Open Meeting: Lower Limb Prostheses

Meeting Date & Time: February 22, 2024, 10:00 a.m. ET
Location: Virtual Meeting

JODY WHITTEN (0:00:04): All right. It is eight o'clock and I'm going to go ahead and begin. Hello everyone and welcome to the DME MAC Open Meeting. My name is Jody Whitten from the Noridian Medical Policy Team and I'd like to thank everyone for taking the time to join us today to discuss the lower limb prosthesis proposed local coverage determination. We have 12 stakeholders scheduled to present their comment today and we've already gone through our check for most everybody.

But just as a reminder, once it's your turn to speak, we will unmute your line from our end, but please make sure if you have your line muted that you unmute your side as well. Now, I would like to turn the meeting over to Dr. Sunil Lalla for his opening remarks. Please go ahead, Dr. Lalla.

DR. SUNIL LALLA (0:00:53): Thank you, Jody. Good morning, everyone, and welcome to our virtual open meeting. Thank you in advance to our registered speakers and also our attendees on the phone.

Today we're soliciting public comments regarding the proposed lower limb prostheses local coverage determination.

I'm Dr. Sunil Lalla. I'm the Jurisdiction B Medical Director and also, today, we have with us from CGS, Dr. Robert Hoover, the Jurisdiction C Medical Director. Representing Noridian Solutions are Dr. Smitha Ballyamanda and Dr. Angela Jenny, Medical Directors with Jurisdictions A and D, respectively.

And as you heard, moderating the phone lines and keeping us all on track today, is Jody Whitten from Noridian. Speakers, kindly take your cue to speak from her.

We're looking forward to hearing your comments today regarding the LLP LCD. Please do remember to put these comments in writing and send them to us via email at LLPLCDComments@cgmadmin.com. Details for submitting comments are also available on all of the DME MAC websites.

Please remember that we can only respond to the written comments. These comments must be submitted no later than Saturday, March second, 2024.

Also, today, we will be recording our meeting, and this recording will be posted on the DME MAC websites. By attending today, you are giving your consent to the use of recorded voice and comments by signing onto this meeting.

Please do be careful about sharing any personal health information in your verbal comments. We have about a dozen speakers who have a pre-registered to speak. Each speaker will have five minutes to express their comments. We respectfully request that you do adhere to that timeframe to be fair to everyone.

We're only permitting registered, commenters to speak today but anyone can submit written comments to the email address I mentioned earlier. For each speaker today, we ask that you introduce yourself, the organization that you represent, and please do remember to disclose any conflicts of interest that you may have with this topic.

For those listening in on the phone, please mute your phone line and computer, and whatever you do, do not place this call on hold, because then we're all going to be listening to wonderful background elevator music. Speakers should be prepared to begin their comments immediately after being called upon.

I'll briefly touch on some of the highlights of the proposed LCD. DME MACs have proposed modifications to coverage criteria for microprocessor controlled prosthetic knees for Medicare functional class- classification level two beneficiaries with lower limb amputations who require a prosthetic knee based on the best available evidence. Additionally, this LCD delineates coverage criteria for prosthetic feet to be modified to allow coverage of a compatible foot when coverage criteria for MPK are met. KX, GA, GY, and GZ modifiers have also been posed for inclusion

for these codes to facilitate claims processing and to assist in the prevention of improper claim payments. I'll now turn it back over to Jody to introduce the speakers and proceed. Thank you, Jody.

JODY WHITTEN (0:04:48): Thank you, Dr. Lalla. As mentioned, we do have 12 individuals scheduled registered to present their comments. Unfortunately, at this time, the first three, I do not show on our attendee list, but that there is a time limitation for today's meeting. It is five minutes. I will give you a 30 second warning, to let you know that your time is coming close to the end and with that said, our first speaker is going to be Dr. Kannenberg. We're just scrolling over to your slides right now Doctor Kannenberg, and we will unmute your line.

DR. ANDREAS KANNENBERG (0:05:27): Yeah, thank you, Jody. Is there- I don't see a button here on GoToMeeting to share my presentation?

JODY WHITTEN (0:05:35): We have it and we will advance it as you-

DR. ANDREAS KANNENBERG (0:05:39): Ah, okay.

JODY WHITTEN (0:05:39): tell us to.

DR. ANDREAS KANNENBERG (0:05:40): Okay, okay, good.

JODY WHITTEN (0:05:41): [inaudible] the first slide.

DR. ANDREAS KANNENBERG (0:05:40): Yeah, good morning, everyone. Good morning dear Medical Directors.

My name is Andrea Kannenberg. I'm the Executive Medical Director of Ottobock Healthcare, the requester of the change in the LCD provisions. So, and of course, I'm a full-time employee of Ottobock and Ottobock is a manufacturer of microprocessor knees and, of course, there is certain conflict of interest here. Next slide, please.

So, first and foremost, Ottobock is basically in agreement with the proposed LCD. Next slide please. We would like to thank you for the thorough review. Thank the DME MACs and CMS for thoroughly reviewing Ottobock's LCD reconsideration request of March 2022 and your acknowledgement of the substantial growth and development of the body of evidence and the benefits of microprocessor knees to the MFCL two mobility population.

We think that the proposed changes to the LCD for the most part properly reflect the current state of the evidence and represent a great advancement and progress for prosthetic care, rehabilitation, and participation of Medicare beneficiaries who are limited community ambulators. However, we respectfully ask you to reconsider a few provisions to protect Medicare beneficiaries from potential harm. Next slide, please. So, in total, we have three requests. Next slide, please.

The first one is that the proposed LCD would grant limited coverage of non-microprocessor prosthetic knee mechanisms that are currently limited to beneficiaries with K3 and K4 mobility only. So most of these mechanisms are or just have fluid swing control additions, pneumatic or hydraulic spin control additions to stance control mechanisms that are also available to K2 patients. However, there is one type of knee that is hydraulic or fluid stance and swing control coded L5828. That requires further consideration, and we respectfully ask you to reconsider this provision, specifically for this fluid hydraulic stance control code L5828, as it provides good function at the cost of low stability and safety, because non-microprocessor hydraulic stance control requires good residual limb strength and coordination from the patient to prevent knee collapse at any given moment. Thus fluid stance control non-microprocessor knees would expose beneficiaries with K2 mobility to an unacceptable fall and injury risk. Next slide, please.

These considerations on fluid control were also one of the main reasons for introducing K level restrictions to the coverage of prosthetic knees back in 1995 and we think that for non-microprocessor hydraulic stance control these reasons are still valid to this day, and therefore, respectfully ask to allow billing of L5828 for beneficiaries with K2 mobility only in combination with the MPK codes L5856 and L5858. Next slide, please.

Here we have a proposed language for this provision. So fluid pneumatic swing control knee units that lists all the codes that describe non-microprocessor knee mechanisms with fluid, swing control, and we would take L5828 out of that list or control addition fluid L5848 or fluid stance control L5828 in combination with electronic microprocessor stance control L5856 and L5858 only, that this code should be covered under limited circumstances as put forth in the current …

JODY WHITTEN (0:10:26): You have 30 seconds left, sir.

DR. ANDREAS KANNENBERG (0:10:29): Yep. Next slide, please.

Second request is the proposed LCD also grants coverage, limited coverage for microprocessor

swing control knees L5857. We ask you respectfully to reconsider that provision, because these knees are not indicated for functional level two, they don't have stumble recovery, so they don't qualify for fitting in beneficiaries who are limited community ambulators. So, the reason to make these knees is to save the weight for the big hydraulic units that are necessary for stance control and just use small pneumatic or hydraulic units for swing control but these are not able to handle the body weight and cannot provide stumble recovery. Next slide, please.

JODY WHITTEN (0:11:26): Thank you, Dr. Kannenberg. Your time is up.

DR. ANDREAS KANNENBERG (0:11:29): Okay.

JODY WHITTEN (0:11:32): And now, we will move on to our next speaker. Our next speaker is William Lifford. William, your line is going to be open in just a second here.

WILLIAM LIFFORD (0:11:48): All right-

JODY WHITTEN (0:11:48): Oh-

WILLIAM LIFFORD (0:11:49): Everybody can hear me now?

JODY WHITTEN (0:11:50): Yep. We sure can. You have five minutes.

WILLIAM LIFFORD (0:11:53): Good morning, everybody.

First of all, I'd like to say thank you to the DME MAC Medical Directors for their efforts here to come up with the proposed new coverage criteria for microprocessor-controlled knees and to understand the needs of Medicare beneficiaries who are K2 level ambulators. Their efforts will increase access to advanced prod- prosthetic technology for Medicare amputee beneficiaries and that's always a great thing.

The other thing is that we should thank the Medical Directors looking deeply into the real reason why microprocessor knees are so beneficial to amputees. Since Medicare first established coverage criteria for microprocessor-controlled knees systems, the emphasis has always been on the variable cadence responsiveness of these knees.

But everybody on this whole call and the vast majority of prosthetic clinicians in the field, we know that the real reason why access to microprocessor knees is so vitally important for Medicare beneficiary amputees, is because microprocessor knees with stance control, prevent falls - falls that break hips, falls that cause traumatic brain injuries, and, from a financial standpoint, falls that cause thousands upon thousands upon thousands of dollars, falls that cost Medicare far more than the cost of the microprocessor knees that would help prevent them.

So, that said, there are a few elements of the proposed LCD wording that I think could use some clarification. So, my first element is with regard to the requirement that the microprocessor knee must be indicated for K2 level amputees, I think this could use some clarification. Is this going to be a PDAC issue, where the PDAC that determines which microprocessor knees are indicated for K2 amputees and which are not? Or what are the criteria, which determine whether or not any particular microprocessor knee or advanced knee is indicated for K2 amputees?

What about manufacturer's recommendations? Will those be taken into account and what about prosthetist assessment of the appropriateness of any particular knee, microprocessor or otherwise?

So now, there's another section in there where there's a requirement that says that all lower-level knee systems have been considered and ruled out based on the beneficiary specific and functional medical needs and I think this also could use some narrowing down or clarification.

So, will patients first have to trial lower capability knees and fail on them, because that seems dangerous when you consider that fall prevention is the major benefit of microprocessor knees, and does failure mean falling, and is it even ethical for prosthetists to trial people on knees where there's a danger of falling? So that's- that's something that I think we have to discuss in a little more detail and is there a set limit as to how many knees have to be considered to con- you know to- in order to say that we've done a sufficient consideration of lower level knees, and to what extent is the prosthetist's clinical opinion going to be considered in this?

The other thing is when- I'm assuming that Medicare is going to use the prior authorization structure similar to the one we have right now for microprocessor knees and so when we are submitting a prior authorization request, will we have to submit documented results from a-a microprocessor knee trial before a patient can be approved for one? So that's really- those are really my main comments on this. I don't want to take a lot of time. Oh and I actually forgot to introduce myself. I'm so sorry. My name is William Lifford. I'm a certified prosthetist for 25 years,

and I work for Long Island Orthotics and Prosthetics in Bohemia, New York.

So I just want to say thank you again to the Medical Directors and to Medicare for having me to submit comments and I encourage you to continue your work and just to refine and narrow down this criteria, so there are less gray areas and that prosthetists and amputees can be confident that they can get the care they need, be fitted with the high technology, microprocessor-controlled knees that they need in order to stay safe and prevent falling, and I really appreciate it and I just want to thank you again so much.

JODY WHITTEN (0:16:47): Thank you, sir. We will now mute your line, and we'll move to David McGill. Let's see, we'll unm- mute David McGill's line. David, are you there?

DAVID MCGILL (0:17:11): I am. Thank you so much, Jody. My name is David McGill. I am the Vice President of Market Access for Ossur Americas. Ossur is a company that both provides prosthetic patient care all the way from New Hampshire in the eastern part of the US out to Nevada.

We work in both urban and rural markets. So, we see a cross-section of amputees across the country, and Ossur also is a manufacturer of prosthetic components, including knees and feet, potentially affected by the draft LCD. On behalf of Ossur and, also, speaking personally, as an individual with limb loss - I'm a transfemoral amputee and have been for a little over half my life, more than 27 years - I want to commend and thank the DME MAC Medical Directors for their work on this and in particular, I want to thank you for acknowledging that lower mobility patients can benefit from a higher- higher technology solutions to improve their mobility and their safety. We think this is a really important acknowledgement and can have and will have a transformative impact on some subsegments of the K2 patient population and we want to thank you for that and acknowledge that right up front.

With that being said, we believe there are a few areas in the draft LCD that, with additional clarification, could be improved and made clearer for the people who will be having to follow this once the final version of it goes into effect and I'd like to walk through each of those now. The first is the requirement in the proposed LCD that a K2 beneficiary undergo a functional level assessment as a predicate to receiving a K3 knee. We agree with this requirement. Our only suggestion is that the final version of the LCD clarify that a licensed clinical prosthetist is among the kinds of health care providers who are capable of performing that functional level assessment.

The second factor we'd like to draw to your attention is the requirement that the medical record establish a potential improvement in functional outcomes before a K2 beneficiary can receive a K3 knee. We agree, again, with this requirement. We note that in the draft LCD there are a list of a few examples of functional outcomes. We would strongly recommend that that list explicitly include mobility as a functional outcome, as we believe that K3 knees in addition to providing additional stability to K2 users and safety also provide improved mobility, which is a critical factor in overall health.

Third, the draft LCD also requires that as- as Bill Lifford just said, that they- that the medical record reflect that all K2 knees, that entire family of knees, have been considered and ruled out, and while we agree with this conceptually, we believe that it could create a significant administrative burden that doesn't add any real value to the program.

Our suggestion here is that the way you could satisfy this would consist of a- the medical record, reflecting the fact that there are unique functions in a K3 knee that do not exist in the entire family of K2 knees, and b- that those functions map directly to solve clinical problems that are documented in the medical record for the patient claim at issue. We believe those two requirements together would be a good way to satisfy the standard in an efficient, yet comprehensive, way that addresses the original draft LCD requirement.

Lastly, I want to address the requirement in the draft LCD that K3 microprocessor knees be, quote, indicated, close quote for K2 patients and we believe, as- as Bill noted and I believe as Dr. Kannenberg was gonna get to on his last slide, that there needs to be more clarification around what indicated means and it's our position that indicated should be a standard that is satisfied by the medical record documenting a- that the prescribed microprocessor knee has stumble recovery and b-

JODY WHITTEN (0:21:49): You have thirty seconds, thank you.

DAVID MCGILL (0:21:51): Thank you, Jody, and b- that the prescribed knee has the ability to adjust resistance in real time based on the user's gate. We believe those two characteristics are the characteristics that define an appropriately indicated K3 microprocessor knee for a K2 patient. With that, we're looking forward to submitting our written comments to you. We thank you again for this opportunity to speak, and we commend you for the thoughtful and progressive approach taken to increasing access to patient care for some K2patients. Thanks so much.

JODY WHITTEN (0:22:26): Thank you, David and now we will move on to our next speaker, who is Joseph McTernan. We are going to unmute your phone in just a second, or your line, rather.

JOSEPH MCTERNAN (0:22:46): Okay.

JODY WHITTEN (0:22:47): Alrighty, you are unmuted. So go for it.

JOSEPH MCTERNAN (0:22:51): Thank you so much, Jody. Good morning, everyone.

My name is Joe McTernan. I'm the Director of Health Policy and Advocacy for the American Orthotic and Prosthetic Association and I have no direct conflict of interest in this policy, other than the fact that I do represent the industry as an advocate on the whole. AOPA is an organization that advocates for more than 1500 patient care facilities and suppliers that together manufacture, distribute, design, fabricate and fit orthopedic braces and artificial limbs and provide the associated clinical care are necessary to ensure their safe and effective use.

AOPA fully supports the proposed revisions to the Medicare lower limb prosthesis local coverage determination. The proposed coverage expansion for hydraulic and pneumatic knees, microprocessor knees, and related prosthetic feet to certain K2 functional level Medicare beneficiaries, opens access to prosthetic technology to an entirely new population of individuals, who- studies have shown- can benefit from the added stability and stumble recovery that many of these knees offer. When microprocessor knees first came onto the market in the 1990s, the general assumption was that as advanced prosthetic components, they were reserved primarily for use by the most functional amputees. As such, Medicare coverage was initially limited to K3 and K4 functional level beneficiaries only.

It quickly became evident, however, that the increased stability and stumble recovery features of microprocessor knees offer insignificant clinical benefits to patients classified as K2 functional level ambulators. These benefits are well documented in the studies that were submitted in support of the recent LCD reconsideration request. AOPA would like to recognize the efforts of the DME Medical Directors in considering the LCD reconsideration request and the related studies that were submitted.

This proposed revision represents an incredibly progressive step forward and coverage of lower limb prostheses, that best meet the individual clinical needs of all Medicare beneficiaries. AOPA would also like to recognize the foresight of the DME MACs in addressing coverage of both hydraulic and pneumatic mechanical knee platforms and certain prosthetic feet required for the effective operation of microprocessor knees in the proposed LCD revisions.

Without this recognition and inclusion, the proposed coverage of microprocessor knees for K2 ambulators may have been well intended but impractical as all microprocessor knees are currently built on either a hydraulic or pneumatic mechanical platform. As others have stated previously, AOPA does have some limited concerns about some of the provisions of the proposed LCD revision and we'll submit those concerns and request for clarification in our written comments. These comments will be submitted in advance of the March second, 2024 deadline.

They in no way diminish AOPA's support of the proposed revisions to the lower limb prostheses LCD. Revisions are welcome and represent new opportunities for Medicare beneficiaries to have access to the highest level of care and technology that will greatly improve their quality of life. AOPA looks forward to partnering with the DME MACs to educate AOPA members on the specific coverage requirements that the revised LCD will implement for K2 beneficiaries and we will work closely with our members to ensure proper stewardship of this increased access to clinically appropriate care, including providing our members with the resources needed to make sure that they are able to meet the revised policy requirements.

I'd like to just briefly make one personal note, here. I've been in O&P for 30 years as an advocate. I've been with AOPA for most of that time and I can honestly say that there has not been a proposed policy revision that I believe will have a more positive impact on the Medicare beneficiary and patient population and I think that's so important to remember, that at the end of the day this is truly what this is about. This is about making patient's lives better and allowing them to ambulate safely, effectively and have access to technology that is going to help them live and-live normal and restorative lives.

JODY WHITTEN (0:27:29): You have 30 seconds, Joe.

JOSEPH MCTERNAN (0:27:32): Thank you again for your efforts on this and for allowing me to speak on behalf today, on behalf of AOPA today, it truly is an honor, so thank you.

JODY WHITTEN (0:27:42): Thank you very much. Our next speaker I do not show is on, and that is Sean O'Donell. So, we're going to move to Shane Wurdeman. We will unmute your line Shane right now, just give us a second here. Okay, your line is unmuted, Shane, go ahead.

DR. SHANE WURDEMAN (0:28:12): Okay. Greetings to the Medical Directors. My name is Dr. Shane Wurdeman. I'm a clinician scientist with a background as a clinical prosthetic. I've worked clinically with hundreds of individuals with above the knee amputation. I've published more than 60 peer reviewed scientific manuscripts, including a recent clinical practice guideline on transfemoral prosthetic knees, presented numerous abstracts at national and international scientific conferences, served as principal investigator for some of the largest clinical research studies in O&P and now as Vice President for Scientific Affairs with Hanger. I am currently principal investigator overseeing Hanger's efforts in ten federally funded studies, with funding exceeding 20 million dollars.

I am humbled to have the privilege to speak to this committee and the Medical Directors to represent Hangar, the largest clinical service provider for orthotics and prosthetics care in the U.S. By adopting outcomes collection as the standard of care across our 900 clinics, we are uniquely positioned to understand the life journey of individuals that undergo lower limb amputation.

We have historically felt restricted in our ability to help many individuals with above the knee amputations functioning at the K2 level. For all individuals with an above the knee amputation, injurious falls represent a common concern. Individuals at the K2 level can especially suffer tragic and severe consequences when they fall. I have personally sat with many of my own patients as we talked through their most recent fall. I firsthand, have seen significant, long-term impacts that falls can have on future activity, mobility, and overall general well-being.

We wish to begin by commending the committee and the Medical Directors, much to the same sentiment as my colleagues. Commend on the additions that are proposed in this proposed LCD. We fully expect the changes to have long lasting benefits for many Medicare beneficiaries. We appreciate the formal recognition of the value and need for the determination of functional levels based on clinical evaluation.

We would encourage the LCD to memorialize that this determination can be made by qualified health care professionals, including certified licensed physicians, physical therapists and prosthetist. We further extend our appreciation for the formal recognition of the ability for microprocessor-controlled knees to reduce both the risk and rate of falls, as well as associated injury, to reduce energy expenditure and facilitate the completion of activities of daily living for individuals with above the knee amputations and now, including this extension to those at the K2 level, these benefits are in full alignment with our outcomes data collected across our national network of clinics.

Within the proposed LCD, there's also language that a microprocessor-controlled knee is deemed reasonable when non-fluid, non-pneumatic, or non-microprocessor knees have been considered and ruled out. This section could be open to different interpretations, so we asked for consideration of further clarification within the document.

Lastly, the proposed update would extend coverage of non-microprocessor-controlled knees that use fluid mediums, such as hydraulics or pneumatics, to individuals classified as K2. It is specifically the stumble recovery function provided by microprocessor knees that results in stance phase stability. In the K2 population, our clinical priority is stance phase stability. We would encourage expansion of knee access to also prioritize stance phase stability.

In closing my remarks, we will formally submit our comments in writing, but most importantly, we wish to express appreciation on behalf of the provider community and again commend the committee and everyone who contributed to this LCD proposal for their acknowledgement of the current state of the science regarding the use of microprocessor-controlled prosthetic knee joints in the care of people with lower limb amputation. Thank you for your time.

JODY WHITTEN (0:32:44): Thank you very much and we'll move on to our next speaker. Next speaker is Peter Thomas. Peter, I will unmute your line right now. Are you there?

PETER THOMAS (0:32:56): I am, thank you. Good morning, everyone. My name is Peter Thomas, I'm the managing partner of the Powers Law Firm in Washington, D.C. I'm speaking today on behalf of the Orthotic and Prosthetic Alliance which is a coalition of five national provider-based organizations and the orthotic and prosthetic profession, AOPA, the Academy of Orthotist and Prosthetists, the National Association for the Advancement of Orthotics and Prosthetics, the Board of Orthotic Certification Accreditation and the American Board for Certification. I'm also a general counsel of the National Association for the Advancement of Orthotics and Prosthetics and I personally use two artificial limb since age 10.

I've never used a microprocessor, but know many people who have. I've seen people take very serious falls right in front of me as a result of failing to recover from a stumble, or a trip, or a

slip and I cannot thank you more, and the DME Medical Directors more, than for recognizing that microprocessor knee technology will now be extended to K2 amputees, limited community ambulators. When this first, when the LCD first went into effect, there were many questions in the field about the benefits that this population could take advantage of this technology

and although we understood the reasoning behind covering this for a more functional population, there was a recognition that the less functional population could very much benefit from this technology and we're so grateful that at this point, assuming the LCD is finalized as well with some minor amendments that we've heard this morning, we are grateful that this will go forward and finally give Medicare beneficiaries with limb loss the technology they need to be functional, independent and safe in the use of their prostheses.

This current policy derived largely from the consensus document that was published by CMS in 2017 where the NIH and many other federal agency leads, who knew a fair amount about orthotics and prosthetics, recommended that CMS consider coverage of these technologies for K2 amputees.

This is going to have a huge impact on patient access to care in terms of improved function for K2 limited community ambulators, prevention of falls and ultimately I believe it will be cost effective as some of the previous speakers have said. Well, four quick clarifications and I think many of them and it's been mentioned before so I'll go quickly through them. First, the clinical evaluations strongly support this and strongly support prosthetists being involved in these just as current treatment of the functional assessments are conducted. Second, improved functional outcomes. We do have questions, we're hoping for more clarity about this, mobility sounds like an extremely important factor to assess in this, other than and including fall reduction, etc. How is this accomplished? How are the functional outcomes demonstrated? Who assesses this? We'd love more clarification on that. Ruling out non-MPKs, this seems very broad and almost an impossible standard unless, you know, put patients on demo limbs that could be, you know, risk their safety. The current policy says, all non-MPKs should be ruled out. That seems very expansive. We need some clarity to refine that and to understand exactly how that's operationalized. Finally, MPKs must be indicated for K2 amputees. We're looking for greater clarity here to try to figure out what needs to be done to verify that, does the PDAC get involved? We would hope that you would take an expansive view of this. We've waited years and years. The amputee population has waited a long time for this coverage to be granted to this this subsection of lower limb amputees and we're hopeful that several years do not pass before evidence is finally reached at a point where you can say that a MPK is quote, unquote, "Indicated for a K2 amputee." We urge the DME MACs to take a …

JODY WHITTEN (0:37:37): You have 30 seconds.

PETER THOMAS (0:37:39): Thank you. We urge the DME MACs to take a relatively expansive view of this. The practitioners and the patients know the value and the benefits of these technologies, they are standard of care at this point. They've been around for decades. We're hopeful that you won't take a narrow view of this requirement. And finally, let me just say that the O&P Alliance and the NAAOP stand with you and would like to continue working with you to ensure that the microprocessor technology gets to the patients who can most benefit from it and can really make the best of those and have the biggest return on investment, if you will, from improvements in their function and safety. Thanks so much for the opportunity to testify and we will be submitting written comments.

JODY WHITTEN (0:38:30): Thank you so much. Our next speaker is Ashlie White and I am going up to her line right now to unmute it. Let's see, your line is unmuted Ashlie. Are you there?

ASHLIE WHITE (0:38:45): Yes. I'm here. Good morning and thank you to the DME MAC Medical Directors for the opportunity to provide comments this morning. My name is Ashlie White, I'm the Chief Strategy and Programs Officer at the Amputee Coalition. Our organization provides support, education, and advocacy for over 5.6 million individuals who had experienced amputations or were born with limb differences. The Amputee Coalition celebrates and supports the proposed revisions to the local coverage determination for lower limb prostheses and applauds the expansion of beneficiary access to hydraulic pneumatic knees, microprocessor-controlled knees and related prosthetic feet, as the standard of care for a segment of the population who can benefit most from these technologies, those who have been assigned an activity level of K2.

Every day our organization receives and shares stories of individuals who are thriving after limb loss. A common story we hear is, if not for my prosthesis I would not be able to play with my grandchildren, or mow my lawn, or attend community events, or walk in my neighborhood. We also hear the stories of challenges experienced by this community. Unfortunately, falls are among the most common challenges shared by individuals living with limb loss, or limb difference and as many of the speakers have shared today, the benefits of added stability and Stumble Recovery,

specifically for aging individuals, are well documented. This technology is not only supported by the science, but by the countless stories we've received directly from the individuals who have had access to this technology.

The Amputee Coalition will be providing detailed written comments, but would like to suggest additional clarification specifically with respect to the documentation requirement for K3 prostheses to be indicated for K2 patients and what is specifically meant by the requirement that other prostheses be ruled out first. While we would all hope that our healthcare system would foster a streamlined patient experience for evaluation and referral for prosthetic care, we often receive reports from individuals who have had their care delayed as a result of challenges getting cooperating documentation from providers, for confusion about what they have access to and what they don't, and providers not feeling confident that they will be able to meet the requirements for claim approval. So the clarification in this coverage determination, to make access as streamlined as possible, is extremely important and we appreciate your consideration, and, again, we celebrate and support the proposed revisions to the LCD. Thank you so much for allowing us to provide comments today.

JODY WHITTEN (0:41:38): Thank you so much. Our next speaker is Michelle Wullstein. Michelle, you have five minutes. Let me unmute your line first, I guess. It looks like you are self-muted, Michelle.

MICHELLE WULLSTEIN (0:42:11): Can you hear me?

JODY WHITTEN (0:42:12): I can hear you now, go ahead. You have five minutes.

MICHELLE WULLSTEIN (0:42:16): Thank you, Jody. My name is Michelle Wullstein, I serve as the manager of compliance and education for a company called O&P Insight. We provide consulting and billing services to O&P companies, not just around the United States but around the world as well, and we've come to you today thanking you, the Medical Directors, for considering this modification to the lower limb prosthesis local coverage determination, as it will benefit the Medicare Program suppliers and most importantly beneficiaries. We respectfully request a minor modification to the proposed language. Coverage criteria three, for qualification of the fluid or pneumatic knee unit or control addition fluid or electronic/microprocessor states quote, "All lower level new systems have been considered and ruled out based on the beneficiary's specific functional and medical needs.", end quote. We ask the Medical Directors to consider changing the first word, from "All" to "Other", echoing the concerns of the other stakeholders today. We have historically seen other payers, adopt both active and proposed LCD language by Medicare and interpret the language in an extremely literal capacity which, in this case may result in prosthetist having to document and trial all lower level knee systems upwards of 100 plus prosthetic knee options, approximately 20 of which are designated as microprocessor knees. Changing just one word in the proposed language would minimize the likelihood of an extreme interpretation by other payers and would allow the prosthetist to use their clinical expertise and experience to review a select amount of clinically appropriate lower level knee systems for the beneficiary.

We, again, would like to thank CMS for their proposed LCD changes. The beneficiaries impacted by this change will see a significant improvement in functional abilities and quality of life. Thank you very much.

JODY WHITTEN (0:44:10): Thank you so much, Michelle. We are going to go back to the top of my list and double check that we do not see, let's see, Peter Courage. Let's see, I do not show Peter Courage Tawiah on at this point. The next is Faye Groomes, let me double check to see if Faye is on. We do have a lot of people on, so it just takes a minute to scroll through and I do not show Faye, and then, we should check for Ken Heide. Let me double check to see if Ken is on. I did not show Kenneth Heide on and then, I'm going to go back to Sean O'Donell and see if we have him on, hold on just a second while I scroll through, and I do not show Sean O'Donell on as well. Let's see, it looks like we have Ken Heide logging on, so I'll give it just a second or two for him to see if I see him showing up. We just got a message from him saying he's logging in [inaudible], so hold on just a second. Unfortunately, I do not show Ken on so, with that being said, we do want to thank all the commentors today. So, with that, I will now turn the call back over to Dr. Lalla to provide his closing remarks. Dr. Lalla.

DR. SUNIL LALLA (0:46:42): Thank you, Jody. I'd like to take just a moment to thank all the members of the public and the stakeholders for your insightful comments today. Once again, please do remember to send your comments in writing, as only comments in writing will be considered by the Medical Directors. If you do have any full text, peer reviewed articles to help support your comments, that have not been included in the bibliography, please send them along as well and, as noted earlier, the comment period will end on Saturday, March the second. Once we have reviewed, collated and considered all of the comments received during the open

comment period, we'll take these into consideration and make any necessary changes as a result of these comments that we receive. We will then post a final LCD, along with a response to comments document. The final LCD will take effect a minimum of 45 days after the posting of the final LCD. Please refer to the DME MAC websites for any updates. I'd just like to take a moment, again, to thank Jody and everyone else who participated in today's call. We look forward to receiving your written comments and we'll just go ahead and adjourn the meeting at this time. Thank you.

DR. SMITHA BALLYAMANDA (0:48:07): Dr. Lalla?

DR. SUNIL LALLA (0:48:10): Yes?

DR. SMITHA BALLYAMANDA (0:48:12): Hi, apologies for interrupting. This is Dr. Ballyamanda with Noridian, Jurisdiction A. I'm getting information that Ken Heide is on the call, but unable to speak. I just wanted to take a quick moment to give him an opportunity to try to be able to speak here. I think we've emailed and tried to get him the link but would not want to close out without just giving him a moment to see if he's able to speak today.

JODY WHITTEN (0:48:41): Dr. Ballyamanda, he's not on our list right now.

DR. SMITHA BALLYAMANDA (0:48:46): He's not logged in?

JODY WHITTEN (0:48:48): Not on the link. He might be called in, but we can unmute it.

DR. SMITHA BALLYAMANDA (0:48:51): I see.

DR. SUNIL LALLA (0:48:56): Ken, if you can hear us, we realize we can't hear you, but please do keep in mind that, unfortunately, technical difficulties appear to be precluding your speaking but your comments, if submitted in writing, will be given every bit of weight in consideration of any verbal comments that you would have submitted today. So, please do keep that in mind and we look forward to receiving those comments from you in writing.

JODY WHITTEN (0:49:31): Thank you, Dr. Lalla.

DR. SMITHA BALLYAMANDA (0:49:33): Thank you Doctor.

DR. SUNIL LALLA (0:49:34): We'll go ahead and adjourn the meeting at this time. Thank you so much.

DR. SMITHA BALLYAMANDA (0:49:40): Thank you.

JODY WHITTEN (0:49:41): You may now disconnect. Thank you. Have a great day.