

**WPS Proposed Local Coverage Determination (LCD)
Open Meeting Transcript**

Moderator: Dr. Denise Nachodsky

August 27, 2025

1:00 pm CT (2:00 pm ET)

Nachodsky, Denise

All right team. I think we're going to get started here, again. Thank you once again for your patience in the little delay here. But good afternoon to all, to all presenters here and to all people who will be attending this.

Welcome to the proposed Local Coverage Determination (or LCD) Open Meeting, which is conducted by WPS. Today's date is August 27th, 2025, for the records; the time is currently 2:06 PM Eastern Time. This meeting is scheduled for two hours.

As I said, my name is Doctor Denise Nachodsky. I am one of the Contract Medical Directors here with WPS and I'll be moderating this meeting today.

So just as an introduction, what is the purpose, or the role, of an Open Meeting? For any newcomers here I'll just give you a brief summary. The Open Meeting – it is an opportunity for all interested parties to discuss the rationale, to review the evidence and to provide feedback on proposed LCDs. Interested parties are generally those who might be affected by the proposed LCDs, which includes physicians, all of our providers, which we totally appreciate, our beneficiaries, caregivers, vendors and manufacturers. We invite Members of the public and the stakeholders to attend and to provide verbal comments or any statements on the proposed LCDs; there are two of them that we will present today. Anyone attending the call can offer their comments and prior approval to participate in the verbal comments is not necessary

Please note for all that this is being recorded according to CMS regulatory guidance. Before we begin, I would like to ask my colleagues at WPS to introduce themselves, starting with the CMDs who are on the call. Thank you. At the time, I have three colleagues. Take your chance: Who wants to go first?

Vlahakis, Joelle

Hi, I'm doctor Joelle Vlahakis. I'm currently residing in Florida and I am an internist. My training: pediatrician also, and Hospice and palliative medicine. So happy you all are here. Thank you.

Nachodsky, Denise

Thank you so much. And next up?

Campos, Claudia

Hi, my name is Dr. Claudia Campos and I'm a CMD for WPS. Thank you everybody for being here.

Nachodsky, Denise

Thank you so much, Dr. Campos. And then we have Dr. Schaening.

Schaening.Perez, Juan

And thank you, I'm Dr. Juan Schaening. I am a CMD for WPS. My background is internal medicine and I have been a contactor medical director for more than 20 years.

Nachodsky, Denise

Thank you so much. Will the policy coordinators on the line please introduce themselves?

McCary, Michelle

Hi, I'm Michele McCary, I am the supervisor of policy.

Nachodsky, Denise

Thank you.

King, Andrea

Hi, my name is Andrea King and I'm one of the policy coordinators.

Nachodsky, Denise

Thank you.

Schroeder, Tara

Good afternoon. I am Tara Schroeder and I am also a policy coordinator.

Nachodsky, Denise

Thank you. Linda?

Oliver, Linda

Good afternoon, everybody. My name is Linda Oliver. I'm the clinical director here at WPS.

Nachodsky, Denise

Yeah. Thank you very much.

Any other WPS personnel on this call besides Mr. Rich Stanley, who I want to give a big shout out to who coordinates this and is vital to our CAC process. Is there any other WPS staff members on the line?

OK. Seeing not, I think we're going to proceed. So let's go. I'll start with some of the just – logistics and ground rules here. For transparency and in accordance with the CMS regulatory guidance, specifically the Social Security Act, section 1862(1), Section 5 and D and the updated IOM 100-08, the PIM Chapter 13.2.44. Post The Cures Act update, all

proposed drafts were appropriately posted on the WPS portal. WPS posted the proposed drafts to our site on July 17th. This was the MCD date for the respective proposed drafts that we will discuss. The open comment period will begin on that date, which is July 17th, 2025, and will complete on August 31st, 2025. Additionally, these drafts were posted to the CMS MCD portal site.

Our purpose today is to take public comments on the proposed LCDs. That is the only business for today's meeting. Today's meeting is open to the public. It is being recorded and it will be transcribed. Both the recording and the transcription will be posted on our website in several weeks.

All callers are currently muted.

I will introduce the proposed LCD up for comment and then invite our presenters and then subsequently oral public comments after the presentations.

There are two types of comments that we're going to address today. Number one is formal presentations and upfront I would like to personally thank our presenters who took their time, energy and efforts to create PowerPoint presentations for us. They have been submitted and registered in advance. And then, for all the public comments that we may have during this meeting. If you wish to comment, please click on the "raise hand" icon. Rich has that up on the screen so that you can always look back at that. If you are calling in by phone, please press *5. When Mr. Staley calls on you, please make sure that your microphone is on at your end, and that your speakers are silenced. This is to prevent an echo. Before you comment, if you could please introduce yourself, state your affiliation and indicate whether you have a conflict of interest, and if so, what that conflict is. When you make your comments, please be specific so that you can help us, as a MAC, to improve the proposed LCD. If a previous speaker has already made your point, there's no need to repeat it. All you need to do is if you wish to go on the record, if you could just simply say that you agree with the previous speaker. That way you'll be on the record. Each presenter or speaker will be allocated 10 minutes, so that we give equal time to all who wish to comment. Mr. Staley is going to provide a 2-minute warning and he'll close the microphone at the 10 minute viewpoint. If we are unable to address how the presentations within the two hours of this meeting, which I think we should be able to accommodate all, we ask that the presenters submit their comments and their PowerPoint presentation in writing. I do believe that we have received all PowerPoint presentations, but just as a backup, if we need to.

Our purpose today, as the CMDs and this MAC, is to listen to you. We typically do not respond to questions or we're not going to make any comments during this meeting. We might ask for clarification, if necessary, from one of the speakers, but otherwise our role is predominantly just to listen to your presentations and to your comments so that we can get them on the record, so that when we go back to doing response to comments and collecting all your comments as well as others from the other MACs that are involved in the molecular diagnostic program, we'll be able to have it on the record, so that we can answer

appropriately to all. All responses are for educational purposes and do not establish Medicare or WPS policy. Comments are not going to be addressed individually, but they will be compiled, as I said, and addressed in a response to comment document with the final LCD.

Those are the logistics. As I stated earlier, the open comment period for both of these proposed policies is from July 17th, 2025 until August 31.

With that, I'm going to proceed the proposed LCD's for comments are listed in the agenda that Rich has provided. I just want to give you a little background about the Molecular Diagnostics Program. The Molecular Diagnostics Program: It is a multi-jurisdictional, It's a multi-MAC program: it's comprised of multiple MACs that research and develop policy related to molecular diagnostic tests and complex proteinomics and this program is under the CMS regulation and guidance. This program has CMDs with multiple specialties and training, including clinical pathologist as well as PhDs in molecular and clinical genetics etc., That we all collaborate in policy development. All participating MACs adopt the same finalized policy with the same content and the same title of the LCD, except there will be a different LCD identification number.

With that, the first proposed LCD on the agenda is DL40251: That is Molecular Diagnostics biomarker testing for risk stratification in ductal carcinoma in situ (or DCIS). The lead CMD is myself, Dr. Denise Nachodsky. The policy coordinator is Andrea King. Thank you so much for all your help, Andrea. A brief summary of this draft policy includes that biomarker test, molecular or proteinomics that enable risk stratification of Ductal Carcinoma in Situ, (or DCIS) patients into sufficiently low risk Patients who may safely forgo the use of adjuvant radiation therapy, or for patients who should not forego the use of radiation therapy, or receive a higher intensity intervention are currently not covered by this contractor. However, should evidence be further developed to meet reasonable and necessary standards, such a test may be considered for coverage when all of the following criteria are met: Regarding the patient: the patient must have a diagnosis of DCIS and not have concurrent invasive breast carcinoma; The patient must not be in consideration for mastectomy; should not have received radiation therapy for breast cancer in the same breast; This patient should have a formulated treatment plan that includes radiation therapy and consent to its use; And intent to forego the use of radiation therapy if determined to be placed in the sufficiently low risk category to the test; These patients have not been previously tested with the same or similar test; and along with any sample used be within the validated intended use and population of the test.

The test must have successfully completed a technical assessment; and demonstrate significant improvement in accuracy or identification, a sufficiently low-risk patients compared to existing risk stratification tools and methodologies, including non-biomarker, clinical and laboratory findings, or combinations of such findings (and including such findings within its internal algorithms), such as those found in nomograms and risk scoring systems, in appropriately designed and controlled studies published in Peer reviewed, published

literature; or demonstrate equal or superior performance in risk stratification to any other biomarker that has already met the criteria above, that I stated.

For definition, I just want to clarify that sufficiently low risk: The purpose of this policy, this term is defined as a stratification group of patients wherein the absolute risk reduction of the Ipsilateral Breast Tumor Recurrence (or IBTR) from radiation therapy is estimated to be 5% or less when compared to breast conserving surgery alone, regardless of individualized factors (such as their age and intolerance to radiation therapy or any other comorbidities).

So that is a brief summary upfront for all of us and for people who may not, who may be just calling-in, you now know what this policy is in regards to. We have several presenters for this proposed LCD. I would like to present the first presenter and that first presenter is Dr. Pat Withwort – Whitworth – Sorry if I mispronounced your name – who is speaking on behalf of Prelude Diagnostics. First presenter, You're free to present right now. If you have a PowerPoint presentation, I'll let you do that IT stuff with Rich.

Staley, Richard

Yes, Just tell me next slide and I will advance the slides for you.

Pat Whitworth

OK. Please forgive this will be very fast and I will try to remember to say next slide so that we don't waste the time we have. [Echo]

Should I turn off my speaker?

Staley, Richard

Yes, if you could turn your speaker off, that's going to cause that echo.

Pat Whitworth

There we go. I'm Pat Whitworth. I'm a surgical oncologist practicing breast care for 30 years. My career dedicated to advancing best practices in breast care through research and education. I've served as chairman of the American Society of Breast Surgeons and Vice chair of the Breast Committee for the American College of Surgeons Oncology Group. I am presently Chief Medical Officer for the company that makes the biosignature test, PreludeDX, next slide.

There are three groups of patients in the breast conservation treatment of Ductal Carcinoma in Situ. The largest group of patients, 70% of patients with DCIS having breast conservation do not have any recurrence at 10 years, in spite of having no radiation treatment. About 30% of patients would have a recurrence without radiation treatment and about half of those do not have a recurrence if they get radiation treatment. There is still a group even after radiation treatment, who fail at 10 years. Next slide.

The draft LCD requires revision to correct major deficits. First off, it misunderstands

fundamentally the clinical utility of this test and current medical practice. Next, it is unaware of the recent publication that does demonstrate superiority of the test over clinical pathologic factors. Third, it doubts, without basis, statistically significant published, peer reviewed evidence. And finally, it ignored the subject matter expert consensus opinion in the Contractor Advisory Committee. Next slide.

The LCD begins by identifying three clinical utility classes: 1 – sufficiently low risk patients who may forgo adjuvant radiation treatment. 2 – patients who should not forego the use of radiation treatment, and 3 – patients who may need a higher intensity or different intervention.

After this, the LCD never addresses clinical utility class 2, or clinical utility class 3 in any way. It only addresses clinical utility class 1 and it fails to understand the utilization even in that class of patients. The LCD assumes that the test should be used or will be used as the principal or sole determinant for the decision to give radiation treatment or not, to the patient. This is a fundamental misunderstanding. The actual clinical utility of the test, in line with the NCCN guidelines, is to inform shared decision making. Because DCIS patients do not have a different survival with or without radiation treatment and different patients have a different preference for risks and for treatment. 30% of patients having breast conservation in this country would suddenly be deprived of this information if this LCD were allowed to stand. Next slide.

The misconception that the LCD perpetuates is that a patient with an elevated risk would have radiation, and a patient with a low risk by the biosignature would not have radiation. In fact, the NCCN guidelines emphasize the informed patient's preference, and that is the utility of the test; not making the determination or dictating whether the patient does or does not get radiation treatment. Next slide.

The patient will be informed of her risk of recurrence within 10 years, with or without radiation. You can see a patient like this depicted here, with an elevated score of 5.8, has a substantial reduction in her risk of recurrence at 10 years. Many patients who get this result will choose to have radiation treatment, but a number of patients who have this same result will choose not to have radiation treatment. They will be well informed and their personal preference, especially understanding that they have no survival difference with either treatment, their personal preference may be to go without treatment. Next slide.

There is a particular class of patients with a very high score. In fact, this 9.2 score denotes a subtype called residual risk subtype, who have an elevated risk even after radiation treatment. This would be that third clinical utility class, also not addressed by the LCD, who may need more intense treatment. Next slide.

Finally, patients with a low score may indeed choose to have radiation treatment based on their own personal preferences. Once again, this test is not intended, and is not used, to

make a sole determination whether the patient does or not does not have radiation as misunderstood by the LCD draft. Next slide.

Joe Sparano, within the last year, in the Journal of Clinical Oncology, reported that a gene expression assay that provides prognosis and prediction of treatment benefit reduces patient anxiety and decisional conflict and does influence the ultimate adjuvant treatment decision, which is the clinical utility of this test. Next slide.

Reported also within the last year is a clinical utility study including over 2000 patients, where the test influenced and in fact, corrected or changed the decision for recommending or not recommending radiation treatment in 38% of cases with patients who were about to forego RT getting radiation and patients who were about to get a recommendation for radiation, not getting it. Next slide.

Once again, this is not a binary decision. Patients with low scores did often get radiation treatment. Patients with elevated scores usually got radiation, but not always. Not a sole determinant. Not used in the way that the LCD assumes. Next slide.

The LCD states the test must have significant improvement in accuracy over existing tools, published in peer reviewed, published literature. Unfortunately, the LCD writer did not have this new publication, which came out about the same time that the LCD draft came out. But we have made this available to the contractor and we think this changes the opinion - the view – of the contractor substantially. Next slide.

Why do clinical pathologic features not really help us make a decision? You can see here, the most important clinical pathologic feature, high nuclear grade, still give us about the same breakdown. Patients who have high nuclear grade, about 2/3 of those patients do not fail at 10 years in spite of having no radiation treatment. Next slide.

Combinations of clinical pathologic factors is seen in the RTOG 9804 study, or in the Memorial Sloan Kettering Nomogram, also failed to identify patients who do not benefit from radiation treatment. You can see at 10 years, a substantial reduction. In 15 years, an elevated risk, any substantial reduction with radiation treatment for these supposedly low risk patients. In addition, this study could never be conducted in the real world. It is a randomized controlled trial. These are important, but often are not repeatable in actual practice. For instance, in this study, a 3mm margin was required, and so patients were – have had to be taken back to the operating room in 49% of cases and this resulted in an average margin not of 3mm but of 10mm. Next slide.

In the real world, in a combined cohort of 926 patients: patients who met criteria for the RTOG 9804 low risk group, half of the time those patients were reclassified by the biosignature as having an elevated risk and actually had a 20% recurrence risk at 10 years if they did not have radiation treatment. On the other hand –

Staley, Richard

Two minutes remaining.

Pat Whitworth

If a patient was low risk by the RTOG 9804 criteria, and also low risk by the biosignature, they did, indeed, have a low risk and no benefit from radiation treatment. So the test is obviously superior to standard low risk criteria in truly identifying the correct patients. Next slide.

That publication that just came out, that the contractor did not have available at the time the LCD was drafted, here demonstrates that patients who meet these low risk criteria either identified by RTOG 9804, the Memorial Sloan Kettering Nomogram, or the VNPI, or just simple age and grade; About half of those patients actually have an elevated biosignature risk and have a substantial reduction in risk, statistically significant with radiation treatment. Next slide.

On the other hand, patients who are identified as elevated risk by clinical pathologic criteria, if they are actually low risk, and this is about a third of those folks, are low risk by the biosignature. They don't have a statistically significant benefit from radiation treatment. Next slide.

The LCD states the clinical pathologic risk assessments have demonstrated the ability to identify sufficiently low risk patients. This is incorrect. Clinical pathologic tools can identify groups with lower risk, but not individual patients with lower risk. This is the value of genomic testing. Many individual patients within the clin path low risk groups have high risk biology that is only identified by the biosignature and these account for the recurrences that occur within those so-called low risk clin path groups. Next slide.

There was a concern that clin path features are what makes the biosignature effective, and this is incorrect. Age and size are used only to evaluate a particular biologic pattern, which may be high or low risk depending on the patient's age. Next slide.

Staley, Richard

And I'm sorry, time is up.

Pat Whitworth

Next slide.

Then the LCD doubts statistically significant published peer reviewed evidence. It actually cites the overall risk with radiation treatment from the randomized controlled trial, where tissue is available and the assay could be formed on the – could be performed on the tissue that was available from the suite DCIS study. All modern authors agree that the rationale for treating DCIS is to prevent invasive recurrence. And in that study, the only reduction in risk

was invasive recurrence occurred in patients who got radiation treatment. Patients who were in the low risk group did not have any real reduction in recurrence risk at 10 years. Next slide.

Nachodsky, Denise

Hey, Dr. Whitworth? Dr. Whitworth? I'm sorry – Dr. –

Pat Whitworth

You can see here in that study that in the elevated biosignature risk group, there was a 9% absolute reduction, which was statistically significant and in the low risk group there was a 1% reduction which was not statistically significant. Again, this could perpetuate the idea that the test is a binary test, determining whether the patient gets radiation or not, not the actual use of the test. The continuous risk scores are what we use in clinical practice. Next slide.

Nachodsky, Denise

Okay, is this the summary point? Because we are over by several minutes at this point.

Leona Hamrick

I don't think he [inaudible].

Pat Whitworth

This is the same thing that happened in the early 2000s with the NSA BPB 20 results using the Oncotype test, looking at systemic treatment.

Leona Hamrick

I think he has his mic turned off.

Nachodsky, Denise

Yeah, yeah.

Pat Whitworth

Next slide.

Patrick Borgen MD

His speakers are off. I believe Pat's speakers are off.

Nachodsky, Denise

OK. If you could put into the chat, so that we can continue –

Pat Whitworth

Next slide.

Leona Hamrick

I'm gonna text him. I'll text him. Right now he only has two more slides and one of our presenters is in the operating room, so I think we're OK.

Nachodsky, Denise

OK.

Pat Whitworth

I hope this isn't taking... The test also identifies a group with particularly elevated risk. This is an activated HER2K RAS pathway. Next slide.

So that the biosignature now identifies three separate groups: the low risk group, the elevated risk group with a very low risk after radiation and the residual risk group with an elevated risk even after radiation treatment. You can see that that is a group of patients in clinical utility Class 3 and the other, in the middle there, is a group of patients in clinical utility Class 2. Next slide.

To conclude, the LCD should be amended to provide individual coverage for the DCISionRT™ test. Non coverage is inconsistent with the fact that the test is presently covered for breast DCIS patients because it provides new clinical diagnostic information not obtained by other tests or combinations of tests non-Coverage will necessitate continued adjudication by administrative law judges, overturning denials. Individually for Medicare beneficiaries and non-coverage would suddenly deprive 30% of DCIS patients, having breast conservation of current best medical practice, as identified by the Contractor Advisory Committee. Thank you.

Nachodsky, Denise

Alright, thank you. I understand that.

Pat Whitworth

You're muted.

Nachodsky, Denise

Yes. I think Doctor Whitworth, you may not have heard all of our stuff if you aren't - If you cannot hear because your speakers aren't on. Thank you for this presentation; Your colleagues can tell you that. At this – it was very informative. I will ask that though you stated that you had the updated article that you sent it once, if you could just, for completeness sake, please resend that last article that you said was updated at the time that this draft was prepared and proposed.

Pat Whitworth

Thank you.

Nachodsky, Denise

Thank you. At this point, I'm also going to say without – Trying to show professionalism and

respect for all of you, if your speakers are off and you don't understand what Mr. Staley is doing, if you're cut off all of a sudden, it is because your 10 minute mark has been well, then exceeded. Thank you so much.

At this point, are there any questions from the CMDs on this presentation?

Schaening.Perez, Juan

I have no questions. Thank you.

Nachodsky, Denise

All right, no comments from my colleagues? I'm going to proceed with. Are there any comments from the general public on this proposed LCD and presentation?

Leona Hamrick

This is Dr. Hamrick. I've just got a question. Doctor Vincent Reed is supposed to speak around 2:45. He's in the operating room. Would it be possible for him to join later and speak at a later time? He's trying to wrap up a surgery.

Nachodsky, Denise

We're going to go with the other two who proceed before him. And as I said, this is a scheduled meeting with time frames and we have another policy to present. So, we're going to go according to what the schedule is. If unfortunately he – which is far more important – is taking care of a patient in the operating room, which we thank him for taking care of our beneficiaries, then he should just provide his slide presentation to us, so that it can go to the whole committee for looking at it.

OK, our next presenter is Doctor Patrick Borgen vs Borgen, I hope I didn't mispronounce your name; Who is also speaker on behalf of Prelude. If you'd like to proceed at this point, I'm thank you.

Patrick Borgen MD

Yes, thank you very much. Can you hear me alright?

Nachodsky, Denise

Yes. Can you hear us?

Patrick Borgen MD

Great. I'd like yes, perfectly.

Nachodsky, Denise

OK.

Patrick Borgen MD

My speakers are on, I promise. I want to thank Dr. Nachodsky and Mr. Stanley and the WPS

team really for this privilege. My name is Pat Borgen, I'm the chairman of the Department of Surgery at Maimonides Medical Center, and I'm the founder of the first safety net breast cancer program in Brooklyn, which is now America's third largest city. Prior to this for 18 years, I was the chief breast surgeon at Memorial Sloan Kettering Cancer Center and was the senior investigator on the MSKCC Nomogram, which we will, which we will talk about. So again, thank you very much. I do not have any financial or contractual relationship with Prelude. Next slide please.

So I'm going to go off this slide for just a moment because I think that the most important thing to understand about ductal carcinoma in situ is that we have misunderstood it as a disease entity, for most of the last 30 years. We assumed that all DCIS, if incompletely treated, would become invasive breast cancer; that it was an obligate precursor. We now know conclusively that that is not true. At the beginning of my career, in 1990, DCIS was found in 1.9 out of 100,000 women. Today, it's over 35 per 100,000 women. We began to see DCIS with the popularization of mammography and the better mammograms got, the more DCIS we saw. And so that made us realize that there is a reservoir, maybe a very large reservoir of DCIS that was really not destined to harm the patient that's in front of us. And so, what Dr. Whitworth introduced very elegantly is the fact that what we need to do is match the treatment to the disease. And across all of oncology, that's the magic. In the – at the turn of the Millennium, we didn't have the genomic tools and so, at Memorial, we developed a nomogram, which was the best that we had in 2002. But many investigators still use that as a reference. I'm flattered, but it's wrong. We we have to really take a look at the genetics of these tumors. So, we can advance. You can click the slide twice. Here.

So the study that Dr. Whitworth showed basically asked: "Do doctors believe the test results? And does it affect their actions?" And the answer was an overwhelming yes. There were 2007 women from 63 centers whose doctors were asked: "would you or would you not recommend radiation therapy in the patient in front of you?" Then they were provided the DCISionRT™ test results. And of course, as Dr. Whitworth showed you, and I won't belabor it, Their recommendations changed almost 40% of the time. Next slide please.

Of 580 women who their doctor said I would not recommend radiation, 1/3 of them or 183 patients were recommended to undergo radiation therapy. And equally importantly, of 1400 women initially told "you need radiation therapy," 41% were not recommended radiation. This is critically, critically important. And it's nowhere more important than at a hospital like ours, with a very financially distressed patient population where every single treatment we give is critically important. And matching the treatment to the disease is really, vitally, vitally important. We could not make these determinations without this biosignature. Next slide please.

I won't belabor the details, but there was a very high percentage of patients looking at different scores on the test, where the treatment decisions were changed. And in the highest risk, a recurrent score of more than 4, 80% of patients who were not recommended to undergo RT were subsequently recommended. So, next slide please.

And when we look at a 4S plot, really the DCISionRT™ test was one of two strongest drivers of radiation therapy recommendation, and this was – this is extremely, extremely important on how we make our clinical decisions. All of the other things that we use – next slide please.

Dr. Whitworth also said that this is not a yes/no answer, and that's true. Some patients with a low recurrent score still elected to undergo radiation, and that's really understandable. And some patients with a higher score elected not to undergo. So this is really a sort of a linear relationship. And we believe passionately in shared decision making and you can't do that without understanding the biosignature of these tumors. And so this test is really critical to me and my patients. Next slide please.

The other tools that are out there – VNPI stands for Van Nuys Prognostic Index; This is another nomogram, if you will – are very historically interesting, but only historically interesting. We cannot suggest – my father worked for NASA and he had a slide rule and he was pretty good on the slide rule, but nobody would replace a calculator today with a slide rule. And really, my Nomogram from MSKCC, in all intent and purpose is that. And so, we have to open up the hood. We have to look at the engines that drive these cancers and we have to predict what class is this – is this DCIS that needs or will benefit from radiation or not? Next slide please.

And we can go to the next slide please.

So, the Draft LCD really needs to be improved and Pat covered these issues addressing the published literature, showing how much this test adds value over conventional clin path. It claim not to know about the residual risk subtype. Remember, those are the patients who have a high risk of recurrence, even with radiation therapy. And it it may be appropriate to talk about a bigger operation in those patients. The draft did not address public literature showing the DCISionRT™ test changing recommendations, which of course, absolutely in the predict study, it did, and we're doing a large follow-up study.

And so I'm going to conclude a minute and a half early to make up for my colleague, Dr. Whitworth, and emphasize in the real world, in a very, very, very large practice in a very urban area, this test is really absolutely essential for us, as the as the Oncologists, to getting it right for our patients. So again, thank you very much for this privilege. I really appreciate it.

Nachodsky, Denise

Thank you. First of all, a couple comments. Number one, Dr. Borgen. I just love your humor and it's just very sweet. But, I really my comments for this is: your presentation was wonderful. I really – the importance of collaborative, shared decision making with the patient and with the physician and with peer reviewed medical literature is vital. And the importance that you stress that women, and men, you know, who may also, unfortunately, have a have breast cancer: It is to be individualized. It is something that is a decision that needs to be

made with their MD and with the patients – knowing the whole patient. And I think that that is sometimes lost when we have to go by protocol, or saying, well, this is, you know, evidence based medicine. So, I truly applaud you for the importance of considering that.

Patrick Borgen MD

Thank you so much for the kind words. I really appreciate that. Thank you.

Nachodsky, Denise

That is – and then lastly, you're stating your age, here. I started to laugh, as you see, during your father's time, he used a slide rule. We were getting out of that part. Then we went to the calculator era. The new era, all they do is go to chat-AI and get the answer.

Patrick Borgen MD

Right.

Nachodsky, Denise

So there's been big changes here, but I think we need to move back to our part is. But again, I totally appreciate that.

Patrick Borgen MD

Thank you.

Nachodsky, Denise

You had a very nice presentation that I think is – academically, it helps all of us understand at the MAC level, who may not be in your specialty. So once again, much appreciated.

Patrick Borgen MD

Thank you.

Nachodsky, Denise

At this point, I'm going to ask if any of my colleagues, my fellow CMDs, have any comments.

Schaening.Perez, Juan

No comments. Thank you.

Patrick Borgen MD

Thank you, doctor Nachodsky. I appreciate your kind words. Thank you.

Nachodsky, Denise

I have two shy fellow colleagues -CMDs. So we'll let them be shy, okay? Is there any comments from the general public?

Okay. And with that, we are going to then proceed with our next presentation, which is by Doctor Chawla. And again, please forgive me if I misspelled your name incorrectly. And Dr.

Chawla is colleagues of the other two, and is also a speaker on behalf of Prelude. I will let the two of you take it away.

Ashish Chawla, MD

OK. Thank you. Can you hear me OK?

Nachodsky, Denise

Yes, thank you.

Ashish Chawla, MD

OK, I can hear you as well. So definitely will try to keep things within time. And again, just want to reiterate that I appreciate the privilege and the opportunity to speak to you all today.

Just my background: I'm a radiation oncologist. I'm the department chair and Division Chief of Radiation Oncology at the Inova Schar Cancer Institute in Northern Virginia; one of the larger radiation oncology practices in the east coast United States. We have 25 providers – MD's and APPs – in our practice. In this role, I am actually the lead breast radiation oncologist; It's about 80 to 90% of my practice is discussing, very much in a shared model, decision making about the use of radiation therapy for breast cancer all the way from DCIS through stage four. I've been the lead breast radiation oncologist here at Inova for about 10 years, and been with this practice for about 15 years.

So our previous two speakers both have tremendous and very impressive surgical backgrounds. So, slightly different perspective as I'm a radiation oncologist, Who – and as our treatment options and our strategies and number of treatments and technologies have changed, so have the discussions about the pros and cons of our treatment. And I think the most important fundamental thing I've heard in the half hour before this that, I want to just reinforce: is how much of the decision making is not a binary, “Yes, you must do this” or “No, you can't do this.” That's never the discussion I have. I have multiple DCIS consults per week for radiation oncology discussion and we use, of course, the traditional clinical and pathologic features that I was trained on, and of course we use Dr. Borgen's – that we have used for many years – Dr. Borgen's MSKCC Nomogram. That was our go to, about a decade ago. And as he humbly admitted to, and I agree, it's no longer the main tool. It's not the main thing we use. We use many different things, but the use of genomics has revolutionized the way we care for many cancer patients, not just DCIS. And I believe this test is a really, really, great example of that, as I'm as I'm about to show – talk about – from the radiation oncology perspective.

To be clear, I have absolutely no relationship financially with anyone that would have any impact on this discussion, so I have no disclosures.

Primarily, I believe, respectfully, that this draft should be retracted for the specific reason that this discusses the omission of radiotherapy, which is obviously a part of how we use this test; identifying low risk patients who may, based on a very good discussion of risks and

benefits, choose to omit radiation therapy. But it does – I want to focus on the fact that it ignores the test's role in identifying patients who, I, as a radiation oncologist, may otherwise recommend to not do radiation. Prior to this test, many patients with low grade, low volume, big margin disease that I would – after a good discussion with the patient – we would choose not to do radiation, but that this test result can, on the flip side, switch us to recommending radiation or having a strong discussion about the use of radiation therapy, because it is identifying patients in whom, for whom, clinical pathologic features simply were not sufficient in identifying that risk. And it's been validated that this is a tool that gives us information that traditional clinical and pathologic features of disease does not. And it's simply not only about omitting radiation, it's about individualizing the recommendation to do, or not do, radiation therapy in a way that we cannot do without this test. It would fundamentally impact my ability to appropriately counsel and guide my patient's care.

So I do believe that it's a reasonable and necessary test for the treating clinician. I order DCISionRT™ for the vast majority of the patients in my practice, and so do my colleagues. We have a group of five breast-focused radiation oncologists in my practice. We have collaboratively discussed this at the local, regional and national level and feel very strongly about the use of this test, even though it actually does, on balance, reduce the use of radiation therapy. We are all about individualized care and having all the information in front of us that allows us to counsel our patients the best way possible. Next slide.

So I'm not going to read this wordy slide, but I wanted to make sure – the slide is very important and provides good information; It's a great slide – but I'm going to just paraphrase. And I think the idea, again, is that this test did not it – It fails to address the role for identifying patients with high risk disease; with disease that would otherwise be considered low risk based on the traditional factors and the nomogram, but based on the results of this test, we know that the risk is actually higher than predicted. And that can be, for radiation oncologist and a patient, the difference between doing radiation versus not. But also, the many nuances within radiation therapy, there's a lot of data about using boost for radiation therapy, or not, for high risk patients, and the genomic score benefits us in that way as well. There's options of partial breast irradiation versus whole breast irradiation. The idea that radiation therapy is a binary yes/no discussion with patients is actually no longer the case. And in addition to both identifying patients that may not benefit from radiation who we otherwise would recommend it, or the flip side, where it helps us identify patients who would benefit from radiation where I otherwise would not recommend it; It also then gives us information to help customize those recommendations that meets that patient's needs or their appetite for risk versus benefit. And that's the discussions we have all the time. Radiation therapy has changed dramatically, as have most technologically driven fields, over the last 10 to 15 years. And this tool is really important in helping us have those types of discussions. So what is not addressed really in this situation is those patients who have low risk clinical pathology but are determined to be high risk based upon this genomic test. And I think that was something that was, perhaps, not fully addressed in the draft. Next slide.

So, the test itself reclassified patients with low risk clinical pathology and identifies those who

have elevated 10-year ipsilateral breast tumor risk and therefore would benefit from radiation therapy. So a real-world example is a patient with Grade 1 or Grade 2 DCIS ER/PR positive, small volume, large margins. These are patients we were trained on, and who I have routinely discussed the appropriate omission of radiation therapy based on only those numbers that I have available to me for prediction, based on those clinical pathologic features. And what DCISionRT™ has given us: validated – and I think we've shown this, but I think there's a further slide that will show this again – validated information that it is a more useful piece of information than the clinical pathologic features to help counsel patients in whom that risk is actually higher. So again, to emphasize, this is not just a test about omitting patients who we are predicting derive a low – a small benefit from radiation. It does that and that's important, but it does the opposite as well. So the papers that are mentioned here, are showing that low risk CP clinical pathology are frequently classified as “elevated risk” and have an elevated 10 year ipsilateral breast tumor risk that would not otherwise be identified by any of the traditional features of disease that we look at. And that's in both the Bremner and the Vicini papers.

A large prospective study demonstrated that patients with “low risk” clinical pathology who were initially not recommended radiation therapy, using this test, they are recommended. We are recommending radiation therapy for a good number of these patients. So the idea isn't – and I'd say this to my patients and to others in practice all the time – the idea of this test isn't “less radiation” or “more radiation.” It's using radiation when it's going to be most beneficial to that patient. That's what individualized cancer care is all about. This is not a new concept. We use genomics as a radiation oncology chair. We use – I know that we use this in prostate cancer, breast cancer, lung cancer, skin cancer, melanoma. This is, as I think you all know, something that we feel very strongly about across the board. And the goal is individualized, personalized decision making. Next slide, please.

And the other factor that I don't think was necessarily fully addressed here in the draft was the residual risk subtype. So this is a – what's considered a very high-risk subgroup of patients that are being identified using genomic profiling. Where, even after radiation therapy –

Staley, Richard

Two minutes.

Ashish Chawla, MD

- a group has been identified that has a high elevated risk of recurrence. This may inform the use of boost for radiation therapy, enhance surveillance for patients or, in some patients, if they don't feel that that risk reduction is sufficient with breast conserving surgery and radiation, then they may be counseled towards future consideration of prophylactic mastectomy. Again, it's not that any of these are right or wrong answers. It's that the patient has the information that she deserves to have to help make that decision in conjunction with her treating physician. And she can hear about what the toxicities of radiation are with modern techniques, weigh that against the predictive benefit and make an informed

decision, which is what this is all about. So the high-risk, the residual high-risk group, is really a group that's not otherwise addressed through any other test that I'm aware of. And this has validated data that has shown we're identifying patients who, even after lumpectomy and radiation, have a residual risk that is quite significant and can guide further decision making. And that's a really important use of this test that is scientifically valid. Next slide, please.

Finally, this is just showing this in graphical form – what we were just talking about – which is identifying a small but clinically significant percentage of patients who we identify as residual risk. And the importance of identifying these patients is something that we as radiation oncologists feel very passionate about. The breast surgeons and the medical oncologists we work with feel the same way. So we're really proud to utilize this test in practice. We really do feel, based on all of the studies and evidence that have been presented today, feel strongly that this is a vital part and frankly would be a dramatically negative impact on my ability to care for patients in an individualized way that I that I intend to, If this test were not available to my patients. So I, again, thank you for the time to present this information from a radiation oncologist, a breast-focused radiation oncologist's perspective and again appreciate the time allowing me to make some of these points. Thank you for your time.

Nachodsky, Denise

Thank you so much, Dr. Chawla for your presentation. Very much appreciated. And with that, do any of my colleagues have any comments?

Campos, Claudia

No comments, and thank you.

Vlahakis, Joelle

I do not, but I just wanted to thank our last speaker for his perspective in radiation oncology.

Nachodsky, Denise

Thank you, Dr. Joelle –

Schaening.Perez, Juan

And, no comments. Thank you.

Nachodsky, Denise

Thank you. We're going to get Dr. Campos in there to say thank you. You know how I –

Campos, Claudia

I did say thank you and no comment.

Nachodsky, Denise

As you can see, as you can see, many, the public here: I like to get everyone involved one way or another and to create fun. So thank you all.

Thank you very much for that presentation. Dr. Muscato had a remark: Dr. Muscato, I'm going to ask – your comment: if the test is really predictive, then the information is potentially important to the patient – that is a comment that we'd appreciate that you would please put in writing and send to us, so that when all the MACs get together, re-looking at the literature, and the slides from all of our presenters and all of the comments at the closure on August 31st, we can re-look and give response to comments.

Next, Doctor Reid, is he out of the OR?

Staley, Richard

I do not see Dr. Reid on the line at the moment. I will make sure that his Proposal – the – his presentation that he sent to us gets included in the policy comments email box.

Nachodsky, Denise

OK. Thank you so much. Much appreciated. And we'll see you at – Let's get through our other policies so that people can make comments. And then, if Dr. Reid is out of the OR at that time, then perhaps we can get him to kind of jump in and conclude if we still – if we're within our time frame.

So, If there's no other comments from anyone in regards to this proposed LCD, I'm going to go on to our next proposed LCD on the agenda, which is DL40249: Molecular Diagnostic Testing for Solid Organ Allograft Rejection. The lead CMD is myself, Dr. Denise Nachodsky, the policy coordinator is Tara Schroeder, and thank you, Tara, for your involvement in this.

So, a brief summary of this proposed policy is: The Medicare contractor, meaning all of the MACs, here, will provide limited coverage for molecular diagnostic tests used in the evaluation and the management of patients who have undergone solid organ transplantation. These tests can inform decision making along with standard clinical assessments in their evaluation of organ injury for acute rejection. These tests may be ordered by qualified physicians or providers operating within their scope of practice. Considering the diagnosis of acute rejection, helping to rule in, or rule out this condition, and when assessing the need for or results of a diagnostic biopsy. They should be considered along with other clinical evaluations and results, and may be particularly useful in patients with significant contraindications to invasive procedures.

So molecular diagnostic tests that assess a transplanted allograft for rejection status are covered when all of the following criteria are met: Number 1 – the tests must provide information about at least one of the two following clinical status: Status Number 1 – to be acute, active rejection, or Number 2 – cellular or antibody mediated rejection. That is the status.

Additionally, the test must provide information that the intended use of the test must be to inform clinical decision making as per the following: to assist in the evaluation of adequacy of

immunosuppression or response to treatment; or wherein a non-invasive or minimally invasive test can be used in lieu of a tissue biopsy; or as a rule-out test for acute rejection in validated populations of patients with clinical suspicion of rejection with a non-invasive or minimally invasive test to make a clinical decision regarding obtaining a biopsy; or for further evaluation of allograft status for the probability of allograft rejection after a physician-assessed pretest review of clinical and biological factors are concerning for the risk of rejection; or to assess rejection status in patients that have received a biopsy, but the biopsy results are inconclusive, unexpected given the patient's clinical laboratory presentation, or is limited by insufficient material; or, lastly, to assess for subclinical rejection of an allograft (example - surveillance testing) according to a clinically validated cadence, and what I mean by that is it's in peer reviewed, published evidence or established national consensus guidelines, utilizing the minimum number of test timepoints that have demonstrated clinical utility appropriate for the specific transplant type. Data right now shows, at the current time, the current evidence suggests a maximum number of surveillance timepoints for evaluation in the first-year post-transplant for kidneys is 4, heart 12, and lung 12. After the first year, surveillance timepoints may continue at a decreased frequency of 2 per year.

The test must also demonstrate analytic validity, clinical validity and a MoIDX technical assessment, as outlined in the draft policy, they need to be met to establish the test is reasonable and necessary.

Are there any comments from my colleagues or the general public on this proposed LCD?

Campos, Claudia

Thanks Dr. Nachodsky, no comments.

Nachodsky, Denise

Rich, make sure that's down in writing, OK. And thank you. thank you, Dr. Campos.

Schaening.Perez, Juan

No comments. Also thank you.

Nachodsky, Denise

Thank you, Dr. Schaening. And we're going to get Dr. Joelle: any comments?

Vlahakis, Joelle

No, but if you don't hear from me, there's construction on my end. So I'm – I've been very quiet.

Nachodsky, Denise

All right. Thank you so much my fellow colleagues. Is there any comments from the public?

Staley, Richard

And just a reminder, "raise hand" icon, or press *5 if you're on a touch tone phone.

Nachodsky, Denise

OK, I see no remarks for this one. I want to thank all who've been here. The representative that was speaking on behalf of Dr. Reid, I I forget your name, and I'm sorry that I missed it when you were speaking. Is Dr. Reid out of the OR?

Staley, Richard

Do not believe that she is still on the line.

Nachodsky, Denise

OK. I thought I heard you in the background there. OK.

Well, anyone who is also attending, and is a colleague, and also Rich: if you could just send up an e-mail to Dr. Reid thanking him that he's taking care of patients, which is far more important, though we do appreciate that he did prepare a presentation, if he could just – Rich, if you have those slides – if not, just send off an e-mail stating that we will be sending his slides to the MolDX program so that we will have his data and his comments for review.

Staley, Richard

I will do that.

Nachodsky, Denise

Thank you so much.

And if there are no other comments from anyone, I do want to thank everyone who took time out of their busy schedule to attend this open meeting and for any public comments and for my colleagues who have provided comments, as well as the policy nurses who are vital to helping us write these policies and keep us on track. I want to thank the speakers: You had excellent, informative presentations. Please remember that people who were too shy to make comments, you certainly can still write them in until August 31st. Please submit them to the Medicarepolicycomments@wpsic.com. Include the topic of the LCD on the e-mail subject line. If you do have supporting scientific literature, please attach that in either a PDF or a Word document, to the policy comments mailbox. Just note, per regulatory guidance, WPS cannot just follow an e-mail link. That is why we need the PDF of the literature.

I want to thank again all my colleagues here, a very special thank you to you, Rich for your coordination and all your behind the scene work that you do to make this a successful Open Meeting. If there are no further comments, this concludes our meeting and thank you very much and have a great afternoon. I will adjourn this at 3:09 PM Eastern Time. Thank you once again.