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Moderator: Dr. Ella Noel

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12:00 pm CT

Coordinator: Welcome and thank you for standing by. At this time, all participants are in a listen-only mode until the question and answer session of today's conference. At that time, you may press star 1 on your phone to ask a question. I would 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. Ella Noel. Thank you. You may begin.

Dr. Ella Noel: Hi. I'd like to welcome everyone to this afternoon's conference. We are having a proposed local coverage determination open meeting today, February 29, 2024. The purpose of this meeting is to give you an opportunity to provide input into the development of the proposed local coverage determinations. These local coverage policies are proposed policies that must be based on published evidence as required by the 21st Century Cures Act.

Today's meeting will be conducted in accordance with the guidelines established by the Centers for Medicare and Medicaid Services. This meeting is being recorded and will be transcribed. The final document will be available on the NGS Web site.

The process for today's meeting will be as follows. This meeting is an open forum for receipt of your comments regarding only the proposed policies that will be mentioned momentarily. Please be assured that all comments provided will be considered by the medical directors in the policy process development. Please state your name, affiliation, and disclose any conflicts of interest before speaking. All written materials related to your comments should be submitted to one of three places. There is an email at partblcdcomments@anthem.com, Or you can send it through snail mail by LCD comments, PO Box 7108, Indianapolis, Indiana, 46207-7108, or by clicking on the public comments block, which is located on the top left-hand corner of the proposed LCD on the Medicare coverage database.

The official comment period on these policies started on February 15, 2024, and will go through March 23, 2024. Your comments are most welcome.

I'd like to take this opportunity to introduce the contractor medical directors that are here today; Dr. Stephen Boren, Dr. Mark Duerden, Dr. Gina Mullen, and myself.

We will have five policies to present today. The first will be DL33394, Drugs and Biologics; then it will be followed by DL39726, KidneyIntelX and KidneyIntelX.dkd testing; DL35000, Molecular Pathology Procedures; DL35936, Facet Joint Injections for Pain Management; and finally, DL39770, Cervical Fusion.

We are honored to have speakers today who will comment on the Molecular Pathology Procedures and the KidneyIntelX testing. No speakers are registered for the other three proposed LCDs.

Given the number of registered speakers and the tight schedule, we can only allow 10 minutes for presentation. Therefore, in the interest of time, if you have similar comments as the previous speaker, please only speak to your unique comments. Thanks for understanding. I will be running a timer, and I will warn you as your time is running out, and then I would ask that you stop once we get to 10 minutes.

So let's go ahead and get started. I will call Dr. Mullen to the floor first, and she will go ahead and get started. Dr. Mullen?

Dr. Gina Mullen: Yes. DL3394, Drugs and Biologicals Reconsideration, off-label coverage of infliximab for microscopic colitis is provided. The Bortezomib article has been retired. Currently the provision of off-label coverage of infliximab for microscopic colitis and the retirement of the Bortezomib article are open for official comment.

The floor is now open for comments on DL33394, Drugs and Biologicals. There are no registered speakers for this topic. Operator, are there any comments from anyone who has called in?

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

Dr. Gina Mullen: As there are no further comments being offered today, comments related to DL33394 are now closed.

DL39726, KidneyIntelX and KidneyIntelX.dkd testing.

Kidney disease is a public health epidemic affecting over 850 million people globally and is one of the most common causes of premature death worldwide. The Centers for Disease Control and Prevention estimates that 15% of U.S. adults or over 37 million people in 2018 suffered from chronic kidney disease, CKD. Nearly 95% of people with CKD suffer from early-stage CKD, example CKD stages 1-3. Early-stage CKD is under-diagnosed and under-treated largely because it is asymptomatic at this time in the disease's progression.

In a lifetime, KidneyIntelX or KidneyIntelX.dkd test is considered reasonable and necessary when all of the following criteria are met.

The results are used to facilitate therapeutic prognostic decision-making in the medical management of the selected patient population and the results are used to assess the risk of progressive decline in kidney function in patients over the age of 21 years with type 2 diabetes and existing early stage chronic kidney disease, CKD stages 1-3b and the test is ordered by the treating physician or qualified non-physician practitioner, and the test is performed in a CLIA-certified laboratory qualified to perform high-complexity testing and the specific reason for the test must be documented by the treating practitioner in the medical documentation and demonstrate that the test is medically reasonable and necessary.

KidneyIntelX or KidneyIntelX.dkd test is not medically reasonable and necessary for patients with EGFR less than 30, patients with EGFR greater than or equal to 60 mils per minute per 1.73 meters square without albuminuria, patients with ESRD or on renal recovery treatment, patients who are pregnant, patients who are currently hospitalized, and patients taking etanercept.

KidneyIntelX or KidneyIntelX.dkd is not covered as a screening or standalone diagnostic.

The current evidence concerning KidneyIntelX or KidneyIntelX.dkd as a test to identify and stratify patients with type 2 diabetes and early stage chronic kidney disease into low intermediate and high risk for near-term rapid progressive decline in kidney function suggests that the early identification of high risk patients by the test allows for more intensive patient management, selection of appropriate medications, and appropriate specialty referral or consultation.

Also, the clinical principles that more proactive care leads to better health outcomes and improved quality of life for patients including slow disease progression, avoidance or delay of kidney failure and need for hemodialysis were supported by our CAC subject matter expert.

Now, the floor is open for comments on DL39726, KidneyIntelX and KidneyIntelX.dkd testing. We have five registered speakers today.

Dr. Freedman, welcome and please begin.

Dr. Barry Freedman: I greatly appreciate this opportunity. I'm Barry Freedman. I'm Chief of the Section on Nephrology at the Wake Forest University School of Medicine. I'm also principal investigator of the KidneyIntelX Clinical Utility Study that's being performed at Wake Forest...

Dr. Ella Noel: Excuse me, Dr. Freedman, could you talk just a little bit louder?

Dr. Barry Freedman: I'm sorry, is this better?

Dr. Ella Noel: Yes, thank you.

Dr. Barry Freedman: Great, I'm sorry.

I'm also the principal investigator of KidneyIntelX Clinical Utility Study at Wake Forest Baptist Medical Center and Atrium Health. It's a pleasure for me to be able to present for the first-time outcome data of KidneyIntelX testing over time.

I'm going to present combined results from two clinical utility studies, one being performed at Mount Sinai School of Medicine in New York, and the other one at Atrium Health, Wake Forest Baptist here in North Carolina.

I want to apologize. There are some slight numerical errors on these slides, although the content is generally correct. I will point out and speak to those typographical errors.

The data I'm going to present is on patients in the two clinical utility studies who underwent repeat KidneyIntelX testing at baseline, and 12 months later, the 12-month one-year visit had a window of plus or minus three months, so repeat testing was done anywhere from 9 to 15 months.

Nineteen different physician groups at the medical centers participated with more than 100 providers enrolling their patients. I'm going to show you the evidence that I believe strongly supports the clinical utility of KidneyIntelX test results, where they led to management changes by the providers, and management changes generally refer to changes in care, including new treatment with kidney and heart protective medication, SGLT2 inhibitors, and GLP-1 receptor agonist therapy.

And obviously, the KidneyIntelX test assesses the impact on risk of rapid progression of kidney disease over five years, with greater than a 40% decline in EGFR over time or development of kidney failure in the five-year period, and that's a validated outcome of this test.

If I could have the next slide, please.

I'm going to show you the outcome results in the 839 patients who had the two tests, the baseline and approximately 12-month KidneyIntelX test in the combined data from Wake Forest and Mount Sinai. I'll point out in the box on the bottom, there are some slight numerical errors.

Just to make the point of the actual numbers in those groups, 49.1% of the 839 patients were low risk on KidneyIntelX testing, 43% were intermediate risk, 7.9% had high risk at baseline. So 50.9% total of the 839 participants were intermediate or high risk at baseline.

And what this graph shows is the rate of change in use of these kidney and heart protective medicines, SGLT2 inhibitors. You can see that starting from the pretest baseline level to the post-test result, there was a 43.5% increase in prescription of SGLT2 inhibitor therapy among patients with high-risk scores and a 67.9% increase in prescription of SGLT2 inhibitors in patients with an intermediate risk score. And again, these two groups combined are 50.9% of the sample that had diabetic kidney disease and a repeat test. In the low-risk

group, 49% of the sample, there was also a 22.3% increase in prescription of SGLT2 inhibitors.

If we look at GLP-1 receptor agonists, again, a 20.7% increase in prescription of these heart and kidney protective medications from before the test to after the initial baseline test came back. There was a 17.6% increase in use of these drugs in those with an intermediate risk score, and a 15.9% increase in the group with a low-risk score.

If we look at the combined usage of either and or the GLP-1 receptor agonists, SGLT2 inhibitors, or both, you can see that from pretest to the result at baseline, a 25.6% increase in use of these relatively recently released protective medications based on the test, a 32.3% increase in those with an intermediate risk score, and a 15.6% increase in those with a low risk score.

The most significant increase in utilization from baseline was seen with SGLT2 inhibitors, which have longer been known to be kidney protective in the intermediate and high-risk groups. And again, I'll just point out that there's a 67.9% increase in prescription of these drugs in intermediate risk group, 43.5% in the high-risk group.

Overall, in the high-risk group, there was more than 50% utilization of an SGLT2 inhibitor after the test came back. And if we look at use of either the GLP-1 receptor agonist or SGLT2 inhibitor, in the high-risk group, more than 70% of patients were receiving one of those medications after the test. So, I strongly believe that the results of this test resulted in changes in practice by the treating physicians towards these kidney and heart protective medications.

Next slide, please.

This is a data showing how the KidneyIntelX testing, in my mind, helped improve disparities in healthcare. My group at Wake Forest has long worked on disparities in healthcare, part of a major genetic finding, a single gene, APOL1, causes more than a third of kidney failure in African Americans. So, we've long been focused on African American kidney health.

During this large study of 839 patients at both Mount Sinai and Wake Forest, African Americans made up 34% of the total study population. You can see 32% at Wake Forest and 36% at Mount Sinai. And when we look at the representation of African Americans in the KidneyIntelX risk categories, although they're only 34% of the study population, 52% of the participants who had a high-risk score were black. And the numbers are very similar across Wake Forest and Mount Sinai if you look separately. Blacks are at about their typical representation in the low and intermediate risk groups. It's in this high-risk group that blacks are disproportionately represented. So, we've done data at Wake Forest in the Wake Forest sample.

I can tell you that given relatively equal degrees of proteinuria and GFR kidney function, African Americans in our site were three times more likely than non-African Americans to have a high risk score on KidneyIntelX testing. So the

disproportionate risk for kidney disease we see in the black population is shown clearly using this KidneyIntelX test.

If I could have the next slide, please.

The next slide is, again, the data from Wake Forest, not the combined data with Mount Sinai. This is the Wake Forest alone data that we presented at the National Kidney Foundation meeting last year. And again, just remember, I pointed out that at Wake Forest, African Americans were three times more likely than non-African Americans to be in the high-risk group. This shows the prescription of SGLT2 inhibitors based on the baseline and post-test results in the black population and in the non-black population. And at Wake Forest, the non-black population was predominantly European-American.

I want you to first focus on the high-risk group all the way to the right. And you can see in the blue bar at 8.3%, that is the percentage of black patients with diabetic kidney disease that were on an SGLT2 inhibitor at baseline. And if you look at the gray bar in the high-risk group, 26.7% of European-Americans were on an SGLT2 inhibitor. So, we saw a tremendous disparity in prescription of this kidney protective medicine where African Americans were much less likely to receive it than non-African Americans.

However, after the KidneyIntelX Test returned with a high-risk score, you can see the black population use of SGLT2 inhibitors jumped from 8.3% to 25%. In the non-African American group, it went up from 26.7% to 33.4%, so it went up even higher. But the point is that after the KidneyIntelX Test, use of these kidney protective medicines in African Americans went up markedly, very close to the level we saw in the white population.

Similar data for the intermediate-risk group, 19% of blacks before the test in the intermediate group were on the SGLT2, it went up to 31.5%. In whites, it was 13.3%, it went up to 28% when an intermediate-risk score on the kidney KidneyIntelX returned. In my mind, a lot of the disparities in prescription of these very protective medications were erased once the KidneyIntelX score came back in an intermediate or high risk group, and blacks were more often prescribed these medications.

Next slide, please.

This shows change in risk profile in the entire population of 839 patients for patients who started in an intermediate-risk score. And again, the intermediate-risk score in our population was 43% of all participants. Two-thirds of them, 67% on retest at 12-month stayed in the intermediate-risk score. However, 26% of them actually improved from intermediate down to low-risk score on repeat testing, while 7% of patients worsened and became high-risk on repeat testing at 12 months.

Next slide.

This is a breakdown in the change in the biomarker concentrations for patients whose risk category changed. And again, in red, we see that 7% of patients whose risk score went from intermediate to high. You see marked increases in KYM-1, TNFR2, and TNFR1 circulating biomarkers, which went along with the change in clinical category, whereas the 26% who improved saw a drop-in level of these circulating biomarkers on repeat testing in 12 months. So, I think this shows the biology is changing over time in patients based on the scores.

And if you go to the next slide, it shows the impact of treatment.

Dr. Ella Noel: Excuse me, Dr. Freedman, you have a minute left.

Dr. Barry Freedman: Thank you.

And in those group, patients who changed, the percentage of patients who were given an SGLT2 inhibitor, 31% -- that made up 31% of the population that moved to low-risk, only 3% who got an SGLT2 inhibitor moved to high-risk. However, if they were not prescribed a kidney-protective medicine like SGLT2 inhibitor, 9% moved to high-risk, only 24% moved to low-risk. So the SGLT2 inhibitor reduced the 9% increase to high-risk down to 3% in those who had an intermediate risk score. So I believe it impacted care and it impacted clinical outcomes. I thank you for your attention to my presentation.

Dr. Gina Mullen: Thanks so much, Dr. Freedman. Next is (Dr. Effendi). Welcome, and please begin.

Dr. Effendi: Thank you. I greatly appreciate for this opportunity. I'm a primary care physician serving an adult population, particularly those underserved for more than 20 years. During my initial discussions with analytics, I was drawn to the concept of utilizing data, advanced biomarkers, and AI capable of complex calculations and predictive analytics. This approach not only offered a safer and more intelligent alternative to a traditional placebo-controlled trial, but also provided me as an overworked, understaffed physician an opportunity to be a part of transformative change.

Many innovative scientists know that true changes occur at the elemental level where actual interactions happen between a patient and a doctor where rubber meets the road. The analytics simplified approach to patient risk management, coupled with sophisticated behind-the-scenes analysis, sparked a paradigm shift in the way I practice medicine. This progress became evident as I realized the extent to which I was not fully adhering to guidelines in managing diabetic patients that was just confirmed by Dr. Barry Freedman.

While I believe I was doing a commendable job, occasional patient non-adherence, infrequent visits, work overload, forced to six months led to gaps in care. Furthermore, I discovered that existing clinical and lab tools, hemoglobin A1Cs, even for microalbumin, primarily provided insights into past events rather than predictive capabilities.

Understanding the significance of new biomarkers, such as TNF1, TNF2, and KYM-1 alongside AI machine learning, enabled a more precise risk assessment over the course of a year that transformed my journey, dramatically altered my patient attraction and treatment plan.

As a primary care provider, it gave me the opportunity for preemptive treatment for the first time. And here is the strict guidelines, early referral for high risk patients.

I, just for -- to exemplify our case study, initially, when I started, I was deficient, as Dr. Barry rightly said, on many of the medicines. Then I improved over a period of a year, I added -- and I'll just present one case where the hemoglobin A1C was 7.4, and albumin calibration was 36.

In my previous life, I would have said that, you know, hey, no problem, this is not a big deal. Call in six months with some medicines, and then six months later, if hemoglobin A1C came down to 7.2, I did a good job. But this was in my previous life, because I considered them as low risk, because there was no precise method to risk stratify them.

So that model -- so this patient was -- again, was on GLP-1 and GLP-2 of statins, and weight was reduced from 218 to 254 pounds. But the intermediate risk came at 45, and I was surprised at that as to why. And then I understood the significance of this test. And then it enhanced even in my further case, where I tried to look for what were the reasons, how could I bring down the intermediate risk to low risk? And I found out that sometimes blood pressure was high, 141 over 85. I started to tightly control that, tried to further decrease his weight, and tried to add lifestyle changes. This all happened because this tool gave me a comprehensive look at diabetes, rather than in segments or parts.

And reflecting on this journey, I advocate for two key strategies moving forward. One is incorporating regular repeat testing or monitor risk assessment for monitor risk assessment and track patient progress. Early utilization of predictive tools, even at the pre-diabetic stage, to facilitate proactive interventions and mitigate disease progress.

Food for thought, we are labeling -- we say, you know, hypertension or no hypertension. Heart disease or no heart disease. But when it comes to diabetes, we say diabetes, impaired fasting glucose, pre-diabetes, and diabetes. Although as doctors in the, you know, in remote areas, we know that pre-diabetic patients are having complications, early complications. I would say that these tools should be available for pre-diabetic population. Not only we will reduce people going on dialysis, but people having heart surgeries, and actually weight loss surgeries will also go down.

So, this is what, you know, I wanted to say.

Dr. Gina Mullen: Thank you so much.

Dr. Effendi: Can you hear me?

Dr. Gina Mullen: Yes. Thank you.

Next is Dr. Tokita. Welcome, and please begin.

Dr. Joji Tokita: Are you able to hear my voice?

Dr. Gina Mullen: Yes, sir.

Dr. Joji Tokita: Just a second. I'll hold the slides here.

Next slide, please.

First off, I am an Academic Nephrologist at Mount Sinai Hospital, and I am the principal investigator for the Real World Evidence Study conducted at Mount Sinai Health System, which is sponsored by Renalytix.

Next slide, please.

So, I believe the previous speakers, including Dr. Friedman, have more or less covered this information. So, in the interest of time, I'm going to kind of move through some of the slides very quickly.

As was previously covered, in terms of clinical validation, there were five published validation studies evaluating chronic kidney progression in more than 5,000 patients; actually so far using our information over a five-year time horizon. And the KidneyIntelXs results demonstrate robust risk stratification for kidney outcomes in multiple external multi-ethnic cohorts.

In this particular instance, there was an 18-fold increased risk of progression in the high versus low-risk individuals, and a seven-fold independent risk gradient after adjustment for key clinical variables. Of note, two-thirds of the patients, almost seven out of 10 patients, scored a high-risk experience subsequent progression of chronic kidney disease following testing.

Next slide, please.

In terms of clinical utility, over 90% of primary care physicians would use KidneyIntelX to identify risk of kidney progression in early-stage chronic kidney disease patients.

I can tell you at Mount Sinai, the experience is generally speaking -- and I think the prior speakers also confirmed this, is that generally speaking, the primary care clinicians feel they're doing a pretty good job. It's been very clear, having implemented this effort, that the reality is quite different, and it's not so simple, I think, as the previous speaker just mentioned, to rely on existing A1C blood pressure parameters to ascertain for looking at risk.

So, we have experienced, I think, a market C-change in the approach to chronic kidney disease identification, and then, frankly, risk stratification, which,

under normal circumstances, at best, happens very rarely, because it's very complicated and time-consuming to perform.

We did note that escalation in actions taken to optimize cardiometabolic kidney health, including adjustments in medications, as well as referrals to subspecialty care, which could include nephrology, endocrinology, and other allied care, were significantly impacted following implementation of the program.

There are appropriate follow-up actions noted within the first six months, and we noted, as the previous speakers also did, a significant increase in SGLT2 prescription, as well as GLP-1 receptor agonist use in intermediate and high-risk patients, as well as increases in ACEs and ARBs, as one might imagine.

Next slide, please.

More than 60% of the patients evaluating clinical studies here are actually are Medicare eligible. I would say the bulk of the patients that we see at Mount Sinai are Medicare eligible. I think this has made it simple for our patients to have access to the test in this particular context, and you can see here the number of subjects in each of the risk categories and the potential impact if we extrapolate this to wider use across the population at large.

Next slide, please.

The KidneyIntelX test actually demonstrates improved risk stratification compared to KDIGO. You can see here, looking at the top bar, if you use KDIGO risk strata, higher risk versus low risk, there's a two-and-a-half-fold higher risk of progression than low risk, whereas KidneyIntelX risk stratification does a much better job resolving this risk difference.

I mean, if there's a small number of patients, this is not a problem. But if you are dealing with large populations of patients and limited resources, as is the case virtually across the entire healthcare system, this presents a significant issue and misallocation of limited resources. So really, I think this has been a game-changer for us in terms of helping us optimize and direct care where it's needed most.

Next slide, please.

Repeat testing with KidneyIntelX is superior. I think this is more or less a continuation of the prior slide.

For prediction of kidney outcomes compared to standard of care, as I mentioned, a few of the takeaways that we have encountered or key conclusions from our work is that this test has been validated and has strong data for use in multi-national, multi-ethnic cohorts. It is a very simple test for primary care doctors to use, meaning it doesn't require a lot of parses in the chart, which more often does not happen.

It identifies patients who would derive the greatest benefit from use of adjunctive medications like SGLT2, GLP-1 receptor agonists. It captures early improvements in kidney health with these medications. And I think repeat testing is, in my view, still a question that has to be answered. But again, with these unique characteristics, which are unlike anything available in the market, I think this is a game-changer for us.

Next slide, please.

When you look at early improvements in kidney health, with implementation of improved SGLT2 inhibitor use compared to placebo, you can see here, year one, on the Y-axis is kidney dose predictive probability, and you can see here the change in the difference between (candidate) flows and placebo outcomes.

Next slide, please.

This is an overview slide for our Mount Sinai 12-month data, decision impact and effectiveness study. I'm not sure if this is -- do I have time? How much time do I have left?

Dr. Gina Mullen: You have four minutes.

Dr. Ella Noel: You have ...

Dr. Gina Mullen: Sorry, Ella. I'm sorry.

Dr. Ella Noel: That's okay, Gina. Go ahead and tell him again.

Dr. Gina Mullen: Yes, four minutes and 30 seconds.

Dr. Joji Tokita: I don't know if Dr. Donovan is on the line, but he may -- this is the slide I'm actually not familiar with, so.

Dr. Michael Donovan: We can make him run right into that, I believe.

Dr. Joji Tokita: Say it again.

Dr. Michael Donovan: I think this is my presentation that's on the screen right now. I think it's coming up.

Dr. Joji Tokita: Yes, I think this is yours.

Dr. Michael Donovan: Yes, it is.

Dr. Gina Mullen: Okay. Well, thank you, Dr. Kokita -- Tokita. I apologize. Is that the end of your presentation?

Dr. Joji Tokita: Yes.

Dr. Gina Mullen: Okay. Thanks so much. Dr. Donovan, welcome, and please begin.

Dr. Michael Donovan: Thank you so much. I appreciate it.

My name is Michael Donovan. I'm the Chief Medical Officer for Renalytix. I'm also the Medical Director for the lab. We'll go to the next slide.

I'm an employee of Renalytix, which is my conflict between just slides right there.

And then the next slide.

I'm just going to speak to what Joji, Dr. Tokita, shared, which is a real-world evidence study, which is running across all the boroughs in Manhattan currently. And it's the introduction of the KidneyIntelX into that environment. And it's a prospective data collection. And this is the one-year study period, which is published in the Journal of Primary Care & Community Health. And that was a follow-up to the six-month interim results, which was demonstrated at least in this one-year data of the sustainability of this approach and its impact on the decision-making and outcomes of patients that are part of this study.

We go to the next slide.

And at Mount Sinai, so this is 2,500 patients, which were the 12-month data associated with this group. They were all part of the intended use to all type 2 diabetic patients, and this early stage, chronic kidney disease, 1,2,3-D, and the median age is 68. So, it's heavily represented by the Medicare population within the context of this cohort.

And just looking at the risk distribution, based on the KidneyIntelX assay, you see these three different categories here. Low is represented 49%. Intermediate was 40%. And the high risk group represented 11%. And it's very comparable to what Dr. Freedman had shared with regards to the Wake Health atrium experience with this test in the study that they're running there. And it's very comparable to also what we've demonstrated in our validation studies, which were published and also available for the group.

And on the next slide.

So, looking at some of the outcomes of the presentation and the publication that was shared, and obviously we can't go through all of it online. But risk-based actions with respect to the impact that the test has in the context of using the risk-based tool to be able to define parameters of progression of disease. And so 85% of the enrolled patients were seen by their primary care physician within the first three months post-test, which is different than what is traditionally done in the context of the population that's every six or 12 months, but they were using risk as a tool to be able to understand an approach, which I think has been represented by (Dr. Effendi) as well as Dr. Tokita is a necessary element for establishing what is the risk of progression within the context of this population.

And we look at this and how these folks are actually using the test itself is looking at this increase in new referrals to practices such as endocrinology or

nephrology. And obviously those are important ways to be able to define the population and utilize the resources that are currently available that would be the limits in terms of the endocrine and the nephrology space for managing patients. So this allows you to define the population that is most needed with respect to that referral. So, there are four times increase in new referrals post-test in the high-risk group compared to the low-risk group. So there's very effective use of the referral of the specialty services in the context of risk.

And then the increased post-test clinical actions demonstrated in the bottom part of the slide are reflective of a combination of referrals as well as medications that are used. And something I will touch upon is the medication side, but you see 43% of high-risk cases actually were driving towards referrals or novel medications versus the 19% in the low risk. So, folks are using this as a tool to be able to both effectively utilize resources that are available as well as demonstrate that understanding of risk in the context of this complex disease.

And on the next slide.

So, some of the areas that we touched upon in this brief presentation that Barry Freedman went through was the usage of the medications in the context of these approaches. And obviously the field has dramatically changed by the introduction of SGLT2 inhibitors as well as GLP-1 and how they are being used and which patient groups they should actually be used on as part and parcel to why these types of personalized medicine tools are very critical. And increased usage post-KidneyIntelX is really quite demonstrated -- and nicely demonstrated I think in the figure here, which is from the publication and looking at that increased usage in the high and intermediate versus low group for the SGTL2, you see that 61% in the high-risk group versus the 15% in the low-risk group. So you're seeing this dramatic -- sorry, 25% on this slide, dramatic shift in terms of the changes within the context of the SGLT2 usage.

And if you move to the GLP-1, you see a comparable association -- oh, sorry, can you just -- thanks. So that's just at the high and intermediate risk, again, compared to the low-risk group pre and post-test. And then the combined usage represents that 70% of the patients were actually prescribed either or a SGLT2 or a GLP-1. And this is coming forward with regards to the appropriate use for the right patients with these individual therapies is quite important in terms of the overall presentation of the risk and their management decisions that are associated with that, which in this case is reflected in the agents that are currently being used.

And on the next slide, so some of the outcomes of this that we saw in the context of the study, this is the improvement piece of this, of the clinical measures that are used to help reflect on the decisions that are made, the changes that are made in the context of this group. And the top half, the reduction in A1C levels, as you can see, represented in the high-risk group from baseline 8.2% to 7.5% is a clinical and statistical change and improvement with regards to A1C level, most likely represented by the use of increased use of the SGLT2 inhibitors in the context of this group, in concert

with some of those other changes like referrals to nephrology or endocrine services and associated patient response with regards to compliance that's also built into what we're seeing here.

If you look at that in the other variables, uACR levels, as we heard about microalbuminuria is an important element of this disease process that the reflection of the pathophysiology is occurring within the diabetic kidney. And we're seeing the changes within the intermediate risk group with albuminuria of the 20% reduction of all from the high to the low.

And then we look, focusing on the intermediate-risk group patients that had new prescriptions for SGLT2 inhibitors. And we saw 50% reduction in the uACR level. So these are ways to really understand the influence of these medications and the patient in the context of their use. And then the outcome is actually an improvement in my (microalbuminuria), which is actually an improvement in kidney health. So nice variables to actually demonstrate, and we have seen some of this in the six-month time that this is sustainability of this approach at the year mark.

And on the next slide.

So continuing on with the measures that we were observing at the 12-month time, we did notice that looking at EGFR slope, which is really a true marker, a predictive marker, if you will, of the future health of the kidney and what will happen in the likely scenario with regards to progression and without interruption and then with interruption of that progression of disease. And we did notice an improvement in the EGFR slope across all risk categories.

As you can see both on the table, as well as on the graphic representation above pre and post-test enrollment and then use of most likely medications, as well as consult services and effective management, it's reflected in the improvement in the overall EGFR slope of these patients, which is a very good measure of understanding, as I mentioned, of the future health of the kidney. And it's a measure that's used in the context of many of the approved clinical trials that have demonstrated to use of these medications like SGLt2 inhibitors in combination with the management of patients.

If you look on the next slide, I just tried to illustrate some of this a little bit in a more visual tool of risk stratification like we're using and speaking about today.

The challenge, if you just resort to the table on the left, which is the (Cadigo) heat map that we use to be able to categorize patients is how we define our intended use. We have very challenged if you just use those clinical markers with respect to disease progression because there's been many publications that demonstrate the trajectories that are reflected from that table are not really coincident with the actual progression of disease. And so risk prediction helps to identify those right patients that are most likely going to progress of their disease. And then that being a tool to utilize these agents like SGLT2 inhibitors and GLP-1 or the combination of those.

In that pre and post-test setting, we're demonstrating this improvement in the use of those agents in the context of those patients. And that is reflected in the next slide. So how is that represented in the future health of what we're actually demonstrating?

And these agents have been known, published through phase three advanced trials of their importance with regard to both kidney disease progression as well as heart failure and hospitalization. And that reduction in risk for both of those agents is quite important and quite significant. You see the SGLT2 are a higher representation of that, but both of them actually behave quite nicely in the context of this cardiac kidney metabolic intersection here, which we're actually demonstrating, not by us, but the actual improved clinical trials.

And so that becomes a very relevant factor for …

Dr. Gina Mullen: One more minute left.

Dr. Michael Donovan: Okay, thank you.

That becomes very relevant for the next slide, which is to demonstrate that why is that important? Well, in normal aging, your EGFR levels will continue to decrease, but it's not pathologic reduction of your EGFR. Whereas if you have chronic kidney disease that is uninterrupted and you actually progress, that will actually continue over time to kidney failure. So, you're really interrupting that cycle. And by that, you're adding additional 15 years of freedom from end-stage kidney disease. That was the evidence that was provided to support the use of these agents in terms of that delay in dialysis. So, it's the future efforts of what we're actually seeing today, the outcomes of those will actually only show benefit for patients in the future.

And then the next slide.

So just a final slide here, just to go through what the world evidence of HEDIS measures, those are measures to understand improvements with regards to health, improved A1C levels, 8.2 to 7.5, their property screenings, that ability to test for uACR is just so important and compliance moving that up to 95% is quite significant because it is a true measure of the overall kidney pathophysiology, as I mentioned.

Specific targets for HEDIS blood pressures and HEDIS -- and reduction of blood pressure of 140 over 90 would also be able to demonstrate it in the RWA 12 months with a 33% of baseline and 61% at 12 months. So dramatic improvement.

Person-patient survey metrics, really into this whole idea of conceptual understanding of diabetes and heart disease as it comes through this entire approach. And then as we heard, most of these patients are already on ACEs and ARBs. This actually helps to improve ACEs and ARBs in terms of both their titration as well as their type. Thank you very much.

Dr. Gina Mullen: Thank you, and that's time.

Dr. Michael Donovan: Thank you.

Dr. Gina Mullen: No problem, appreciate that.

Mr. McLain?

Dr. Thomas McLain: Yes, I am here, thank you.

Dr. Gina Mullen: Great, welcome, and please begin.

Dr. Thomas McLain: Thank you for the opportunity to speak to you today. My conflict is I'm employed by Renalytix.

If we skip forward a couple of slides, in -- next slide to -- and another one, thank you. Type 2 diabetes is a significant challenge in the Medicare population. More than 60% of type 2 diabetes patients who are over 65 will develop kidney disease. So that's what we're looking to address. That's why we focused on Medicare patients.

On the next slide, this is also a huge cost for the Medicare program. About 15% of the Medicare budget is spent on treating patients with kidney disease. So anything that can bring an early understanding of risk, better management to delay or prevent progression towards the SKD will have a cost benefit for the health system as well.

On the next slide, what we also know with type 2 diabetes and kidney disease, there are significant associated cardiovascular events. In fact, cardiovascular mortality in type 2 diabetes patients is concentrated in those with CKD. This is so important that AHA last October said, this can't be diverse specialties focusing on these patients, but an interdisciplinary team led by primary care needs to fully address cardiovascular kidney and metabolic disease. And our test is directed towards primary care, which needs to take the lead there.

On the next slide, what we've really tried to do for primary care is create a very simple and actionable report that I think we've demonstrated with the clinical data shared today. We need to improve management, and particularly improve pharmacy management for these patients that is driving improved health.

And again, on the next slide, this only serves to reinforce with Kaplan-Meier curves that when we focus on the high-risk patients, we're focusing on patients who are at 15 times greater risk of having a significant event in the next five years.

So with that, on the next slide, we also are confident with the risk assessment that this socioeconomic, this racial disparity in the incidence and the consequences of disease are also being informed by KidneyIntelX testing. And not only are we understanding that increased risk in that population, but it's leading to equitable access to the therapies that will make a difference in those outcomes.

So with that context, I'd like on the next slide to move to a discussion of our support for the proposed LCD.

And on the next slide, we appreciate all of the work NGS has done. We are a strong supporter of what is present here in the coverage determination that is being proposed.

First of all, it follows closely the FDA-intended use criteria for the test. It's clear that this is an LCD that addresses a major healthcare challenge in this population. And it's clear that the basis for coverage that you've cited is in line with this robust evidence that we've developed and that we are confident in the appropriateness of this, again, based on the fact that as you've learned about these studies, 60% of those study participants were Medicare eligible.

On the next slide, we would like to propose certain changes to be considered for the draft coverage determination. And we will cover these in our comment letter.

It is clear from our work with clinicians that these biomarkers, when you reassess risk at a point in the future based on medical necessity to take another look at that, that the risk score itself can be highly predictive as to whether the patient and the clinician, that there's adherence to what will reduce risk and push out the progression end-stage kidney disease or the cases where other factors may be at play and that risk is not being reduced.

The second point is, as we looked at the intended use criteria, they have to do with the diagnosis of diabetes, the diagnosis of chronic kidney disease, which really drives the intended use. We would like consideration of the information that's available on the test requisition form and would propose that the TRF could be considered part of the medical record.

In addition to those more policy-driven considerations that we will bring forward, on the next slide, we had two technical corrections that we will also address in our comments.

First, the proposed ICD-10 codes that are listed in the supplement do not cover, based on our experience and our claim submission with NGS, all of the ICD-10 codes that are used for this patient population. In addition, there are dates for the cutover from the laboratory-developed test to the FDA test. We did not make that transition in the U.S. as of January 1st, and so we will propose dates that are in alignment with that transition that is expected to happen in the second quarter of this year.

In wrapping up my comments on the next slide, we certainly thank NGS again for their work in developing this. We strongly support the LCD. In our comment letter, we will come back in those areas of proposed policy changes and technical changes in the coverage determination as written. And I just wanted to reinforce that if there is any other information or evidence that we could share or provide, that Renalytix would welcome the opportunity to work with NGS.

And with that, I want to thank you very much for the time today.

Dr. Gina Mullen: Thank you so much, Mr. McLain. And thanks to our speakers for your presentations and comments.

Operator, are there any comments from anyone who has called in?

Coordinator: As a reminder, please press star 1 if you would like to make a comment.

I'm showing no comments at this time.

Dr. Gina Mullen: Thank you. If there are no comments being offered today, comments related to DL39726, KidneyIntelX and KidneyIntelX.dkd testing are now closed.

Dr. Ella Noel: All right, up next, we'd like to have Dr. Boren take the floor.

Dr. Stephen Boren: Thank you very much. The presentation is DL35000 with Molecular Pathology Procedures, new LCD request for CPT code, which is really a yellow code, 0119U, the Ceramides Risk Score, ceramides by liquid chromatological tandem mass spectrometry, plasma quantitative report with risk score for major cardiac events, although the ceramide risk score may have promise as an indicator of potential cardiovascular events. Additional research is required to fully understand the value of the risk score in therapeutic medical management of the patient's condition. Testing is therefore not considered medically necessary. Only the topic of ceramides is open for official comments.

So, we have our first speaker would be Dr. Jeffrey W. Meeusen -- I hope I pronounced that right -- from the Mayo Clinic.

Are we ready to begin now?

Dr. Jeffrey Meeusen: Can you hear me now?

Dr. Stephen Boren: I could hear you, but it's better, but I can hear you.

Dr. Jeffrey Meeusen: How about now?

Dr. Stephen Boren: It's better. Thank you, sir.

Dr. Jeffrey Meeusen: So, my name is Jeff Meeusen, and I'll be presenting initially on behalf of my colleagues at Mayo Clinic.

Next slide, please.

So, I am the Director of Clinical Specialty Laboratory specializing in cardiovascular lab medicine at Mayo Clinic, and my colleague, Dr. Vlad Vasile, is a consultant in the cardiovascular medicine lab -- the cardiovascular lab medicine, and neither of us have any conflicts of interest to disclose.

Next slide, please.

So, we wanted to talk through a few items considering the recent statement by NGS or decision made by NGS. The first is the placement of coverage for ceramides, the second being the cardiac risk testing coverage comparisons, and then finally the utility and medical outcomes associated with ceramides.

So, first of all, placement decision for ceramide testing and molecular pathology and procedures is inappropriate. We understand that in often instances, PLA codes, which are based on scores derived from various inputs, are genetic tests, and that the clinical utility of treating to these types of tests may not be as well described.

However, this is not a genetic test. We would like to advocate that maybe this be reconsidered by a different group or in different contexts, and that this is a phenotype, not a genotype. We are physically measuring ceramides, which are species in the blood, using, as we say, liquid chromatography tandem mass spectrometry. And so, despite the fact that we're using a PLA code to calculate a score, this is not, again, not a genetic test and not appropriate for a molecular pathology consideration.

Next slide.

So, coverage comparisons. Other cardiac markers that do not fall under the NGS or CMS coverage decisions would include testing such as NMR lipoproteins, LP(a), LP little a lipoprotein, Apolipoprotein b or ApoB, high sensitive CRP. All of these are used when managing cardiovascular risk and assessing patients' need for statins, lipid lowering therapy, and other interventions, none of which have garnered a coverage decision from the NGS.

We would ask that ceramide should be given the same coverage approach, and our request was submitted because it uses a PLA code, and NGS currently denies all PLA codes until coverage policy is established. So again, perhaps this was a misunderstanding involving the use of a PLA code for a measured biomarker, an actual phenotype biomarker.

Next slide.

Here I will turn things over to my colleague, Dr. Vlad Vasile. Are you on the phone, Vlad?

Dr. Vlad Vasile: Yes, I am. Can you guys hear me?

Dr. Stephen Boren: Yes, sir.

Dr. Vlad Vasile: Okay, perfect. So, I'm going to talk on the clinical utility of the thermite testing, which we have been using at Mayo Clinic for a few years now, so I can talk from experience, and I will also bring some data in. So, this is, again, not new testing. You know, we've been using it since 2016, and these risk scores, they do have value for our patients.

Next slide, please.

So, as you probably are aware, the cardiovascular mortality and morbidity continues to increase despite the fact that we have now new means to address and prevent cardiovascular disease with atherosclerotic cardiovascular disease having a leading role in morbidity and mortality.

When we assess patients for atherosclerotic risk, we have several tools in the toolbox. One of these tools that is endorsed by the guidelines is the ASCVD risk calculator, and this is a well-established tool that clinicians use for stratifying the risk of patients for primary prevention.

But this calculator is not perfect because coronary artery disease is a multifactorial disease, and so it would be very, very difficult to find the calculator that takes into account all the risk factors and understand the exact risk of these patients.

So, it does have some criticism, and if you look at the C statistics of the ASCVD risk calculator, it's about 0.5 or 50-some percent, which what really means, it means that it simply has a flip of a coin. You have 50% chances of being right or 50% chances of being wrong using this calculator.

We do have other tests that we can use to stratify patients such as the coronary calcium score that we use for patients that are deemed to be at intermediate risk, patients that have some risk factors but not substantial risk factors such that we need more information to risk stratify these patients.

But this type of investigation that, again, is endorsed by the cardiology guidelines also has significant criticism. It is a test that we do not recommend repeating. It is a test that gives some information the first time when we use it, but it is not a reproducible test. It does have a radiation associated with it, and then there are some issues related to cost, as well as issues related to the fact that the coronary calcium scoring is going to be expectedly high for patients that will start lipid lowering therapies. So, for this reason, we do not use the coronary calcium scoring to follow up on patients with atherosclerotic disease or to follow up their risk.

Next slide, please.

I just wanted to remind everybody that coronary artery disease is a very complex disease, and plaque is a very complex structure that involves many pathways that crosstalk, and these pathways are the lipid pathway, the inflammation pathway, and thrombosis pathway. And this is a very active process with cells getting in the plaque, getting out of the plaque, creating more or less stability or instability of the plaque.

Next slide, please.

So, with that information, when we discuss about biomarkers of atherosclerotic risk, we have some biomarkers that we use in clinical practice, and these pertain to the lipid pathway, of which, of course, the most known and established biomarker is LDL cholesterol, or biomarkers that belong to the

inflammation pathway and high sensitivity CRP is probably the representative here, also biomarkers that pertain to the thrombosis pathway. Again, all these pathways are involved in plaque formation, plaque stability, and plaque instability.

And here comes the role of ceramides. Ceramides are phospholipids that are involved in all three pathways. They're involved in the lipid pathway, inflammation pathway, and thrombosis pathway. And so, as a cardiologist, I see ceramides as a very comprehensive biomarker that looks not only at the lipid pathway or inflammation pathway, but it looks comprehensively at the majority of pathways that are involved in plaque formation. And to date, we do not have another biomarker that offers similar value as ceramides. So, again, a very comprehensive biomarker of atherosclerotic risk.

Next slide, please.

We have validated the ceramide score at Mayo Clinic a few years ago in a cohort of patients with established coronary artery disease by coronary angiogram.

Next slide, please.

Can we move to the next slide? Thank you.

And we have established that really the score correlates with patient's risk and patient survival. And we have scores now that we categorize these patients from zero to two as low risk to the highest risk, 10 to 12.

Next slide, please.

There's many -- there are many studies that are reported in the literature and show the value of the ceramide score. And I'm just bringing here one important study, the FinRIS study, that really shows the importance of ceramides that we use in this course. Ceramides 16, 018, 024, 0 -- and 241 that we use to establish -- that we use to calculate the score. And you can appreciate here that the higher these ceramides, the higher the risk of death. And this is for primary prevention, but there are other studies also for secondary prevention.

Next slide, please.

As you can appreciate here, when we looked at our patients, when we compared the ceramide score with the CRP, the high sensitivity CRP, clearly the ceramide score adds value in predicting atherosclerotic risk and death.

Next slide, please.

We also looked at Mayo Clinic in a cohort of subjects at average risk. So these are not subjects that had coronary artery disease. These are subjects in the community. And again, the ceramide score predicted atherosclerotic events, heart attacks, strokes, very accurately, as you can appreciate here.

Next slide, please.

One important aspect that I wanted to draw the attention upon is the fact that ceramides or the ceramide score is modifiable with interventions, interventions that we use on a daily basis in the preventive cardiology clinic. The ceramide score will go down with Mediterranean diet, will go down with aerobic exercise training.

Next slide, please.

And we'll also go down with statin therapy, and I'm not showing this here, but the ceramide score will also go down with PCSK9 inhibitors. And so this biomarker not only provides information regarding the atherosclerotic risk, but also is a biomarker that we can track, we can follow. And to date, we do not have another biomarker like …

Dr. Stephen Boren: One minute left.

Dr. Vlad Vasile: … that we can track or follow. And so, I wanted to underline this because it is important because it has value similarly to the coronary calcium score, but coronary calcium score cannot be tracked.

Next slide, please.

So, to put everything together, the ceramide score is the robust biomarker of atherosclerotic risk that can be used for primary and secondary prevention. In opposition to the core (count), it is a reproducible biomarker. We can repeat it. It is useful to assess response to intervention because we take the baseline score of the patient. And then after the intervention, we show that the score of the ceramides goes down in parallel with their atherosclerotic risk. That also motivates patients to stay on the right track. And it is no radiation. It is very cost effective, very easy to interpret by providers, and Mayo Clinic providers are used to the ceramide score. And there is, to date, no other test that is reproducible and modifiable by lifestyle interventions or therapy. And if not covered, I think it would apply to patients.

Dr. Ella Noel: You're out of time, sir. Thank you.

Dr. Vlad Vasile: Oh, I'm -- that's all that I have. Thank you for your attention.

Dr. Stephen Boren: Dr. Noel, I would like to comment on something that Dr. Meeusen said that bothers me quite a bit. I thought I heard him say that NGS does not pay any PLA codes. Is that what you said, sir?

Dr. Jeffrey Meeusen: I believe it was in our slides that way. That is our understanding is that there was a blanket decision on PLA codes. I don't know if I have any of my other colleagues on the line from Mayo Clinic.

Dr. Stephen Boren: Well, I can tell you for a fact today, we paid a number of PLA codes today. I can tell you yesterday, we paid a number of PLA codes. I'll tell you also for a fact, Tuesday and Monday, we pay them every day, some codes we don't pay.

Dr. Ella Noel: If I can interrupt Dr. Boren, what I'd like to explain is that we can no longer have blanket policies taking T-codes, PLA codes, and saying they're all uncovered or non-covered. We have to look at them individually now. So that may have been true at one point in time with the T-codes. I don't know that it was ever true with the PLA codes, but it is definitely not true. It's an urban legend.

So, I hope that answers everybody's questions.

Dr. Stephen Boren: Thank you, Dr. Noel.

Dr. Ella Noel: You're welcome, Dr. Boren.

Dr. Duerden, would you like to go ahead and start on facet joints?

Dr. Marc Duerden: Yes, I would. Thank you.

For our first slide, this is regarding the previously established facet joint injection policy, and this was based partially on a reconsideration. Excuse me -- this LCD is being taken to this open meeting for consideration of three areas.

First is the issue of non-coverage of a third level in a facet procedure. Second is regarding the use of anesthesia in conjunction with the facet procedures, particularly the radiofrequency ablation, also known as RFA. And third, this is regarding the request for an expansion of therapeutic facet joint injections as a first-line option. Otherwise, this LCD is not open for official comment, but aside for those three areas.

Next slide.

In this presentation, I'd like to first indicate that this revision is regarding the language and clarifying language and providing the supportive evidence for the use of anesthesia in conjunction with the set procedures and the RFA, and in particular, the use of moderate or conscious sedation for the use of the RFA.

Second, the other revision that was done was that the number of levels covered by this policy is further clarified and is reviewed in the rationale and the decision-making and concluding that there will no longer be indications for a third level of a facet procedure.

And third and finally, in response to a reconsideration regarding the expansion of the therapeutic facet injection as a first-line treatment option, we have added into the LCD additional evidence in the summary of evidence section, as well as the rationale for the decision that's explaining. And the decision is that no additional coverage changes are being made as a result of this reconsideration request.

Actually, what I'd like to do now is open the meeting up to any additional comments or questions.

So, operator, if you can see if there's anyone that would like to make a comment or question.

Coordinator: As a reminder, please press star 1 if you have a comment.

I'm showing no comments at this time.

Dr. Marc Duerden: Thank you. Due to no comments being provided in the end of that presentation, I will close my presentation regarding the facet joint procedure in the draft LCD, DL35936. And I'll turn the time back over to Dr. Noel.

If you want to go to the next slide, Dr. Noel, I'll take off and go into my part as well if you want. But I'm turning it over to you just if there's anything else you want to do administratively.

Seeing no additional need for administrative things, we will now move to the discussion regarding DL39770 for cervical fusion. This is a multi-jurisdictional collaborative LCD that is new. This regards that the use of cervical fusion alone or in combination with other surgical spine procedures is frequently performed and that there are essentially three categories that this LCD will address, and that is the issue of a cervical radiculopathy, a cervical myelopathy, and an unstable spine.

The LCD specifically goes into discussions regarding the need for the presence of the condition being present for at least 12 weeks and that the nerve compression causing an impact or negative impact on the activities of daily living and that other pain sources and neurologic deficits have been excluded and that the imaging is consistent with the clinical myotome and at least one of the following, which is that there is a cervical degenerative disc condition which can be seen with cervical spondylosis, including but not exclusive of herniated nucleus pulposus, narrowing of the intervertebral disc space, disc osteophytes, facet hypertrophy, synovial cyst, ligamentum hypertrophy, et cetera.

It can also be seen with tumors, primary or metastatic. It can be seen with post-infection and needs to be proven with radiologic studies. And finally, the indication is that the cervical fusion is needed or can be used for fine instability which is defined by subluxation or translation of more than 3.5 millimeters in the static lateral views and dynamic radiographs or a sagittal plane angulation of more than 11 degrees.

If we can go to the next slide.

In addition to the previous discussed indications for cervical fusion, this LCD also provides limitations for the cervical fusion in particular, but the use of a cervical fusion for axial neck pain with or without a radiculopathy or myelopathy has low quality evidence and the benefit for surgery has not been established. Therefore, cervical fusion for axial pain is not considered reasonable and necessary.

This LCD will also address the exceptions that are needed for the conservative therapy requirements in the policy prior to the use of a surgical fusion, and in brief it discusses the exceptions being primarily a myelopathy of a particular class or progression of the neurologic deficit. It could be a radiculopathy

presenting with progressive motor weaknesses or weaknesses interfering with activities of daily living and severe radicular pain defined as limiting the ability to perform activities of daily living and severe pain on a visual analog scale and the associated confirmatory imaging for that radiculopathy and third the exception would be the cauda equina syndrome.

The policy also goes on to further explain that the optimal surgical procedure for cervical fusion has been explored by various approaches and that there are no clear benefits or disadvantages of any particular approach for the cervical fusion and therefore that is not going to be defined in the policy as there is no evidence to support one surgical approach over another and the decision for optimal surgical approaches are usually determined by the surgeon and the patient, the consideration of the pathology and the evaluation of the specific risks and benefits for that patient.

Go to the next slide.

Dr. Ella Noel: Thank you, Dr. Durden. Oh, I'm sorry.

Dr. Marc Duerden: Yes. This includes the presentation on the cervical fusion and so I would like to open up this portion of the meeting for any comment.

Operator, if you could check anybody in the queue if there is anybody that needs to make a comment.

Coordinator: Yes, we have a comment from Brenda Byer. Your line is open.

Brenda Byer: Good afternoon. I'm specifically wondering going back to the RFA and the -- currently the additional levels for the third level injection, it says that the third level has to be reviewed with the medical records and it's only approved based on medical necessity, but we can't get an explanation as to what constitutes medical necessity for additional levels. Do you have any insight to that?

Dr. Marc Duerden: I'd be happy to take that offline because it sounds like you have some specific questions, and I can address the issue that -- so you're talking back on the previous LCD, first of all, I just want to make sure that's clear in the record.

Brenda Byer: Correct.

Dr. Marc Duerden: And you're addressing the new limitation, number seven, second sentence, which reads three or four level procedures are not medically necessary and therefore not covered.

Is that correct?

Brenda Byer: Yes, is that just how it is currently then if there's no coverage whatsoever? Because previously it was that they would be reviewed for medical necessity if you sent in the medical records, but there's no clarity as to what constitutes medical necessity. But if what I'm hearing or comprehending is that it's just not covered period, regardless, then that answers the question.

Dr. Marc Duerden: Yes, I -- okay, I appreciate that. And yes, that is what that second sentence of limitation number seven is now being changed to. That is correct.

Brenda Byer: Okay, thank you.

Dr. Marc Duerden: Closing that section, I still will have the operator open up comments for anything regarding cervical fusion. Anybody in the queue.

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

Dr. Marc Duerden: Excellent. Okay, Dr. Noel, I'll close my section of the presentation and turn the time back over to you.

Dr. Ella Noel: All right, I'm being told that I have a housekeeping item to take care of on draft LCD L35000, molecular pathology procedures. We did not open up the floor to the phone line. So, if the operator could check to see if anybody wants to make a comment on the ceramides, we'd like to hear from them.

Coordinator: As a reminder, please press star one to join the queue.

I'm showing no comments at this time.

Dr. Ella Noel: All right, thank you. I'd like to thank all of the speakers who participated today, and as well as the observers. As I said earlier, this meeting is being transcribed and will be available at our Web site. We hope you found this a useful use of your time this afternoon attending the proposed LCD open meeting process.

The comment period ends on March 23rd, 2024. Please send in your written comments to us so that we may address them. There are several places to send those. One is to PartBLCDComments@anthem.com. There is a snail mail address, National Government Services Incorporated, LCD Comments, PO Box 7108, Indianapolis, Indiana, 46207-7108. And I believe there's also a link on another page that you can access on the Medicare database that will take you right to our comments.

We will tabulate those comments and develop response to comments documents, make final changes to the LCD, and then present those as finalized LCDs.

Thank you very much. This meeting is now closed. Have a nice day.

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

END