

Open Meeting: External Breast Prostheses

Meeting Date & Time: August 26, 2026, 10 am ET

Location: Virtual Meeting

Michael Hanna: Good morning, everyone, and welcome to the open meeting for the External Breast Prostheses LCD reconsideration DL33317. From an agenda standpoint, we'll have welcome and introductions, an overview of the proposed LCD, we have presentation of oral comments from 4 stakeholders and, finally, closing remarks and next steps. With that, I'll turn over to Doctor Jenny with Noridian Healthcare.

Dr. Angela Jenny: Good morning, everyone. Welcome to our virtual open meeting. Today we'll be soliciting public comments regarding the proposed External Breast Prostheses Local Coverage Determination. My name is Doctor Angie Jenny and I'm with Noridian Healthcare Solutions, the Jurisdiction D, DME MAC. Also from Noridian is Doctor Smitha Ballyamanda, with Jurisdiction A. Representing CGS Administrators are Doctor Sunil Lalla and Doctor Robert Hoover with Jurisdictions B and C, respectively.

We look forward to your comments regarding the proposed LCD updates. Please submit these comments and send them to us via email at EBPLCDCOMMENTS@cgsadmin.com. Again, please remember that we can only respond to written comments. These comments are due by Saturday, September 5, 2026, when the comment period closes.

Also, we will record the meeting today which will be posted on the DME MAC websites. You are giving your consent to use the use of your recorded voice and comments by signing into this meeting.

Please be careful about sharing any personal health information in your verbal comments. We only allow registered commenters to speak at today's meeting but anyone can submit written comments to the email addresses, address I mentioned earlier.

For our speakers today, we ask that you introduce yourself, the organization that you represent, and any potential conflicts of interest that you may have with this topic. For those who are listening, please mute your phone line and computer, if applicable. Speakers should be prepared to begin their comments immediately after being called upon. Next slide.

Now let us go into a little bit about the proposed LCD. For the External Breast Prostheses LCD, the DME MACs are proposing the removal of the not reasonable and necessary determination for breast prostheses, silicone or equal, with integral adhesive. Remember, this is a proposed LCD so don't take any processing actions until we finalize the policy in the near future, based on the comment that we receive during the open comment period.

I'll now turn it back over to our moderator, Michael Hanna, to introduce our speakers for today.

Michael Hanna: Thank you, Doctor Jenny, for those opening comments. The first stakeholder comment is from Taimur. Taimur, if you would unmute your line for us please.

Taimur Mehmood: Hey, good morning.

Michael Hanna: You're ready to begin, sir.

Taimur Mehmood: Alright. Thank you very much, Michael and Angie. Good morning, everyone, my name is Taimur Mehmood. I am the CEO of Amoena USA. I have no other financial stake in this topic beyond my association with Amoena.

Amoena is a breast care company based in Kennesaw, Georgia. We design manufacture forms and wellness products for women recovering from breast cancer surgery, and um, we serve women in all 50 states and more than 80 countries worldwide.

I want to begin by thanking the DME MAC medical directors and CMS for opening this reconsideration of the L33317. Amoena requested it and we strongly support it. Clear coverage policy matters to the millions of women who depend on these products and we're grateful to the contractors for taking the time to revisit it.



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Let me put the population in context. There are more than 4 million breast cancer survivors in the United States today, and over 320,000 women will be newly diagnosed with invasive breast cancer this year. Um, the median age at diagnosis is 63. That figure matters here. It means that the women this policy serves in the main are medical, are Medicare beneficiaries. This is not a young population at the margins of the program, it's at the center of it. The medical benefit of an external breast prosthesis is well established in the public record. After a unilateral mastectomy, the loss of one's breast weight shifts the body center of gravity and produces measurable asymmetry in the shoulders and neck. One analysis found abnormal posture in more than 80% of women following mastectomy. A randomized controlled trial of more than 700 women found that wearing an external breast prosthesis significantly improved body image and quality of life and separate trial evidence shows that it measurably improves posture. These are medical outcomes, not cosmetic ones.

The reconsideration before you concerns the adhesive attachment form billed under L8031. For a specific and clinically identifiable group of women, this form is not a matter of preference, it's a matter of access. Women managing or at risk for upper limb lymphedema are advised to avoid the pressure of shoulder straps and to distribute weight evenly across the chest wall. An adhesive form attaches directly to the chest wall, allowing these women to follow that guidance and wear a prosthesis at all. The same is true for women with chest wall pain or radiation-altered tissue, that a strap-held pocket form cannot accommodate.

We're not asking you to find that the adhesive forms are universally superior. We're asking that the women who medically need this option not be denied coverage for it. The evidence in this record supports removing the current denial.

Amoena supports this reconsideration. Uh, we thank the medical directors for their work on behalf of breast cancer survivors, and we stand ready to serve as a resource throughout this process. Thank you for the opportunity to comment. I yield back the balance of my time.

Michael Hanna: Thank you, sir. We appreciate it. The next stakeholder comments comes from Michelle Wullstein at O&P Insight. Michelle, will you unmute your line for us?

Michelle Wullstein: Sure, can you hear me, Michael?

Michael Hanna: Yes, Michelle, your audio is coming in fine.

Michelle Wullstein: Thank you so much, and thank you to the DME MAC Medical Directors for this opportunity to comment on the proposed changes to the external breast prosthesis local coverage determination.

I personally oversee compliance and education for O&P Insight. We are an O and P consulting firm serving orthotic and prosthetic business, businesses, many of which dispense post-mastectomy items. Now, our unique vantage point working with both individual clinics while being able to monitor industry-wide trends, provides us an objective perspective on how medical policy changes, audits, as well as fraud investigations affect the broader O and P field. Now, firstly I'd like to start by stating that we fully support the removal of the non-coverage language for the L8031 and we believe that this, um, that Medicare coverage of this prosthesis will significantly benefit post-mastectomy patients and the industry as a whole. However, we'd also like to challenge the medical directors to consider an additional change by adding a pricing data analysis and coding verification requirement, for both the L8030 and the L8031, as a critical fraud prevention measure. The current LCD language prior to these proposed changes, may have inadvertently created an opportunity for incorrect coding by billing the L8030 instead of the L8031 to circumvent non-coverage restrictions and secure and proper reimbursement, whether it was done intentionally through fraud measures or through misunderstanding by those suppliers. A PDAC coding verification requirement would close this loop, deter fraudulent billing practices and help protect Medicare program integrity.

So in summary, we urge the DME MAC to not only finalize the proposed coverage language for the L8031, in order to improve patient access to medically necessary items but also consider implementing a PDAC coding verification requirement in order to safeguard program integrity and ensure equitable reimbursement across the industry.

This concludes my comment. Thank you.

Michael Hanna: Thank you, Michelle. Appreciate your commentary this morning. The next speaker is Joe McTernan. Joe, would you unmute your line for us, please?

Joseph McTernan: Yes, good morning, Michael. Can you hear me okay?

Michael Hanna: I can, sir. Your audio is fine. Go ahead, please.

Joseph McTernan: Outstanding, thank you. My name is Joe McTernan. I am the Director of Policy and Regulatory Affairs for the American Orthotic and Prosthetic Association. AOPA, which is the acronym for us, has been representing orthotic and prosthetic providers, suppliers, and manufacturers since 1917, well over 100 years. We currently have over 1,800 active patient care facility manufacturer and supplier members that are associated with our organization.

Full disclosure, I am not in any way, have any relationship with Amoena as the submitter of this application, nor does AOPA at the moment. Amoena is not currently an active AOPA member so we do not have any direct financial or otherwise interest in this LCD. We do have interest, though, in making sure that there is adequate access to Medicare beneficiaries to have this very important coverage available. So AOPA is in full support and encourages the DME MAC medical directors to finalize the LCD as proposed, to add— or to eliminate— I'm sorry, to remove the reasonable and necessary— not reasonable and necessary determination from the L8031 HCPCS code. As Taimur said and Michelle reiterated, this is an incredibly important benefit that should be available to Medicare beneficiaries when there is medical need and when documentation supports the medical need to have a breast form with an integrative adhesive. As Taimur said, there is an entire population of post-mastectomy patients that, because of complications due to upper extremity lymphedema or radiation effects on skin and on chest wall sensitivity simply cannot medically tolerate a mastectomy bra as the primary means of supporting and suspending a breast form. Increasing— not increasing, but enhancing the LCD to include coverage for L8031 provides an option for these patients that have for many years, simply not had an option and have had to find other ways to accommodate all of the comorbidities that are associated with not being able to wear or to properly use an external breast prosthesis.

As Taimur said, and I'm sorry I keep— I keep— I keep reiterating, he did such a great job of making the points that he made but as Taimur said, this is not and has never been intended to be a claim of superiority of L8031 over L8030. This is simply an option for patients who are unable to clinically utilize a mastectomy bra as a means of suspending an external breast prosthesis, and it opens up a benefit to a population that simply has not had access to it before.

One thing, one point I would like to make is that we are so encouraged by the willingness of the DME MACs in recent years to consider and to really dig into the literature on these LCD reconsiderations, this and others, it is very, very encouraging, and we look forward to

continuing to work with the DME MACs on future reconsiderations on things within the external breast prosthesis realm, subjects like potential coverage of custom breast forms,

and then in other areas as well. So, just wanted to reiterate— reiterate AOPA's support for this policy and our appreciation for the collaborative work that the DME MACs have— have really engaged with the provider community and the supplier community over the last few years.

That concludes my comments today. Thank you.

Michael Hanna: Thank you, Joe. We appreciate that. And our final speaker this morning is Mr. Peter Thomas. Mr. Thomas is your line unmuted, please?

Peter Thomas: It is. Can you hear me?

Michael Hanna: Yes, sir, your audio is fine. Go ahead, please.

Peter Thomas: Great, thank you. Uh, my name is Peter Thomas, and I am the general counsel of the National Association for the Advancement of Orthotics and Prosthetics, that's NAAOP. I also serve as counsel to the O&P Alliance, which is comprised of four national nonprofit organizations, um, AOPA, NAAOP, and then ABC, and the Academy of Orthotists and Prosthetists, all of which strongly support this proposed LCD DL33317. Other than those affiliations, I have no conflicts of interest.

And, uh, just want to reiterate many of the points already made. No reason necessarily to repeat them. Just simply to say that this is an incredibly important option for women who can't tolerate other forms of mastect— post-mastectomy care, uh, and so this is viewed by us as a very important step forward. Again, not necessarily better for everyone but certainly, um, can provide meaningful benefit to those who cannot otherwise use other forms of post-mastectomy care, as I said.

So, um, there, I did note in the draft LCD some comments about the evidence-base and the relative age of some of the study cohorts, I would add that while the average age of identification of, uh, of, um, the need for a mastectomy procedure is 63 years old, which is very close to the Medicare age, 8 million people below the age of 65 are also Medicare beneficiaries, uh, based on disability status, and they, of course, are not immune, uh, from, uh, breast cancer either. Um, so, uh, that's just another, um, reason why the evidence base appears to be, in our view, very much

on point, uh, to the patient population that's being served by this LCD, uh, and we feel strongly that this will open up an avenue for additional options in this area for those who are not currently being served. So it's clearly, um, something that the NAAOP and the O&P Alliance support, to remove this, uh, non-coverage determination and allow, uh, individual, um, medical necessity determinations based on medical need.

I would repeat or parrot what Joe just said about additional LCDs. We are grateful to the DME MACs for bringing forward previous LCDs in other areas involving prosthetics and orthotics in particular, as well as the broader DMEPOS benefit. We do see a lack of access around custom form breast prostheses and, um, hope to work with the DME MACs in the future, um, to, uh, address that as well, but in terms of today's discussion, just want to be as relevant and on point as possible. We urge the DME MACs to finalize the proposed LCD 33317, and thank you very much for, um, making, uh, for moving forward with this policy.

Michael Hanna: This concludes our stakeholder comments. At this point in time, I'd like to turn it back over to Doctor Jenny with some closing remarks. Doctor Jenny.

Dr. Angela Jenny: Thank you. We want to thank you for your thoughtful comments today.

Once again, please remember to send your comments in writing to the appropriate email address. As another reminder, the comment period will end on September 5th, 2026.

Once we have considered and collated all of the comments received during the open comment period, we'll consider any changes necessary as a result of the comments received, and then follow the PIM Chapter 13 process to determine a possible final LCD, along with a response to comments article. The final LCD will take effect a minimum of 45 days following the posting of the final LCD.

For any updates, please ref— please refer to the DME MAC websites. I want to thank everyone for participating today. We will formally adjourn this meeting now. And please see this slide that is posted. Thank you.