National Government Services
Moderator: Dr. Olatokunbo Awodele
June 20, 2024
11:00 a.m.

Coordinator: Welcome, and thank you for standing by. For the duration of today's conference, all participants will be in a listen-only mode. I'd like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Dr. Awodele. Thank you. You may begin.

Dr. Ola Awodele: Thank you. Good afternoon, everyone. I'd like to welcome you on behalf of NGS. I'd like to welcome everybody to our open meeting. Today is June 20th, 2024, and it's a J6/JK combined open meeting. I'd like to turn everybody's attention, if you're logged in and can see the screen, to just remind you that there's no audio access via computer.

Instead, to be able to listen in audio-wise and participate during the comment section, you will need to use the call-in information that is up on the screen. The call-in number is 1-800-619-3379, and you will need a passcode, which is 6393158. Again, computer audio is not available. Thank you. Next slide, please.

And then another reminder is that this call is being recorded and transcribed, and will be posted on our website at a later date. Next slide, please. So, again, on behalf of myself, I'm Ola Awodele, on behalf of - then we have other CMDs, Dr. Duerden, Dr. Lawrence, Dr. Mullen, Dr. McKinney, and Dr. Noel, all NGS contractor medical directors, we would love to welcome you to this JKJ6 Open Meeting. Next slide, please.

We have two draft LCDs on the menu for today, on the agenda. The first one is DL33579, and it's Transesophageal Electrocardiography, also known as TEE. The second one is DL39863, and that is Artificial Intelligence-Enabled CT-Based Quantitative Coronary Topography, in brackets, also known as AI-QCT, and Coronary Plaque Analysis, also known as AI-CPA. Okay, next slide, please.

So, the first draft is transesophageal electrocardiography, also known as TEE. This draft LCD is being brought just for clarification of some area under the limitation of coverage. It was causing some confusion which made it seem as if anesthesiologists were not able to do this.

We have since clarified the language, and we've revised the section for intraoperative TEE when performed for transcatheter pulmonary valve

replacement, mitral valve repair, paravalvular regurgitation repair, left atrial appendage occlusion closure, and ventricular septal defect closure, to now state that any physician, the anesthesiologist, anybody who's going to be doing it, the more important thing is it has to be done for anything other than monitoring intraoperatively for it to be billed and paid separately. Next slide, please.

We did not receive any requests for presentations or formal comments, and as such, we don't have any scheduled for today, but I would like to open the floor for anybody who has additional comments for this draft who would like to go on record. So, operator, could you please request for comments on this limited portion of the LCD, which changed this specific language, or clarified this language? Could you please open up the lines - call for comments, and open up the lines of commenters. Thank you.

Coordinator: If you would like to make a comment, please press Star 1.

Dr. Ola Awodele: I'm going to allow for a minute or two to give people the ability to navigate the Star 1.

Coordinator: I'm showing no comments at this time.

Dr. Ola Awodele: Okay. Thank you very much. Well, that ends - next slide, please. So, I just would like to let everybody know that the comment period will end on 7/14/24 at 11:59 p.m. So, if anybody wants to submit any comments, all formal comments must be submitted in writing to NGS. Next slide, please.

This concludes the portion of the open meeting regarding DL33579, transesophageal electrocardiography. And at the end of the open meeting, there will be a slide on how to submit comments formally to us. Thank you very much. And I'm going to hand this over now to Dr. Gina Mullen to discuss the next draft. Thank you. Dr. Mullen?

Dr. Gina Mullen: Thanks so much. This is for draft DL39863, Artificial Intelligence-Enabled CT-Based Quantitative Coronary Topography, AI-QCT, Coronary Plaque Analysis, AI-CPA. This is a collaborative LCD with CGS administrators, Noridian Healthcare Solutions, NGS, Palmetto GBA, and WPS Government Health Administrators.

A contractor advisory meeting titled Non-Invasive Technology for Coronary Artery Plaque Analysis was hosted on May 25th of 2023, and available on the website. The comment period closes on 7/14/2024. Next slide. AI- QCT, AI-CPA, using CCTA, is considered reasonable and medically necessary as a diagnostic study when the patient is eligible for CCTA, and the patient presents with acute chest pain and no known CAD, and is classified as one or both, either intermediate risk, and/or CAD-RADS 2 and CAD-RADS 2 category on CCTA, and has had a cardiac evaluation that is negative or inconclusive for ACS. Next slide.

The test is never covered for screening, i.e. in the absence of signs, symptoms, or disease. There are no contraindications to CCTA. It is not in conjunction with invasive coronary catheterization. It's not to be used with normal CCTA results, such as a CAD-RADS score that is equal to zero or with no plaque disease. It is not to be used with high-grade stenosis greater than 70% or CAD-RADS 4 and RADS 5, recent MIs that are 30 days or less, unstable coronary symptoms, and not to be used for

surveillance. Next slide.

This new collaborative LCD has limited coverage to ensure access for a clearly-defined subset of patients where benefit has been established. While further investigation defines the role of this emerging technology beyond this population - excuse me, I'm sorry. The role of this technology for surveillance or monitoring, response to treatment has not been established in the literature and, therefore, is limited.

I would like to turn the floor over to Dr. Amit Pursnani, a cardiologist at Northshore University Health System in Evanston, Illinois. Dr. Pursnani, are you on the call?

Dr. Amit Pursnani: Yes, I'm here. Can you hear me?

Dr. Gina Mullen: Yes. Yes, sir. I'll go on mute.

Dr. Amit Pursnani: Fantastic. Well, thank you, first of all, for the opportunity to present and speak at this meeting. Just as a little bit of background, I'm a cardiologist at Northshore University Health System. I oversee our cardiac CT and MRI programs, and have been a principal investigator on the D-CODE study, and I'll be sharing research on that today. Next slide. These are my disclosures. Next slide.

On this agenda, I will talk about AI quantitative coronary plaque analysis, some prognostic data to show the utility of this beyond just coronary CTA stenosis evaluation and FFRCT. And I'll present some information on its accuracy in comparison to the gold standard of intravascular ultrasound. I'll also make a request to expand coverage for patients who also fall in the CAD-RADS category of 1 through 4, based upon supporting evidence from the D-CODE study. Next slide.

This is the advanced registry. This is a large registry of over 4,000 patients who underwent coronary CTA and were followed for a variety of hard outcomes. In this registry, they evaluated quantitative plaque using the AI-CPA algorithm. And they looked at the association between quantitative plaque metrics and clinical events at one year.

And as you can see in this table here, that higher amounts of non-calcified plaque, total plaque, as well as low attenuation plaque, were associated with increased adverse clinical events at one year. And what's important is the adjusted hazard ratio as well, which adjusts for a variety of different demographics, risk factors, as well as fractional flow reserve information. So, patients who have a non-calcified plaque greater than 323 millimeters cubed here, had an adjusted hazard ratio of 1.5, and similar results were seen for total amount of plaque, as well as low attenuation plaque. Next slide.

So, AI-CPA is also extremely accurate at quantifying and characterizing coronary plaque, and this was studied in the REVEAL plaque analysis. The REVEAL plaque analysis was a prospective study comparing quantitative coronary CTA plaque analysis with intravascular ultrasound, which is an invasive means of quantification of plaque volume.
This is a study that was - the analysis was adjudicated by a blinded core lab. This study enrolled clinically stable patients with known coronary artery disease from 15 centers globally, and what they found was that AI-CPA is accurate in measuring and characterizing coronary plaque without requiring invasive procedures such as

IVUS. The correlation curve is sort of on the right side with an R value of 0.91, and showed 95% agreement with the gold standard of IVUS. Next slide.

For the last couple of minutes, this relates to the request to update the draft coverage indication that will allow for AI-CPA across the spectrum of CAD-RADS category, including CAD-RADS 1, 2, 3, and 4 patients. Currently, the draft policy reads to only include CAD-RADS 2 and 3. And some of the supporting evidence that I'll show, primarily sort of the supporting evidence for this, comes from the D-CODE study. Next slide.

So, the D-CODE study was a proof-of-concept study where three practicing cardiologists with Level 3 CT reading skills who managed patients in a preventive cardiology setting, assessed data on 100 patients, looked at their demographics, their clinical history, their lipids, their labs, as well as their coronary CTA reports, and came up with a management decision based upon a schema that's delineated in the table to the right.

So, they started with a management plan, and consensus, determined a management plan that ranged from either stage 0 all the way to stage 3 plus, with incremental sort of increase in the types of and intensity of medical therapy. The investigators were then given the information on the quantitative coronary plaque analysis, and were given an opportunity to revise their medical management plan, choosing, again, from Stage 0 to Stage 3 plus.

The primary endpoint of the study was looking at reclassification rate from the initial management plan just based upon the coronary CTA report, risk factors, lipids, and clinical history to the management plan (unintelligible) of quantitative plaque analysis.

Dr. Gina Mullen: Sorry. I'm sorry to interrupt. If everyone could be on mute, there is a dog barking. Thank you.

Dr. Amit Pursnani: And what we found, next slide, is that there was a significant - actually, prior slide for a second. In the schema in the middle, you can see the numbers of patients that were classified into stage 0, 1, 2, and 3, the majority being initially sort of classified in stage 2 medical therapy. But after having access to the quantitative coronary CT plaque analysis report, you can see the changes to these various stages.

So, some of the patients in Stage 2 were downgraded, but the vast majority either stayed the same or were upgraded to Stage 3 medical therapy. Also, of note is that if one started at Stage 3 medical therapy, those patients were upgraded to what we call stage 3 plus medical therapy after having access to quantitative plot analysis. Another point of interest is that nearly 50% of patients with a calcium score of zero were reclassified. Next slide.

These reclassification rates are held across a spectrum of coronary artery disease. As you can see on the left, across various coronary artery calcium scores with the reclassification rate, for example, of 47% in those with a calcium score of 0 all the way up to 96% in those with a calcium score over 400. Reclassification rate was also significant across a range of cholesterol levels, as well as a range of maximal stenosis levels. Overall, the availability of AI-CPA led to a change in patient management in 66% of cases. Next slide.

Importantly, AI-CPA data led to a change in management of patients regardless of the CAD-RAD stage, including a 40% reclassification rate in patients who were classified as CAD-RADS 1, 63% in those with a CAD-RADS of 2, up to 94% in those with a CAD-RADS of 4. So, really the D-CODE trial gives us information that reclassification based upon AI quantitative plaque analysis happens across all stages of CAD-RADS. Next slide. That concludes my presentation. Thank you.

Dr. Gina Mullen: Thanks, Dr. Pursnani. And one second before you go on mute. For some listeners are only listening in and do not have access to the slides, and also for those who may be visually impaired, can you and other speakers speaking today also state your disclosures? I know you referenced the slide, but if you could state your disclosures, that would be great.

Dr. Amit Pursnani: Yes, I have research grants and consulting fees that I take from HeartFlow.

Dr. Gina Mullen: Thank you so much, Dr. Pursnani. I appreciate your time. Next slide, please.

Dr. Amit Pursnani: Thank you.

Dr. Gina Mullen: The next presenter is Dr. Roosha Parikh, a cardiologist at St. Francis Hospital in Roslyn, New York. Dr. Parikh, are you on the call?

Dr. Roosha Parikh: Yes, I am. Can you hear me?

Dr. Gina Mullen: Yes, Dr. Parikh, the time is yours. I'll go on mute. Thanks so much.

Dr. Roosha Parikh: Okay. So, today I'll be talking about Artificial Intelligence-Enabled Cardiac CT-Based Quantitative Coronary Topography, or CT, and Coronary Plaque Analysis. My name is Roosha Parikh. I'm an Associate Director of Cardiac CT at St. Francis Hospital and Heart Center in Roslyn, New York, and I also practice multimodality imaging, so CT, MRI, echo, nuclear, PET. Next slide, please.

So, these are my disclosures. I serve on the HeartFlow speaker bureau, and I've previously received an honorarium from Siemens, which is now completed. Next slide, please. So, this slide shows that despite advancements in cardiac testing therapy for patients and disease, the traditional stress testing misses a lot of heart disease.

So, currently, the total annual cost that's projected by 2035 is about $366 billion. The coronary artery disease prevalence is increasing, cost burden is increasing. One in five people die from heart disease. Despite all our advances in technology, diagnosis, management, lipid-lowering therapy, it's still the leading cause of death in the U.S. And most cardiac events, heart attacks, death, occur in patients with non-obstructive coronary artery disease. Next slide, please.

So, this slide shows us that plaque informs the risk of cardiac events. So, some plaques are more concerning than others. On the first graph on top, you see that the total plaque volume, as there's a higher total plaque volume, it is associated with higher patient risk of myocardial infarction. So, you can see if the total plaque volume is less than 238.5 versus more than that, the hazards ratio increases by 7.3 for adverse cardiac events.

And then, again, plaques are of different varieties. A calcified plaque is unlikely to

change shape quickly, and soft plaques can rupture and thrombose quickly without warning. So, in that sense, low attenuation plaque on coronary CTA, which we can visualize, is indicative of plaque that it has a lipid-rich necrotic core, which is more prone to rupture.
So, if the low attenuation plaque burden is more than 4%, the hazards ratio increases to 4.65, as opposed to low attenuation plaque burden of less than 4%. So, higher low attenuation plaque is associated with higher risk of myocardial infarction, even though there is non-obstructive stenosis. Next slide, please.

So, this slide shows that there's a differential utility of FFRCT and plaque in terms of outcomes. This graph is a representation from the ADVANCE-DK plaque study, where we looked at 841 symptomatic patients and the long-term or three-year outcomes. There was assessment of HeartFlow FFRCT, as well as plaque analysis. The end point was cardiovascular death or spontaneous MI.

So, when you look at the graph with the green and yellow line on the bottom, these were FFRCT negatives that had lower hazards ratio of abnormal plaque events compared to patients with abnormal FFRCT, which had a higher hazard ratio. You can further see the difference of FFRCT with AI quantitative plaque analysis that was negative, or normal, had a lower risk as compared to those patients that had a positive quantitative plaque assessment, with events increasing from 0.24% to 2.56%.

So, even with FFRCT negative, if there was plaque analysis that was positive, it did show worse outcomes. We further on the top see that when you have FFRCT positive or hemodynamically significant stenosis, that there was significantly up to 35 hazards ratio increase in patients that have positive plaque analysis, or positive plaque, with increase in events of about 8.5%, as opposed to patients that did not have any plaque - non-significant plaque analysis, the event was 3.2%. Next slide, please.

So, what's important is, how does all of this plaque analysis fit into clinical care? We do need the plaque information for better clinical care. And in the real world, once I get the quantified plaque data, I plug it into the nomogram data to provide population context of whether a patient's plaque volume is low, medium, or high.

This further helps you stratify the patient for risk of future events. We have outcome studies like Scott Haake that demonstrate that higher the plaque volume is associated with the higher or increased risk of future events. So, this helps you risk stratify the patient for risk of future events. And then most importantly, it helps guide therapy for patients which will have the maximum downstream benefit to prevent future events if they are at risk, in terms of, is it just risk factor modification which is adequate?

Is the addition of preventive dose of pharmacotherapy needed, or more aggressive higher doses or multi-therapy pharmacotherapy needed in addition to the aggressive risk factor modification? So, different levels of risk factor modification and medical therapy based on varying levels of plaque is how I see this being used in day-to-day clinical practice. Next slide, please.

Dr. Gina Mullen: And you have about one minute remaining.

Dr. Roosha Parikh: Sure. So, we have case examples with FFRCT. These are both patients who are 63-

year-olds with symptoms, stable symptoms. Patient A has a positive FFRCT with hemodynamically significant stenosis, versus patient B has no hemodynamically significant stenosis. So, when we talk about short-term risk, the patient A has a higher risk of adverse events as opposed to patient B. But when we add the plaque analysis to these patients, we can see that the total plaque burden in patient B is significantly higher. Next slide, please.

So, here we see that the plaque is significantly higher. Next slide. And so, patient B has a long-term MACE risk that is increased, which is at 64th percentile, as opposed to patient A. Next slide. So, our ask is to ensure that AI-QCT and AI plaque analysis is covered for patients with both stable and acute testing. As written, the draft coverage seems to limit the use to patients only with acute chest pain and no coronary artery disease, and our ask is to update this language to include patients with either stable or acute chest pain, as I showed in the example.

So, the supportive evidence is all studies referenced in this presentation did include the stable patient population. The draft LCD, as written, seems to support coverage in stable patients, as it mentions. The cardiac evaluation is negative or inconclusive for ACS. And the second, the patient is eligible for coronary CTA, as outlined in L33559, which includes indications for both stable and acute chest pains.

And the updated AHA-ACC guidelines from 2021 have recommendations for use of plaque in both populations, which is for intermediate-risk patients with acute chest pain and no known CAD, eligible for diagnostic testing after a negative or inconclusive evaluation for ACS. CCTA is useful for exclusion of atherosclerotic plaque and obstructive CAD.

Next, for intermediate to high-risk patients with stable chest pain and no known CAD, coronary CTA is effective for diagnosis of CAD, risk stratification, and for guiding treatment decisions. And then third, for symptomatic patients with no known obstructive CAD who have stable chest pain, coronary CTA is reasonable for determining atherosclerotic plaque burden and progression to obstructive CAD and guiding therapeutic decision-making.

So, the first two were Level of Evidence A and Guidelines 1, and then the last one was a 2A indication. Next slide. Thank you so much. That's all I have for today.

Dr. Gina Mullen: Thank you, Dr. Parikh, and I was incorrect with that one-minute warning, so that's why I didn't interrupt again. I apologize. I have now set my timer. But thank you for that great presentation. Next slide. Next is Dr. Mark Rabbat. Please, if I'm mispronouncing that, I apologize. Currently, the Director of Cardiac CT and Director of Structural Heart Disease, interventional imaging, a division of cardiology at Loyola University Medical Center, and representing the Society of Cardiovascular Computed Tomography. Dr. Rabbat, the floor is yours, 10 minutes. Thank you.

Dr. Mark Rabbat: Thank you so much. Can you hear me okay?

Dr. Gina Mullen: Yes, sir.

Dr. Mark Rabbat: Wonderful. So, I am a cardiologist in training. I am professor of medicine and radiology at Loyola University, Chicago. And I currently serve as the chair of the Health Policy and Advocacy Committee of the Society of Cardiovascular CT. So,

today I'll be discussing the NGS open LCD meeting on AI coronary plaque analysis. Next slide, please.

So, plaque, as was nicely delineated by the prior speakers, provides prognostic value in predicting adverse cardiac events. And there's substantial data demonstrating that the overall amount of coronary plaque by coronary CTA, has strong association with coronary heart disease events.

And this information offers strong prognostic value than merely the presence or absence of diameter stenosis and clinical variables. And these are some papers underscoring that. So, as you can see, those individuals with larger total plaque volume have overall worse survival and downstream cardiac event rates compared to those without significant plaque volume. Next slide, please.

This is a flow diagram demonstrating clinical workflow. So, a patient presents with suspected coronary artery disease, the CT is performed. Then the CT is interpreted by a physician. Now, if no plaque or stenosis is seen on the CTA, which is essentially a CAD-RAD 0, then primary prevention would be undertaken, and no further imaging and testing would be needed.

Now, if plaque is detected on CTA CAD-RADs 1 through 5, that's where plaque would add value and plaque analysis could be performed. And once the diameter stenosis is in the range of 40% to 90% stenotic, then a hemodynamic assessment would be undertaken. Next slide, please. And this is how AI-CPA, real-world clinical data, and MD decision-making can all tie in together.

So, we've talked about how AI-CPA provides insights with quantified plaque volume as well as type. So, you know, is this - what's the total plaque volume? What's the total non-calcified plaque volume? What's the total low attenuation plaque volume? And we also now have population-level data that can provide context to whether a patient's plaque volume is low, medium, or high.

So, we have these nomograms based off of their age and sex. And we also have large-scale outcome data and studies from the Scott Haake trial demonstrating that higher plaque volumes are associated with an increased patient risk. And having this information and incorporating that with CAD-RADS, which is a reporting system endorsed by the SCCT, the CAD-RADS recommends varying levels of risk factor modification and medical therapy based on the level of plaque. So, we may be more aggressive with our risk factor modification and preventive pharmacotherapy in those individuals with larger plaque volumes. Next slide, please.

So, our first request is update one, to add stable symptomatic patients. So, the draft coverage indications read, "The patient presents with acute chest pain and no known CAD." So, the Society of Cardiovascular CT is requesting that this be updated to read, "The patient presents with both stable or acute chest pain and no known CAD." Next slide, please.

And this is the clinical justification for the first request. So, the American Heart Association, American College of Cardiology, SCCT, as well as other specialty society guidelines for the evaluation and diagnosis of chest pain, support the use of CTA and AI-CPA in the following populations. For intermediate to high-risk patients with stable chest pain and no known CAD, CCTA is effective for

diagnosis of coronary artery disease for risk ratification and for guiding treatment decisions.

For symptomatic patients with no non-obstructive coronary artery disease who have stable chest pain, CCTA is reasonable for determining atherosclerotic plaque burden and progression to obstructive coronary artery disease and guide therapeutic decision-making. And for intermediate risk patients with acute chest pain and no known CAD eligible for diagnostic testing after a negative or inconclusive evaluation for acute coronary syndrome, coronary CTA is useful for exclusion of atherosclerotic plaque as well as obstructive coronary artery disease. Next slide, please.

So, this is our second request to include CAD-RADS 1 as well as CAD-RADS 4 in this statement. So, the draft coverage indications currently read, the patient presents with acute chest pain and no known CAD and is classified as one or both intermediate risk and CAD-RADS 2 and CAD-RADS 3 category on CCTA. So, the Society of Cardiovascular CT is requesting this be updated to read, the patient presents with acute chest pain and no known CAD, and is classified as one or both intermediate risk, CAD-RADS 1, CAD-RADS 2, CAD-RADS 3, or CAD-RADS 4 category on CCTA. Next slide, please.

And this is the clinical justification for our second request. CAD-RADS, the reporting system endorsed by the Society of Cardiovascular CT for reading coronary CT, recommends physicians make significant changes in therapy for patients with plaque dependent on their CAD-RADS level of stenosis. So, although a patient may have mild anatomic narrowing on a CTA, they may have significant atherosclerotic plaque burden.

So, their total plaque volume, their total non-calcified plaque volume, may be quite high even in the setting of an anatomic narrowing that may be non-obstructive. And this applies for both stable chest pain as well as acute chest pain. Next slide, please. Oh, thank you so much.

Dr. Gina Mullen: Thank you. And Dr. Rabbat, is it Rabbat, or how do I pronounce your last name?

Dr. Mark Rabbat: That is correct, Rabbat.

Dr. Gina Mullen: Okay, thank you for your presentation. One thing is I do not believe I heard your disclosures and did not see a slide, unless I overlooked it. If you don't mind just stating those.

Dr. Mark Rabbat: Oh yes, I apologize. I am a consultant to HeartFlow.

Dr. Gina Mullen: Thank you so much. All right, if you could get us to the next presenter, please. All right, Dr. Campbell Rogers, who is the Chief Medical Officer of HeartFlow. Dr. Rogers, are you on?

Dr. Campbell Rogers: Yes. Can you hear me okay?

Dr. Gina Mullen: Yes, sir. We can.

Dr. Campbell Rogers: Great.

Dr. Gina Mullen: Thank you. I will turn the floor over to you for 10 minutes. Thank you

Dr. Campbell Rogers: Great. Thank you. If we go to the next slide, please. And to the next slide after that, please. My disclosures for this are, as mentioned, I am a full-time employee of HeartFlow. I'm the Chief Medical Officer. I'm a cardiologist by background training and practice. And we're certainly pleased and appreciate the time to comment in this public meeting, and we will follow up with written documentation and comments in the written comment period for everything that I mention here.

And I would start by saying that we would like to recognize NGS for the breadth of the draft coverage policy as published. I think it has a really strong background references and literature and reflects a great deal of research, which is wonderful. There are a couple of areas that I will point to that we would like to suggest be reconsidered. If we go to the next slide, please.

I mentioned my conflicts previously. Go to the next slide. And please advance one past this. These points were made by an earlier speaker. Great. So, the first point I would like to make just by way of background is that there is a wealth of evidence in tens of thousands of patients, documenting that more than just the presence or absence of anatomical stenosis, the overall amount of coronary plaque measured by CPA has a strong association with the risk of coronary heart disease events. And go to the next slide, please.

I will give a brief window into the AI-CPA analysis as provided at least by HeartFlow, which is represented on this slide. The information provided includes images of the coronary arteries as seen on CPA, as well as quantitative information as to the cubic millimeters of plaque present in each of the coronary artery territories, as well as information on a nomographic basis as to where the volume of plaque measured for a given patient falls related to their age and sex-matched peers. So, for example, a 50-year-old man with X amount of plaque would be in the Y percentile for 50-year-old men. So, that's the information provided as part of the AI-CPA analysis. Go to the next slide, please.

The data previously reviewed by other speakers to touch on very briefly related to the HeartFlow plaque analysis, AI-CPA analysis accuracy, has been published in peer-reviewed literature, and we'll provide these references in our written comments, showing high accuracy compared to what is widely accepted as the gold standard in this area, which is invasive ultrasound, invasive coronary ultrasound with intravascular imaging. If you go to the next slide, please.

There also, and Dr. Pursnani led this study, has been data published as to the impact of this information on decision-making for patients with coronary artery disease, showing that the majority of patients, when their provider is provided with this AI-CPA information, the majority of patients have an altered management plan based on that information, usually a more aggressive medical plan than had been the case previously. Next slide, please.

This nomographic data we've talked about before, and one of the previous speakers showed an example of this for her patients. Next slide, please. In terms of the requested updates to the draft LCD, there are two that we would like to highlight. Go to the next slide, please. The first is the following. The current draft coverage reads, patient presents with acute chest pain and no known coronary artery disease and is classified as, et cetera.

It is our suggestion this be updated to read, the patient presents with stable or acute chest pain and no known coronary disease and is classified as, et cetera. If you go to the next slide, please, the rationale for this suggestion is as follows. The AHA-ACC guidelines for the evaluation and diagnosis of chest pain, strongly support the use of CTA in both stable and acute chest pain populations, that for intermediate risk patients with stable chest pain and no known CAD, there's a 1A recommendation in the guidelines for CCTA for risk stratification, diagnosis, guiding treatment decisions, et cetera.

The second category of rationale for this suggestion is at the bottom of this slide, and that is that at another point in the same draft LCD, there is an inconsistency, which says that in this draft LCD, the patient should be, "Eligible for CTA, which should be performed in patients with stable coronary symptoms." So, there's an internal inconsistency by excluding stable coronary symptoms from the rest of the draft LCD.

And then second, the very bottom of this slide, there's another LCD in place for FFRCT in which medical necessity is included for both acute and stable chest pain patients. So, there would be an inconsistency with that LCD as well if this were left only for acute chest pain patients. If you go to the next slide, please.

The second of the two suggested revisions is as follows. The current draft coverage reads, patient presents with acute chest pain, no known CAD, classified as one or both of intermediate risk, CAD-RADS 2 and CAD-RADS 3 category on CTA. We would suggest this be updated to read the same preamble, intermediate risk, but then to include CAD-RADS 1, CAD-RADS 2, CAD-RADS 3, or CAD-RADS 4 category on CTA.

This would be accompanied by other edits elsewhere in the draft LCD, for example, changing not to be used with high-grade stenosis over 70% or CAD-RADS 4, to change the over 70% to over 99%, and to strike the CAD-RADS 4 from this exclusion. If you go to the next slide, please. The rationale for this was discussed in the D-CODE study by Dr. Pursnani earlier in this meeting.

But just to highlight, the rationale is as follows, that for CAD-RADS 1 patients, so again, patients currently excluded from the draft LCD, in his study, 40% of patients with that level of stenosis had their management plan changed when this quantitative plaque information was provided, 40%. Second, that for the more severe stenosis, so-called CAD-RADS 4, nearly 94% of those patients who are excluded from the current LCD, 94% had their management changed based on the quantitative AI-CPA analysis.

And these were patients whose change consisted of adding or expanding their medical regimen. So, it was more intensive therapy being prescribed. And by not including CAD-RADS 1 or CAD-RADS 4, these patients would not have the benefit of these management changes which were seen in this study. Go to the next slide, please. Thank you very much again for the opportunity, and we'll be submitting all of these as written comments as mentioned earlier. Thank you.

Dr. Gina Mullen: Thank you so much. Really appreciate it. Dr. Edward Fisher, I have next on the agenda a cardiologist that's representing Cleerly. Are you on, Dr. Fisher?

Dr. Edward Fisher: Yes. Can you hear me?

Dr. Gina Mullen: Yes.

Dr. Edward Fisher: Very good. So, thank you for the invitation to speak today. I'm a clinical cardiologist in New York City. Much has been said by the eloquent speakers who preceded me, and so I'll quickly go through the slides and then talk just a little bit about how this really has been most important to my practice.

I agree that the three changes should be made and will be beneficial to me and to my patients, and that is specifically to add stable chest pain, the eligibility, and to exclude only patients with prior revascularization, and to include the CAD-RADS 1 category. That's all been spelled out very nicely by everyone who spoke before me.

So, I'll speak a little bit about myself and why this clearly has been important to me. So, I am an associate clinical professor of medicine at the Mount Sinai Hospital. For about 10 years, I helped run the hospital's busy echo lab. Now, I have a solo practice in New York City, a proud user of Cleerly, have no disclosures, and I have zero financial ties to the company.

I've been utilizing coronary CT and geography for well over two decades. I think the first cases we did were in 2002 before there were ACC and ACR guidelines. With new patients, I favor an atomic evaluation versus functional assessment, giving it superior prognostic value. 2018, shortly after its inception, I started using Cleerly's artificial intelligence algorithm, the supplement to CT angiograms in many patients.

It is precision medicine. To put it mildly, Cleerly has been a game changer. This NGS local coverage determination document has done a nice job summarizing the evidence for AI-QCT, really enables me to educate my patients about their coronary anatomy extent of disease. In just a minute, I'll say why that's important.

Cleerly illustrates the degree of stenosis and plaque composition with high sensitivity and specificity. Patients sit with me after their study and actually visualize their coronary arteries on my computer screen. Knowing this information enables me to tailor and optimize maximal medical therapy and risk factor management, convince patients, some of whom have been initially hesitant, to take their statins to lower their OVL cholesterol.

Cleerly has helped me manage my patients outside of the hospital. The risks stratify, significantly limit unnecessary testing, procedures, and healthcare costs. It has detected high plaque burden when CTA place patients only in the CAD-RADS 1 category. On the flip side, it has downgraded CAD-RADS 2 and 3 CTA readings, oftentimes overread because of the blooming artifact.

So, Cleerly promotes the health of my patients and takes some of the mystery out of medicine. It allows me to be a better cardiologist to those who place their trust in me. Now, why this is important to me, why I would like to add stable chest pain, (unintelligible) my patients have that, (include) only those with prior revascularization, I do ask that you include CAD-RADS 1 patients.

The reason for that is, as of this morning, Cleerly has read 588 patient studies for me. And (it states), not one of these patients has had a heart attack. Patients have come close, with a few being sent to a catheterization laboratory for stenting and very rarely for bypass surgery. Simply and clearly put, Cleerly is an essential part of

my practice. It's difficult to imagine preventing heart disease in my patients without it. Thank you very much.

Dr. Gina Mullen: Thank you so much for that presentation. I think we are still catching up with the slides, Crystal, if you could.

Dr. Edward Fisher: I ran through the slides that the previous speakers ran through and placed the same emphasis on the three points that I wanted to change. They also quoted the same studies that I was going to quote.

Dr. Gina Mullen: Thank you. I will open the floor. Are there any additional comments for DL39863, artificial intelligence-enabled CT-based quantitative coronary topography, coronary plaque analysis? And I will have the operator instruct anyone who is wanting to make comments how to unmute their line.

Coordinator: Please press Star 1 if you'd like to make a comment...

Dr. Gina Mullen: Operator, are there any comments, any indications, comments?

Coordinator: I'm showing no comments at this time.

Dr. Gina Mullen: Okay, thank you very much.

Dr. Gina Mullen: Thank you. So, the comment period will end on July 14th, 2024, at 11:59 p.m. All formal comments must be submitted in writing to NGS. This concludes the portion of the open meeting regarding DL39863, artificial intelligence-enabled CT-based quantitative coronary topography coronary plaque analysis. I will turn the floor over back to Dr. Awodele.

Dr. Ola Awodele: All right, thank you, Dr. Mullen. This has been quite an interesting draft open meeting for J6/JK. We'd like to thank everybody who took time out of their day to either present or listen, or both. So, to comment on the proposed LCD during the official comment period, click on Public Comments button on the proposed LCD in the Medicare coverage database. That's one way.

Another way is to send an email with the attachments, the literature to support the comments or the recommendations to NGSDraftLCDComments@anthem.com. And a third way, of course, is the ever-reliable snail mail version, which is send a mail with copies of your literature to support your comments to National Government Services, Inc., LCD Comments, P.O. Box 7108, Indianapolis, Indiana, 46207-7108. Next slide, please.

And, sorry, the proposed LCD comments must include conflict of interest disclosures as well. Any other slides? No, that's it. So, once again, we'd like to thank everybody for taking time out of their afternoon to attend this draft open meeting, and this officially marks the end of this meeting. Thank you very much. Have a nice rest of your day. Goodbye. Operator, you may now disconnect. Thanks.

Coordinator: That concludes today's conference. Thank you for participating. You may disconnect at this time.

END