Open Meeting: Knee Orthoses

Meeting Date & Time: August 27, 2025, 10:00 a.m. ET
Location: Virtual Meeting

JODY WHITTEN (0:00:04): All righty. Let's see. Good morning, everyone. It is 10 a.m. Eastern Time, and we will begin our 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 knee orthosis proposed LCD. We have seven stakeholders scheduled to present their comments, and we have divided up the available time to speak by those seven, which will give each speaker nine minutes to present their comments. Just as a reminder, once it's your turn to speak, we'll ask you to unmute your line. Just make sure that your line is unmuted from your end as well. But let's see. Now I'd like to go ahead and just turn the meeting over to Dr. Robert Hoover for his opening remarks, so please go ahead, Dr. Hoover. Dr. Hoover, we can't hear you.

DR. HOOVER (0:01:08): I am still on the same microphone.

JODY WHITTEN (01:13): There you go, now we can, thank you.

DR. HOOVER (0:01:15): Okay, yeah, I don't know what was going on there. So welcome everybody to our open meeting to hear comments on the proposed Knee Orthoses LCD. Remember, this is a proposed LCD, so don't take any actions until we finalize the policy in the near future based on the comments that we received today. Also, a big shout out and thank you to our meeting coordinators for their assistance today. The agenda is on your screen now and you'll see after the welcome and introductions and an overview of the LCD, we'll hear our oral comments. And then I'll come back on with some closing remarks and next steps. Next slide, please. Next slide. There we go.

So, the proposed knee orthosis LCD is a significant change from the current LCD wherein one of the coverage criteria for the unloader type braces requires objective evidence of joint laxity. After reviewing the literature, there are osteoarthritis patients who benefited from knee orthosis to reduce pain and increase mobility but did not have joint laxity. As a result, the proposed LCD criteria reflect criteria that do not include objective evidence of joint laxity and instead centers on coverage of orthosis to reduce pain and increase mobility. Note that the proposed LCD is accompanied by a draft related policy article that's viewed in the attachments section of the proposed LCD in the Medicare Coverage Database. The draft proposed policy article has documentation requirements associated with the coverage criteria you see on your screen.

I'll now turn it back over to Jody Whitten to introduce our speakers for today.

JODY WHITTEN (0:03:28): All righty. Thank you so much, Dr. Whitten.

So, our first speaker today is David McGill, and we are going to unmute your phone right there, your line right now. David, are you there?

DAVID MCGILL (0:03:41): I am. Can you hear me, Jody?

JODY WHITTEN (0:03:43): I can hear you great. Thank you. You have nine minutes. Thanks.

DAVID MCGILL (0:03:47): Perfect. And I promise I won't need nine minutes. I am David McGill. I am the Vice President of Market Access for Embla Medical. Embla is the parent company of Ossur. Ossur is a manufacturer of orthotic and prosthetic components, including knee orthoses. We're also the parent company of ForMotion Clinic. ForMotion is a national group of orthotic and prosthetic patient care facilities. And I want to communicate on behalf of both Ossur and ForMotion our gratitude to the DME MAC medical directors and their staff for considering this request, for performing the necessary analysis on a large body of research and ultimately concluding that an update to the LCD was appropriate. And I want to highlight two key benefits that we think the proposed revisions to the LCD will offer.

The first is to beneficiaries directly. There are there's a cohort of Medicare beneficiaries who over the years, and Dr. Hoover just alluded to this in his introduction, have osteoarthritis but present without objective evidence of joint laxity. And for years, those individuals have not been able to get knee orthoses that would have helped improve their pain and improve their mobility. And you

have now created a mechanism through the use of the new criteria that have been included in the proposed LCD, the revised LCD, for those individuals to receive that intervention.

The second benefit, which is kind of the flip side of the same coin, is we have heard from years from both our own licensed and certified orthotists in the ForMotion Clinic, as well as from orthotists around the United States and physicians around the United States who use Ossur knee orthoses. They've bemoaned the fact that under the existing LCD requirements, there were situations where they knew a new orthosis would help control a patient's pain better, would help improve their mobility, but because of the existing criteria, they could not offer that solution to their patients. And I can tell you from having spoken to those healthcare professionals around the country since the publication of this revised LCD, the feedback has been overwhelmingly positive. And I want to thank you on behalf of all those individuals.

So, to summarize, we commend the DME MAC medical directors for the proposed revisions to the LCD. We fully support them. And as I suspect that the majority of the comments, if not all of the comments you're going to get in response to these proposed revisions, are going to be positive, we urge you to implement the changes as soon as possible so that beneficiaries can enjoy the pain relief improved mobility that these devices offer. Thanks so much for the opportunity to talk today.

JODY WHITTEN (0:06:40): Awesome. Thank you very much, David. Our next speaker is Beth Speerli. Beth, we're going to go ahead and unmute your line. Hey, Beth, we have sent you a message to unmute your line. Beth Speerli. Beth, are you able to unmute your line? There should be a little message coming up to unmute.

DR. HOOVER (0:08:00): Maybe we can move to Mr. McTernan and Beth can sign out and sign back in.

JODY WHITTEN (0:08:03): We surely can. Yeah, that sounds good. Beth, if you would do that, please sign back in. There were instructions sent to you. If you could please follow those, that would be wonderful.

Joe, we're going to unmute your line right now.

JOE MCTERNAN (0:08:22): Good morning, Jody. Can everybody hear me okay?

JODY WHITTEN (0:08:24): We sure can. Go for it.

JOE MCTERNAN (0:08:27): All right. Well, thank you. My name is Joe McTernan. I am the Director of Health Policy and Advocacy for the American Orthotic and Prosthetic Association. The acronym is AOPA, and we represent over 1,500 member organizations that provide direct orthotic and prosthetic patient care. We represent manufacturers of orthoses and prostheses, as well as distributors and suppliers of orthotics and prosthetics.

It's my pleasure to be here today to offer public comments on the proposed revised LCD and policy article for knee orthoses specific to how they are used to treat and how coverage is for osteoarthritis conditions.

AOPA was the submitter of record of this LCD reconsideration request. We made that submission back in August of 2023, and I wanted to take a moment to just acknowledge and appreciate that two years of hard, consistent work went into the review of this process. We know and we fully acknowledge and understand that this is not an easy process for the DME MACs, that there is a significant burden that has to be met in order for the DME MACs to make the decision to, in this case, expand coverage as it will have an impact, a financial impact, on the Medicare Trust Fund. And we just very much appreciate the DME MACs realizing the responsibility to make sure that they cross every T and dot every I. And as being very, very intimately involved in this process for really the first time in my career, it's been incredible to watch and watch it develop, and you know continue to get to get the the responses when I ask questions on progress of where it was. I also appreciate the transparency from the medical directors in letting us know on a regular basis that we had not been forgotten that the LCD reconsideration was actively under review, that it was going to take some time and, you know, the request for patience as they went through their process.

So, some other things I wanted to recognize and acknowledge was the absolute thoroughness that the DME MACs and their teams put in place in reviewing the literature. When AOPA submitted this LCD revision request, we submitted as many, we submitted a library of clinical literature that we were able to find through research channels, through all of our member organizations, every resource we could put into play, we used. And the DME MACs and their team, especially their team of medical directors who are focused on research of this kind, really went above and beyond and found so much additional literature that supported this ultimate proposed decision. So wanted to acknowledge that as well.

As Mr. McGill said, AOPA fully supports the provisions of the proposed LCD revision, including what is in the policy article for documentation purposes. We absolutely appreciate the fact that there is a potential opportunity for bad operators to try and take advantage of this program, and that is in nobody's interest. It's not in AOPA's interest. It's not in Medicare's interest, and it's certainly not in the interest of the beneficiaries who will absolutely be better for having access to this level of care. So, things like radiographic evidence of tibiofemoral osteoarthritis. We absolutely support those requirements.

What is interesting and what we have noted when Mr. McGill talked about the need for this has been long-standing. There has been, we've had reports from AOPA members for years and from referring physicians for years that this is a modality that works, that is effective, that is at least a short-term alternative to surgical intervention for patients who either don't qualify or are not ready to have replacement surgery, but there was simply just not an availability of coverage under existing Medicare policy. It wasn't about effectiveness. It wasn't about clinical ability to treat. It was simply about the fact that the existing policy required joint laxity or a history of recent injury to or surgery upon the knee. That's been evident in the prior authorization program that is in place for knee orthoses where first initial affirmation rates have been hovering in the low 60% range, whereas other categories such as lower limb prostheses, spinal orthoses, AFOs, ankle foot orthoses, et cetera, where there's Medicare prior authorization in place, those affirmation rates have significantly been, have been significantly higher, as high as 80 to 90% for lower limb prostheses. When we've gone through with the medical review staff at the DME MACs the most consistent and most often reported reason for non-affirmation was because there was no objective documentation of joint laxity present for osteoarthritis. So, this will clearly help that, and we fully support the DME MACs moving forward with the revised LCD and policy article as written.

So, I just wanted to summarize and close today by again thanking the DME MACs for reviewing this as thoroughly as they have for putting out a very thorough, very reasonable LCD and policy article that will include coverage of osteoarthritis braces when there no presence of inherent joint laxity or no injury or surgery on the knee. So, thank you very much. Appreciate it.

JODY WHITTEN (0:14:54): Appreciate it. Thank you, Joe. All right. We will move on to Michelle Wullstein. Next slide, please.

MICHELLE WULLSTEIN (0:15:03): Jody, can you hear me?

JODY WHITTEN (0:15:55): I sure can. Thank you.

MICHELLE WULLSTEIN (0:15:07): Excellent. Thank you so much. Hello, everyone. My name is Michelle Wullstein. I am speaking on behalf of O&P Insight. We are a consulting firm specializing in the unique needs of O&P suppliers within the DMEPOS landscape.

I'd like to start by extending our gratitude to CMS and the DME MAC medical directors for this proposed change to the knee orthosis local coverage determination. This is a much needed update that will initiate some positive change for impacted beneficiaries.

Now in reviewing the LCD reconsideration letter submitted by AOPA requesting this change, we wanted to encourage an additional update that was requested by AOPA, elaborating upon the list of acceptable joint laxity tests for support of knee instability in the absence of recent injury, recent surgery, or a diagnosis of osteoarthritis. This information would provide needed clarification to ensure coverage for patients that truly need the device for added stabilization and safe ambulation. Numerous payers have demonstrated a history of adoption of Medicare policy language for coverage and reimbursement with more narrow interpretation of the current language. The clarification regarding joint laxity tests would not only positively impact traditional fee-for-service Medicare beneficiaries, but the beneficiaries of other healthcare payers who choose to adopt this updated language.

Again, we want to extend our gratitude for your willingness to adopt these changes for the betterment of healthcare outcomes for Medicare beneficiaries. Thank you so much.

JODY WHITTEN (0:16:42): Thank you, Michelle. Our next speaker is going to be Peter Thomas. Peter, we are going to unmute your line or send you a request to unmute your line.

PETER THOMAS (0:16:56): Thank you very much. Can you hear me?

JODY WHITTEN (0:16:58): We sure can. Go ahead. Thank you.

PETER THOMAS (0:17:02): Well thank you for the opportunity to speak today. I'm speaking on behalf of the Orthotic and Prosthetic Alliance, the O&P Alliance, that's comprised of five national orthotic and prosthetic organizations, all representing provider interests with a strong interest in preserving access to patient care. Those include the American Academy of Orthotists and

Prosthetists, the AOPA organization, which Joe just spoke, the NAAOP, the National Association for the Advancement of Orthotics and Prosthetics, and the two accreditation organizations, the American Board for Certification and the Board of certification.

My testimony today is in strong support of the proposed revisions to the local coverage determination and the related local coverage article, which grants coverage for knee orthosis and expands coverage for osteoarthritis.

I want to personally thank the DME MAC medical directors and their staffs for a very comprehensive review of this issue and for publication of what by all accounts is a really outstanding new policy.

The proposed LCD represents a long overdue evidence-based modernization of Medicare policy that will improve access to clinically appropriate, non-invasive, and cost-effective care for hundreds of thousands of beneficiaries living with osteoarthritis.

Let me address first the long-standing gap in Medicare coverage in this area. The current coverage criteria for knee orthosis is limited. Almost exclusively to beneficiaries with documented joint instability following injury or surgery. This policy ignores the large and growing population of Medicare beneficiaries with medial and lateral tibiofemoral OA, who experienced pain, loss of mobility and functional decline, but who routinely, they routinely denied coverage for unloader knee braces because they did not meet current coverage policy, and we believe that policy is clinically outdated. We're very pleased to see this update. These denials are particularly concerning because unloader orthoses were specifically designed and clinically validated to treat osteoarthritis by reducing load on the affected compartment of the knee. The exclusion of this use has been inconsistent with both the intended clinical function of these devices and with current evidence-based practice guidelines. By expanding coverage to include patients with OA-related pain and functional impairment who may benefit from varus or vulgus unloading knee orthosis, the proposed LCD directly addresses and corrects this inequity. It better aligns Medicare coverage with contemporary medical standards, which demonstrate that unloader knee braces can reduce pain, improve mobility, and potentially delay or reduce the need for invasive surgical interventions.

The benefits of Medicare beneficiaries and the Medicare program needs to be discussed because this policy really is going to be a major improvement for Medicare beneficiaries. Expanded access to knee orthosis will allow Medicare beneficiaries living with osteoarthritis to maintain mobility, independence, to live in their homes and communities with less pain, to participate in activities of daily living in a more effective way. For many patients, an unloading knee orthosis provides a safe and cost-effective alternative to surgery, reducing both personal health risks and long-term Medicare expenditures. Importantly, the proposed revision removes unnecessary barriers to care, ensuring that all eligible patients, regardless of whether they have had an acute injury or a surgical history, can access this clinically proven therapy.

As the coalition representing orthotist, prosthetists, and related professionals, the O&P Alliance is united in supporting this proposed LCD and related LCA. We believe that expanding Medicare coverage for knee orthosis in the cases of tibiofemoral osteoarthritis represents an evidence-based and patient-centered coverage improvement that reflects both the state of medical science and the realities of patient care. So, for these reasons, the O&P Alliance stands in full support of this proposed LCD and its related LCA.

We also encourage CMS, the Centers for Medicare and Medicaid Services, as well as the DME MAC medical directors to finalize this policy as soon as possible. We are quite aware of the risks of potential overutilization and fraud and abuse, and we wish to say that we stand ready to work with the DME MACs to be as vigilant as possible in preventing fraud and abuse in this new benefit. And so thank you very much for the opportunity to share the Alliance's position. We very much appreciate this new policy.

JODY WHITTEN (0:22:49): Thank you, Peter. Our next speaker is Felix Garcia. We are getting up to your email and I mean your name and unmuting your phone or speaker rather. Okay. You should have received a message, Felix, to unmute your line. All right, I don't see him unmuting. We can go back and check again after the next speaker, which our next speaker is Molly McCoy. Can you go ahead and send Molly McCoy a notice to unmute? Joc?

MOLLY MCCOY (0:23:50): Hello, thank you. Can you hear me?

JODY WHITTEN (0:22:52): Thank you. Yes, we sure can. Go ahead.

MOLLY MCCOY (0:23:55): Awesome. Thank you for the opportunity to speak today. My name is Molly McCoy, a Director within the Clinical and Scientific Affairs Department at Hanger Clinic. We're the nation's largest provider of orthotic and prosthetic clinical services. I'm also a certified prosthetist and orthotist myself with 29 years of experience in the field. And as a career clinician

and representative of Hanger, I want to commend CMS on the work conducted by the DME MAC medical directors to provide such a comprehensive literature review and evidence statement. It's really impressive and much appreciated.

We at Hanger Clinic and the Hanger Institute for Clinical Research and Education wholeheartedly support this change and appreciate the collaborative dialogue with CMS. More specifically, the proposed LCD changes reflect sound policy based on the clinical evidence and will improve patient access to knee orthoses in a timely manner, which will also improve overall patient health and outcomes. Over the course of my career, we have had to unfortunately turn away thousands of patients from potential relief of their osteoarthritic pain, and now these patients have an alternative solution beyond invasive surgery and injections. The Hanger Clinic team greatly appreciates the thoughtful approach CMS has taken to evaluating the current medical policy and putting forth the proposed rule.

We look forward to continued collaboration in future implementation of the proposed changes and to continuing to serve Medicare beneficiaries to the best of our clinical ability. Thanks so much.

JODY WHITTEN (0:25:30): Thank you, Molly.

We do know that Beth had been called away, but we are going to double-check to see if she's available now. So, Jocelyn, would you like to try to unmute or have Beth unmute her line? Okay, no. I just got a message that she is not going to speak, but we are going to try Felix Garcia. If we can try to get him to unmute his line, please. Alrighty, he seems to be not able to unmute his line.

I believe we have received comments from all the rest of our commenters today, so I'm going to go ahead and hand it back over to Dr. Robert Hoover for his closing remarks. Dr. Hoover?

DR. HOOVER (0:26:45): Talking away at the mute button.

JODY WHITTEN (0:26:47): Oh, of course.

DR. HOOVER (0:26:49): I think after doing this for several years now, we'd have this all straightened out. Next slide, please.

JODY WHITTEN (0:26:54): You would think.

DR. HOOVER (0:26:56): So thanks, everybody, for your comments today. We'll certainly take those into consideration. And also ask that even though you made verbal comments here today, if you would submit those comments in writing, That is the official form of communication that we have that we use with our LCDs. Next slide, please.

Going through this process, you heard one of the speakers mentioning it. It is a fair amount of time that it takes to go from a request to a final LCD. One of those steps is the comment period, which is 45 days in length, during which time we have this open meeting. Our comment period for the knee orthosis LCD closes on September the 6th, that's a Saturday. And we ask that all comments, including those of the speakers today be submitted in writing. We prefer that this be done by email, and you can see on your screen now, the email address of KOLCDcomments@cgsadmin.com. That same information is also out on the CGS and Noridian websites under local coverage determination. You can go where we have pages that are dedicated to our proposed LCDs and the comment process. You can also go back through the most recent news articles that have been published by both CGS and Noridian and distributed on our listserv, but they are also on our websites and have this information in them as well for the contact for submitting comments. We ask that you please put in the subject line proposed knee orthosis and then the draft LCD number, the DL33318 comment. And then if you want to send by snail mail, which we discourage, but we also have an email or a snail mail address for submitting those policy comments.

We'd like to thank everybody who attended today. Again, thanks to Jody and our provider outreach staff from Noridian and CGS that worked behind the scenes to have our public meeting be a success. And I'll close the meeting for today, thank you.

JODY WHITTEN (0:29:33): Thank you, Dr. Hoover. You may now disconnect. Have a great day.