temperature does change greatly after eight and 16 weeks of treatment.

Next slide, please.

This is the mean percent reduction in surface area, and as shown here, HPIPC, or high pressure, intermittent pneumatic compression was responsible for improving the wound healing, trajectory, or wound healing rates at week eight, week 12, and week 16. Next slide.

This is a real good example of a photograph of a wound treated with HPIPC. And as you can see, an improvement at week four, week 16, and week 32—a great deal of improvement. We did not achieve healing, but improvement like this together with increased function is a great attribute for palliation in these patients without a surgical option.

Next slide.

So in conclusion, all study subjects that completed more than eight weeks of high pressure, intermittent pneumatic compression had improved healing and improve function in 16 weeks. At

week 16, the peak walking down to significantly greater in the subjects treated with high pressure, intermittent pneumatic compression, and this was statistically significant.

Also, a difference was seen in pain relief, that was significant statistically and noted in subjects treated with high pressure, intermittent pneumatic compression.

The mean reduction in wound surface area was 57% and 71%, at 12 weeks and 16 weeks, respectively.

The HPIPC group had better wound surface areas and wound trajectories, than the control groups.

The patients with CLI were not candidates for revascularization, could very well benefit from high pressure, intermittent pneumatic compression as a palliative intervention.

Thank you very much for your attention. Acknowledgements, which here are shown. This is funded by a grant from the New York Department of Health. The compression pumps are provided by BioCompression Systems. We did—did request, both, Arjo Huntleigh and ArtAssist for compression pumps, but only BioCompression responded to our request.

And the Bronx YMCA provided free temporary memberships. Thank you so much for your attention.

**Belinda Yandell (13:16):** Our next speaker, Dr. Melin, is up next. Dr. Melin?

**Dr. M. Mark Melin (13:26):** Thank you. Does that work okay?

**Belinda Yandell (13:27):** Ah, there you are. Yeah, now we're good.

**Dr. M. Mark Melin (13:26):** Oh Belinda, I'm looking at an e-mail from October 11th, and e-mailing you, sending you my cell phone number. Look, it's a pure pleasure and privilege to be able to participate in this presentation and thank you so much for your efforts to get me on.

**Belinda Yandell (13:47):** Excellent. We're glad to have you.

**Dr. M. Mark Melin (13:48):** Alright, so—so I'm going to—I tell you what, for some reason my connection isn't showing me your slides. I did not get to see Dr. Alvarez's slides. I heard his present—excellent presentation. I'm just so fortunate that he's taking the time and effort to do this really good work. So, I'm, I've got my slides in front of me and I'll just, what is the best for you? Why don't we, just start with slide one?

**Belinda Yandell (14:11):** OK, right now, I'm showing the title slide that introduces the title, the date and your name and who you're with—the Fairview Wound Healing Institute.

**Dr. M. Mark Melin (14:24):** Thank you. I'm a—I'm a surgeon in Minneapolis as part of M-Health Fairview Wound Healing Institute where I'm the medical director, and I'm an adjunct associate Professor of Surgery through the department of Surgery at the University of Minnesota for the past 20 years.

I did my surgical training at Mayo Clinic in Rochester, as well as my vascular surgery training. I'm now a 100% wound care physician for the past five years.

Belinda, in slide two, I have no declarations. I've been involved intimately with a physician led altruistic effort since October of 2019, involving a critical data and literature review, and through this physician collaborative, we've found alignment in the literature supporting the use of intermittent pneumatic compression for critical limb threatening ischemia.

So specifically, we are not addressing nor are we asking for utilization for lifestyle alternate claudication. This is purely for upper and lower extremity prevention of limb amputation, based on peer reviewed literature that is present. And again, the whole effort is validated as we're trying to prevent amputation.

Slide three, please.

I want to acknowledge the Critical Limit Ischemia Global Society, which has been formed as part of the AMP Committee. The AMP Committee has been meeting for about the last 10 years, typically in Chicago.

And that's partly through HMP, which has been a phenomenal source of education. The leadership within CLI, which was established in 2016, was specifically aimed at meeting the unmet needs of critical ischemia and implementing data-based research and interventions to decrease amputations and death due to critical limb ischemia.

Slide four, please.

And the reason I really want to call out the CLI Global Society, as they've shown such significant leadership in working with the CDC to obtain ICD 10 codes, effective as of October first of 2020, that was a major step for tracking treatment outcomes related to critical limb threatening ischemia and the associated death rate that's with things like cerebral vascular accident, myocardial infarctions, et cetera, which we know is a systemic disease that often could present as critical limb threatening ischemia.

Slide five, please.

So, I would like to personally call out, and we're very humbled at, the leadership through the CLI Global Society that has worked in this relationship throughout the vascular specialty community with the coalition members, and some of these include very well-known names, so, Dr. Roddy at Society for Vascular Surgery, Dr. Katzen, Dr. Lookstein who's specifically with CLIGS, and then Dr. Weinberg, Dr. Arslan.

So, this—this leadership really helped in core collaboration, and you can see, this is where physician led leadership working with CDC can have an impact on outcomes by—by identifying specific data.

Slide number six, please.

And specifically calling out a tweet, it talks about the amputation epidemic and what are we going to do about it. And that is the reason we are here today, as a summation of our two year effort—is we want to collaborate with CMS and with our colleagues to end the amputation epidemic, so that we can successfully contribute to upper and lower extremity prevention of amputation based on peer reviewed literature to date.

Slide seven, please.

As we read through the letter that, regarding the LCD, one comment was about a concern of data insufficiency, and that we as the submitting physician led team, had not been able to adequately express within the provided literature that there was adequate evidence of—of data.

And we—and what we're going to show (and Dr. Alvarez is showing this) in our 47 pages submitted, we clearly have—there's clearly evidence that IPC is safe, effective, reasonable, necessary to provide patients with a validated low risk option.

And this is within the context of no option. So when there is no other option, next option is amputation, our premise is that this is the point where arterial intermittent pneumatic compression is so beneficial for helping to decrease amputation rates.

Number eight, please.

So within the ethics component of this, I actually took this before our university IRB and requested that we begin a trial of comparing non treatment versus treatment in legs that were clearly at risk for amputation. And the RCT was heavily questioned as whether or not this was actually ethical, given the published data that was presented. Ultimately, we were asked to withdraw the request because it was not feasible for passage due to institutional ethical concerns. Now, this goes right back then to Steve Kavros' publication when he was at Mayo in 2008, and this was published in a very prestigious journal—Journal Vascular Surgery.

This looked at 18-month follow up of IPC groups versus control groups. And as you can see, in the four—in the IPC group, the amputation rate was at 42% with an overall healing rate of 58%, and an overall survival rate of 83%.

Now when you compare that to the control or sham group, the amputation rate was dramatically higher instead, in fact statistically significantly higher at 83%, the healing rate was statistically lower at 17%, and the survival was moderately decreased at 75%.

Slide nine, please.

So, if it does come to an ethical discussion, and creating sham arms and blinding, we really, in 2021, based on peer reviewed literature, we don't have the opportunity, nor should we participate in studies of this realm, because sham studies that have currently been demonstrated, have already shown us, that—that—that we're losing opportunities to save limbs, and I don't think you could ever get a patient to sign a consent to enter such a—such a trial.

Slide number 10, please.

And comments from a national leader in IPC use and research states—he stated, "Outcomes research in the area of CLI is not easy to design. Limb loss is multi-factorial. Pain is forcing both patients providers to embark on low yield, costly, risky revascularization procedures which ultimately may precipitate limb loss. And in this context, the metric to measure is quality of life years"—much like what Steve Kavros had measured in 2008.

And surprisingly, the data that we could not presented by Dr. Sultan et. al, from Ireland, is one of the largest IPC experiences in the world. And I do think we have to look at our international colleagues as excellent scientists. We work with them all the time, in terms of creating databases and determining demographic health outcomes. So I would—I would ask that, at some point, we have the opportunity to—to review his data as well, within this context.

Slide 11, please.

We have been garnering support, extensive societal support, because ultimately, this isn't about a group of physicians. This is about societal engagement. So we currently have—not only the Society for Vascular Medicine that has, on letterhead, provided us support—we also have from the Association for the Advancement of Wound Care Board.

We have the board certification on letterhead from the American Board of Wound Medicine and Surgery, led by Richard Simman. We have on letterhead from the American Professional Wound Care Association Board, led by Jeff Niezgoda.

We also just received from Dr. Bell, for SALSAL, so "Saving A Limb, Saving A Life," which is an excellent organization that has broad diversity and support from physical therapists, certified lymphedema therapists, podiatrists, and it's—it's just humbling to have SALSAL participate in this.

We are awaiting final documentation from the Critical Limb Ischemic Global Society, from the Society for Interventional Radiology, from the Society for Vascular Surgery, and from the American Board Wound Management boards as well.

Slide number 12.

And this is just to affirm again, what we have as of today, and I had a—I want to also include the Alliance of Wound Care Stakeholders with Marcia Nusgart, and the excellent efforts and support that she's provided over the past years.

We're down to the last two slides, slide 13.

So this is—this is just a philosophical thought. Simon Sinek made the statement, "There are only two ways to influence human behavior: you can manip—excuse me—you can manipulate it or you can inspire it." And Daniel Kahneman, who received the Nobel Prize in Economic Sciences in 2002 and wrote one of my favorite all-time books, called Thinking Slow and Fast. He wrote that, "Intelligence is not only the ability to reason; it is also the ability to find relevant material in memory and to deploy attention when needed."

Really, this is about inspiring change, inspiring a paradigm shift, inspiring a disruptive therapy to the current epidemic of amputations, and we're just simply trying to draw attention to a well-validated option.

So thank you all for listening. Thank you for your participation in advancing to today's opportunity of an inspired, attentive discussion regarding data and the perspective of what we're looking at over the next decade that approaches us. And we want to build the database moving forward. We want this to be an interdisciplinary societal partnering, partnering component for appropriate IPC use so that it does not shift the goalpost into things like intermittent—or to claudication. So, this is a board collaborative engagement, from multiple boards, as we've discussed.

This should be physician led, physician managed, investigator led and monitored, and industry supported, but not industry led.

And we need way points at bi-annual collaborative discussions, that engages boards to achieve the best outcomes.

And truly, this is altruism in medicine because we make no RVUs for prescribing IPC. These patients take a disproportionate amount of time in clinic. I spent an hour with a gentleman today who's on the borderline of losing his left leg, and we're working on using arterial pump right now that his daughter is paying out of pocket for. This is simply the best option when there is no other option.

I appreciate the privilege of the opportunity to speak and thank you.

**Belinda Yandell (25:07):** Thank you, Dr. Melin. I am re-muting your line, and I'm now going to turn the meeting back over to Dr. Gurk.

**Dr. Peter Gurk (25:26):** Thank you, Belinda. Everybody hear me okay?

**Belinda Yandell (25:30):** Yes, we can.

**Dr. Peter Gurk (25:35):** I had interference here, some noise, so I put my headphones on.

Well, thank you, Dr. Melin; thank you, Dr. Alvarez; for your presentations today.

It was very interesting information, and we would request that you submit your comments and presentation to us. You can send those to our web—our e-mail address is PCDRecon@Noridian.com, and the PCD is capital P, capital C, capital D, capital R- Recon (econ in small letters) at Noridian dot com.

Any questions or further comments? Otherwise, I think we're ready to adjourn.

**Belinda Yandell (26:33):** Thank you, Doctor.

Yeah, I think we're ready to end the meeting now. I thank you all for your attendance and attention. Thank you.

**Dr. Peter Gurk (26:43):** Yes, thank you all.