National Government Services, Inc

Moderator: Dr. Olatokunbo Awodele
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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 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 to Dr. Awodele. Thank you. You may begin.

Dr. Olatokunbo Awodele: Thank you, (Courtney). Good afternoon, everyone, and I'd like to welcome you to the National Government Services J6JK Open Meeting. As (Courtney) said, I'm Dr. Ola Awodele, and I'll be the main host for this teleconference webinar. And the other CMD that's also going to be speaking today will be Dr. Ella Noel. She will co-host a segment of our meeting.

Again, please note that today's call is being recorded and transcribed. And other CMDs that work with me at NGS are Dr. Marc Durden, Dr. Janet Lawrence, Dr. Gina Mullen, Dr. Greg McKinney, and like I said earlier, Dr. Ella Noel. We have all together formed a team of NGS contractor medical directors. Next slide, please.

Okay, I just wanted to - this slide shows all the draft LCDs that we have to discuss today. And I don't know if this is helpful, but for anybody who just logged into the webinar, can't hear anything, and so I'm probably speaking to

the choir, because you have to call separately for the audio portion of this conference. Next slide, please.

So, we're going to start with the first draft LCD that we have here, and it's titled - it's DL33395 and titled Pharmacogenomic Testing. The proposed LCD outlines the coverage criteria for genetic tests that evaluate how an individual genetic make-up affects their response to medication.

Testing will be considered medically reasonable and necessary if the patient has a condition where clinical evaluation determines the need for a medication with known gene-drug interactions and if the test results directly impact the drug management of the patient's condition.

The test must meet evidence standards for genetic testing as evaluated by a scientific transparent peer-reviewed process, and demonstrate actionability in clinical decision-making by clinical pharmacogenomics implementation consortium, also known as CPIC guidelines, by being either a level A or a level B suggestion, or be listed in the FDA table of known gene drug interaction. This draft LCD also specifies that genetic testing where analytical validity, clinical validity, or clinical utility has not been established and any duplicative germline testing will be considered not medically reasonable and/or necessary. Next slide, please.

So, we have four people who wrote in requesting to present on this LCD, two of whom have slides and two of whom are just going to be making comments. And so, we will start off by taking the presentation of Lauren K. Lemke. She's a PharmD, a clinical pharmacist specialist of pharmacogenomics at Brown University Health. So, Lauren, please. Is Lauren on?

Dr. Lauren Lemke: Yes. Hello. Can you hear me?

Dr. Olatokunbo Awodele: Okay. Yes, I can hear you, Lauren. Please go ahead. The floor is yours.

Dr. Lauren Lemke: All right, wonderful. Thank you so much. As mentioned, my name is Lauren Lemke. I'm a clinical pharmacist specialist in pharmacogenomics. I work at Brown University Health, which, as of a couple of weeks ago, is the new name for Lifespan, which is a health system in Rhode Island. Next slide, please. Nothing to disclose. Next slide.

So, not to belabor what pharmacogenomics is, but I do want to just juxtapose the one-size-fits-all model, which is, you know, currently, "standard of care," and explain that, you know, using pharmacogenetics can help further understand risk of treatment failure or risk of adverse effects, so providers and patients can engage in a more informed discussion of those benefits and risks of their pharmacotherapy. Next slide, please.

So, firstly, I want to thank NGS for the favorable coverage decision and make my support for the proposed LCD apparent. I also want to acknowledge the importance and significance of the LCD recognizing two of the major sources of recommendations in pharmacogenomics, the Clinical Pharmacogenetics Implementation Consortium, or CPIC, as well as the FDA.

As mentioned in the LCD, CPIC adheres to rigorous and transparent standards, and for the most part is the gold standard in pharmacogenomics for identifying gene-drug interactions that are clinically significant. I also want to acknowledge the significance of this LCD in making a significant stride in closing the gap for access to PGX testing and making PGX testing available to everyone and not just those who can afford it.

So, on the right, I just want to call out that over the last four years now, all of the other MACs across the country have approved LCDs with favorable coverage for pharmacogenomics, and upon approval of this LCD, all Medicare beneficiaries, regardless of their location, will have access to PGX testing if and when they need it.

With that said, I do have a few pieces of feedback and questions on the proposed LCD and the accompanying draft billing and coding article. Next slide, please. And the first of which is a couple of gene-drug pairs that are not accounted for in the billing and coding article. Next slide.

And those would be metoprolol, which is the subject of a new CPIC guideline and was assigned at CPIC level B, and as well as Tamsulosin, whose FDA label cautions against use in CYP2D6 poor metabolizers. And, again, per the covered indications as defined in the proposed LCD, both of these should qualify. Next slide, please. Great.

So, another aspect of the LCD I'd like to discuss is the scenario in which a multigene panel will be covered. Next slide. So, in the draft article for billing and coding that accompanies this LCD, it states that if two or more genes are tested to refer to the molecular pathology procedures article for multigene testing. Next slide.

And this article that's referenced seemingly covers two scenarios, a panel covering five or more genes and then a panel covering between two and four. And the article directs us to use one of four CPT codes for panels greater than five genes, all of which are specific to cancer. And also will point out that both the draft billing and coding article, as well as this billing and coding article that is mentioned, does mention the newer CPT code specific to PGX panels. Next slide, please.

So, wanted to bring attention and explain this a little more, but the CPT code applies to panels that test for six or more genes and must include CYP2C19 and CYP2D6. Next slide. So, again, in the referenced billing and coding molecular pathology procedures article, the PGX panel CPT code is listed under group two with several other genes, but looking at the section that links the CPT codes with coverage and covered indications, I have the screenshot on the slide here, and you'll note that the CPT code for the PGX panel is not listed as a gene that's covered, and the indications are very narrow. Next slide, please.

And in the draft article that is accompanying this proposed LCD, it does provide - again, it does mention this PGX-specific CPT code and gives a little bit more detail, which I've included. So, the CPT code is included in Group 2, which lists the CPT codes and ICD-10 codes accepted for CYP2C19, and both Group 3 and Group 4, which are for CYP2D6. So, as it is, it seems there is little discrepancy between when the PGX CPT code will be covered or not. So, next slide, please.

I think specifying that, you know, referring to that molecular pathology procedures article should be referenced when a panel doesn't meet criteria for the CPT 81418, which again is that PGX-specific article, or PGX-specific panel. I think that would help clear this up, and I also would like to clarify or ask about when the PGX panel will be covered by presenting a hypothetical patient case scenario. Next slide, please.

So, in an example scenario, say we have a patient that is needing a PPI therapy for treatment of H. pylori, and they're not on any other "PGX meds," that is those subject to CPIC level of evidence A or B or listed in the FDA resources, so with just needing pantoprazole, the only gene associated with

that would be CYP2C19.

So, the question in this scenario, would billing for that PGX panel be covered? And I only give pause or question and want to seek further clarification because other Medicare administrative contractors LCDs do specifically call out additional criteria. Next slide, please. Here's a screenshot from another MACs LCD, and it specifies that a multi-chain panel is only considered reasonable and necessary if more than one gene is being considered. Next slide, please.

So, I think I'm in support of not having additional criteria for coverage of a PGx panel for a couple of reasons. One, the cost of a panel in the grand scheme of things is not significantly more than a single gene. And two, barring discovery of additional clinically significant variants, the results that a patient - the PGx results that a patient gets can be used for the rest of their life and inform future pharmacotherapy.

So, it is definitely cheaper to run a panel once than run multiple single genes over time. So, again, would just like to clarify when that multigene panel is covered, and as well as making a distinction between when tests would fall under that PGX-specific CPT code and not, and what billing and coding article should be followed. All right, next slide, please.

All right, my last thing I'd like to talk about is specific to Warfarin and the coverage and actually lack of coverage that's indicated in the LCD and proposed or draft billing article. Next slide, please. So, the draft billing and coding article specifically states that VKORC1 and CYP2C9 are not considered medically reasonable and necessary for Warfarin, citing a national coverage determination that I'll show in a moment. But notably, CYP4F2, which is another enzyme and gene prevalent for Warfarin, is covered by this

proposed and draft LCD and billing article. Next slide, please.

As a reminder, Warfarin is metabolized by CYP2C9 and inhibits VKORC1, and 4F2 does play a role in Warfarin's effect by removing vitamin K from the vitamin K cycle, and therefore is impacting how much vitamin K is available to generate clotting factors. So, all three of these, you know, work together and inform on a patient's, you know, predicted sensitivity or lack thereof to Warfarin. Next slide please.

So, a comment on the National Coverage Determination. It was approved in 2009 and covers the PC9 and VKORC1 only if the Medicare beneficiary is enrolled in a randomized control trial that's investigating the PGX impact on the patient response to Warfarin. Next slide, please. However, since 2009 and that NCD, CPIC has published guidelines for PGX for Warfarin dosing, originally in 2011 and updated in 2016. That includes CYP2C9, VKORC1, CYP4F2, and actually, as well as CYP2C cluster. Next slide, please.

So, I think it could be, you know, irresponsible or not appropriate and a detriment to patients And if we are only using CYP4F2 to guide Warfarin dosage, again, as the CYP2C9 and VKORC1 genotypes can significantly impact their response. And again, we want to make sure we're making the most informed decision.

So, I'm assuming that the language and the specifications in the NCD prevents LCDs from covering CYP2C9 and VKORC1 for Warfarin, but I wanted to confirm this assumption and then ask for guidance in addressing this. So, that way, Medicare beneficiaries can get coverage for those additional two genes. Next slide, please.

Okay, so, in summary, I want to reiterate my thanks and support for this LCD.

My recommendations include addition of metoprolol and tamsulosin, clarification on the use of the PGX panel-specific CPT, and to reconsider coverage for CYP2C9 and VKORC1 for Warfarin.

And then, finally, more of a logistical question, but I was wondering about the frequency at which the billing article will be updated as new CPIC guidelines are published, and FDA resources are updated, and, again, any logistics for this. So, that is all I had. Appreciate the opportunity to speak and, again, very excited about the positive and favorable coverage that this proposed LCD has.

Dr. Olatokunbo Awodele: Thank you very much, Ms. Lemke, and thanks for the - especially for pointing out, we do have some cleanup to do in the billing and coding guidelines. So, thank you in terms of the discrepancies. When it comes to the CPIC and FDA resources and updating, we're going to do our best to stay on top of these guidelines being updated.

That's one of the reasons why it's in the article as opposed to the LCD, so that hopefully it'll be easier - it will be much less of an issue for us to be able to update as it goes along. When it comes to the NCD 90.1, as you rightly pointed out, we do have to follow what the NCD 90.1 says, and to the best of my recollection, I do not believe it allows us for that wiggle room where it says the MAC discretion, I do not believe that that is an option on the NCD, but we will certainly take all your comments into consideration, and we'll take a look at that.

To answer your question about if we can't, what is next to do, that would be an NCD reconsideration, which if you pull up the NCD, you'll see the procedure of how to approach coverage and analysis group arm of CMS, who are the owners of that NCD, and you can follow those instructions and do what is needed to reconfigure that NCD.

And so, once again, thank you very much. And the next person who's going to present is Dr. Gabriel Brooks from Dartmouth Health - Dartmouth Cancer Center. Dr. Brooks, the floor is yours.

Dr. Gabriel Brooks: Thank you very much. Can you hear me?

Dr. Olatokunbo Awodele: Yes, I can.

Dr. Gabriel Brooks: Very good. Thank you. So, I appreciate the chance to speak, and I also want to echo Dr. Lemke in, you know, thanking the panel for the favorable proposal. I was - you know, so the point of my slides is really to discuss the importance of moving ahead with this proposed coverage determination and to specifically talk about the importance of pharmacogenetic testing in cancer care in the case of DPD deficiency. Next slide, please.

So, I have no conflicts relating to pharmacogenomics or DPD deficiency, and I have received unrelated consulting payments for other work. Next, please. So, I am a medical oncologist, and I treat patients with gastrointestinal cancer, including colon and rectal cancer and pancreatic cancer. And this issue is very pertinent to my patients and to patients with these and other conditions.

DPD deficiency is a condition that people don't know they have it until either it's diagnosed through pharmacogenetic testing or until they experience potentially a severe adverse drug event. So, the gene DPYD encodes the enzyme dihydropyrimidine dehydrogenase, or DPD, and deficiency of this enzyme is the syndrome that we're talking about, and it's caused by variants in the DPYD gene.

So, a normal functioning DPD enzyme is essential for metabolizing 5-

fluorouracil and capecitabine, and these are two chemotherapy agents that are closely related to each other, and they're essential for treating colon and rectal cancer, pancreatic cancer, and also used in the treatment of many other cancers, including breast cancer.

So, DPD deficiency is the syndrome of inadequate DPD enzymatic function, but, again, because really the enzymatic function only becomes relevant when patients are receiving these drugs, it's something that is accepted in a very severe condition that can be diagnosed at birth. But apart from that condition, most patients who have clinically significant DPD deficiency are only diagnosed when they develop severe acute chemotherapy toxicity, unless we're screening them, which is the intervention that I strongly advocate for.

And those patients can have mucositis, which is mouth sores, diarrhea, and enteritis, which can be life-threatening on their own, neutropenia, which is low white blood count, and death is a consequence that, although rare, occurs in about 1 in around 1,000 unscreened patients. And it's a complication that can be avoided through screening. Next.

So, about 1 in 25 patients has some degree of DPD deficiency, and again, we only - we don't find these patients in time if we don't screen them. About 1 in 1,000 patients has complete enzymatic deficiency, and patients with complete enzymatic deficiency are very likely to die if they receive a standard dose of chemotherapy with 5-FU or capecitabine.

There are dozens of DPYD alleles, gene variants, that are established as causes of DPD deficiency. I put some of the three most severe and well-known variants, but there are several others, and these are recognized by CPIC as strongly associated with this DPD deficiency syndrome with a level of evidence of A. So, this is covered, very clearly covered by the proposed

coverage determination. Next please.

So, people who carry one of these variants or possibly two of these variants, are at strongly increased risk for severe chemotherapy toxicity and the risk of fatal toxicity. Among the - if you are, you know, among the 5% of patients who carry one of these gene variants, the risk of fatal toxicity goes from much less than 1% to about 3% to 10%. So, it's a very significant increase in risk of a fatal toxicity event, and the only way to identify these people before the event is through screening. Next, please.

So, I wanted to mention that pharmacogenic screening for DPD deficiency is effective and cost-effective as a way to prevent severe and fatal toxicity from fluoropyrimidine chemotherapy. Now, I am the last person to want to say that we should - you know, fluoropyrimidine chemotherapy, these drugs are very important to our practice, so they are essential drugs, and yet we also want to make sure that we're using them as faithfully as we can.

So, having a test that allows us to do that and having a test that can be reimbursed for our patients is critical to offering them safe care. The number needed to screen to prevent one death, this is a conservative estimate, it's likely lower than this, but, you know, about 1,000 patients, if we screen 1,000 patients, we can prevent one death.

And this is really, you know, a very effective intervention to prevent deaths that are very traumatic for families. Obviously, you know, they are the ultimate toxicity event when they do occur. And furthermore, screening for DPD deficiency, even when it doesn't prevent deaths, can also prevent hospitalizations. So, this is an intervention that can prevent death and prevent costly acute care events. Next slide, please.

So, just highlighting that this is a practice that is recommended by the European Medicines Association, the FDA, and included in CPIC guidelines as well. DPD deficiency screening has been adopted by a growing number of leading cancer centers and has been mandated across most of Europe.

So, just making a strong case that pharmacogenic screening for DPD deficiency is medically necessary for patients receiving 5-fluorouracil and capecitabine and the coverage, you know, expressing support for the coverage determination, which would allow us to test for DPD deficiency and other conditions. Next slide.

That may be my last slide. Great. Thank you for the chance to speak, and thanks to Dr. Lemke for her excellent opening comments as well.

Dr. Olatokunbo Awodele: Thank you very, very much, Dr. Brooks. So, we'll move on to Lindsay Murray from AUDT, which is Advocates for Universal DPD/DYPD testing Lindsay, are you on? If you are, please begin.

Lindsay Murray: I am here. Can you hear me?

Dr. Olatokunbo Awodele: Yes, I can. Thank you.

Lindsay Murray: Okay. Hi, everybody. First of all, I want to thank NGS for allowing me to speak here at this meeting. I'm going to not go into such detail on DPD deficiency as Gabe has, but my name is Lindsay Murray, and I am the Vice President of AUDT, which is the Advocates for Universal DPD-DPYD Testing. I am a founding member of the organization after losing my mother in 2021 to a fatal toxicity after receiving less than one round of capecitabine.

Obviously, I didn't learn until after her death that it would have been

preventable. And I wanted to speak at this meeting today to really bring some real-life experience to the stark reality of the impact and patient safety risks that continue to be real for patients within our MAC. It's really, really disturbing to those of us that have lost loved ones that our MAC NGS is the only one that continues to not have PGX coverage. It's putting patients in our area at much greater risk for severe and fatal toxic reactions.

As Gabe said, patients that are DPD-deficient and are not tested before receiving treatment are unable to metabolize these drugs. They essentially burn from the inside out. I watched my mother just deteriorate in the ICU. She had skin desquamation. Her skin was falling off her body. She lost control of her bowels all of her hair was falling out. She had mucositis all through her mouth, sores everywhere.

I stood for seven hours while we were in the first in the hospital holding oxygen to her mouth just so she could breathe. So, these are real-life issues that continue to happen, and, you know, we're really working hard to standardize preemptive testing for patients receiving fluorouracil-based chemotherapies here in the U.S. But it's becoming increasingly challenging to change the standard of care with Medicare coverage disparities nationwide.

So, I'm really hoping that at this point, where we're seeing some movement towards an LCD for PGX testing, that you can hopefully move quickly to make sure that these patients are getting these life-saving PGX tests before they end up like my mom did. You know, this is 2024. We do know that PGX testing is life-saving, and the lack of movement that continues to happen to make sure these patients are protected is truly inhumane, and it's really time to put patient safety first.

PGX testing is certainly a big part of that puzzle. Every patient, I believe, that

continues to suffer and potentially die receiving these drugs, which, just to note, is three in our MAC in the past year that I know of that have known drug-gain interactions, it's a direct failure of this system to continue to protect them. So, I'm just hoping that after this meeting, NGS is able to move quickly to implement this coverage to avoid any future suffering and fatalities.

I know there was an LCD revision that was submitted over 18 months ago. Within that 18 months, as I noted, there's been three patients that have died and numerous other patients that have been hospitalized. So, I think this is just far, far overdue. I'm just hoping that, you know, this problem is - we know this problem is real.

The suffering and fatalities that are continuing to happen without this LCD revision is real. And until NGS really does update this LCD to the human cost of not being able to test because of the financial barrier will also be real. So, I'm really hoping that you take some of these patient experiences and some of these known drug interactions and make this decision in a quick manner to implement so we can really continue to protect patients. Thank you.

Dr. Olatokunbo Awodele: Thank you very much, Ms. Murray. And as you see, we are indeed listening, and we have this draft LCD, which is what we're discussing today, and the prior speakers have expressed support for the decision that NGS has done. And so, thank you very much for your work. And we'll now move over to Dr. Jeffrey Bishop. Dr. Bishop, are you on?

Dr. Jeffrey Bishop: I am. Am I coming through okay?

Dr. Olatokunbo Awodele: Yes, you are. Thank you very much. You may proceed.

Dr. Jeffrey Bishop: Well, thank you for the opportunity to speak, and also thanks to the other

presenters for sharing their positive views as well. So, I'm a professor here at the University of Minnesota. The comments I make are my own. I would like to disclose that I have been a - served as a consultant to OptumRx, but they're for activities unrelated to pharmacogenetics.

So, I just want to make a few comments, mainly as it relates to pharmacogenomics and mental health, and thank you for putting forth the proposed LCD. I'm a board-certified psychiatric pharmacist by clinical training and have spent 20 years doing discovery, clinical, and now implementation-related research related to pharmacogenetics and mental health.

I was excited to see CPIC referenced in the LCD. I've been a committee member for five different CPIC guidelines related to neuropsychiatric medications and in the leadership team for two of those. So, I can make some comments later on with that vantage point. I often speak or volunteer at patient advocacy meetings, so, for example, the National Alliance of Mental Illness, and I speak and deliver CE to clinical practice groups like medicine, psychiatry, pharmacy, nursing.

There are two commonly asked and very hard questions that often - almost always come up in those contexts. And the first is, what type of test should I order - or what test should I order? And I just wanted to say that the proposed LCD channels, a lot of key characteristics that I often relay without endorsing any specific test. So, I wanted to thank you for that.

The other involves questions about what is covered. And when these get into interactive discussions, particularly in groups of geographic heterogeneity, it always segues into conversations of health equity when there's sort of a realization that patients in some areas have access to testing coverage and

others do not. So, I think this LCD is an excellent step to help alleviate that.

So, I think similarities across LCDs for pharmacogenetics is extremely important, as the other speakers mentioned. So, in a treatment for many common mental health conditions, from a clinical practice workflow, we often discuss a short list of options that we've determined to be medically necessary for patients. And the reasons for this are, we don't often have good biological reasons to choose between specific agents within class or groups of medications, and also that promotes a discussion of pros and cons with the patient and facilitates patient engagement.

So, first here, antidepressant and antipsychotic medications, as examples, nearly always have at least one drug with CPIC or FDA guidance related to pharmacogenetics. So, the impact of this data is often immediately important when available. So, it's a common scenario for using pharmacogenetics as information to support these decisions.

So, for antidepressants, you know, I'd say medications like citalopram, escitalopram, sertraline, venlafaxine, are usually on the list of medications that get discussed. And those have PGX relevance in both the CPIC guidelines and the FDA table that's referenced. Antipsychotics, aripiprazole, is nearly always included in the discussion, and that has important guidance as well.

So, I think integrating this into a workflow is easily conceivable where the short list of medications deemed to be medically necessary can be refined or reprioritized when the drug gene interactions are identified. I'd like to make a couple of comments about CPIC, and particularly that I strongly support the inclusion of CPIC guidelines as one of the benchmarks that you have.

We have a regular conflict of interest policy that gets reviewed by a steering

committee that's separate from the guideline committee. The assignment of the CPIC evidence levels for prescribing are clear and transparent. This group's been supported by the NIH with volunteer interprofessional and multidisciplinary committee members selected due to recognition as field leaders in different components of a guideline.

So, prescriber expertise, pharmacists, clinical pharmacologists, gene experts, clinical decision support or informatics are always included. Data capture is very systematic and comprehensive. So, for example, the recent antidepressant guideline that I was senior author on, we reviewed almost 1,400 publications, of which 318 were included in the formulation of major finding statements that helped to support the recommendations and assignment of CPIC evidence levels.

So, there's a huge amount of work that goes into those thorough evaluations, and I think my experience is that we've erred on the conservative side when there are discrepancies or data gaps. And so, I think the LCD is well-served by utilizing this and focusing on the levels A and B as referenced in there is great.

So, one caveat to those guidelines is that they do take a while to generate, and there are often circumstances where new medications with PGX relevance may come to market prior to being on a guideline. And so, that's why I think the FDA benchmark is also very important. The Table of Pharmacogenetic Associations is a good resource and complements along with the CPIC guidance because there are some drugs that have important pharmacogenetics and labeling but don't have guidelines. Antipsychotics are a good example of this.

We have a guideline in progress right now. It just hasn't had the bandwidth to

be supported yet, but the information is included in the FDA labeling for a number of agents. And, from the flip side, CPIC often considers data that may not have been available for new drug applications or labeling updates. So, sertraline is a good example of that, where there's pretty solid pharmacogenetic relevance that is in the CPIC guideline, but the FDA label predated the knowledge of that importance.

One just quick comment about the FDA label is that the FDA pharmacogenetics table, which seemed to be the reference point in the LCD, is that sometimes might lag in updates relative to new drug approval. So, I just wanted to bring awareness that it's not auto-populated in that there could be scenarios, I know there's a new antidepressant that fits this category where it was approved.

It has dosing guidance based on pharmacogenetics. It came after the CPIC guideline, so it hasn't made it into the FDA table, but it's in the FDA label. And so, I might put some suggestions in the open comment period about that, but I just wanted to bring that as an element of awareness. And I guess the last thing I just want to say is thank you again for putting forth this pharmacogenomic LCD, and I'm happy to serve as a resource or answer questions if needed. Thank you.

Dr. Olatokunbo Awodele: Thank you very much, Dr. Bishop. And with that, that ends our comments, our presenters for this particular draft LCD. I just want to remind our presenters to please, please send in your comments in writing to us. They're very informative, and I'm sure they'll be very helpful for us. So, please, I would love for you to do that at policy comment - sorry, I was going to get - I will mention the various ways that you can do that at the end of the meeting.

So, at this time, we're going to open the floor for any oral comments that may exist specifically on this proposed LCD for pharmacogenomic testing. So, (Courtney), I would love you to ask the audience if they have any comments. And please, for the commenters, please state your name and your comment. And remember, we do need to submit it in writing in various ways that I will mention at the end of the meeting. So, (Courtney), please go ahead.

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

Dr. Olatokunbo Awodele: Do we have anybody on that would like to make a comment, (Courtney)? It doesn't seem so.

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

Dr. Olatokunbo Awodele: Okay, thank you very much. So, with that, we will be closing this portion of the meeting concerning pharmacogenomics testing, and we'll move on to the next draft LCD, which happens to be DL35000. It's molecular pathology procedures, and the reason it's being brought to this meeting is because, as you can see on the slide, side, we are removing the specific genes, that's CYP2C19, CYP2C9, and CYP2D6, which we're transitioning into the new proposed pharmacogenomic testing LCD, which we just discussed prior to this.

And basically we're also going to clean up the billing and coding article to reflect the changes in the LCD. So, (Courtney), could you ask anybody, any of the MDs if they would like to make a comment on these changes, please?

Coordinator: Thank you. If you would like to make a comment, please press Star 1. Again, to make a comment, please press Star 1. The first comment comes from

Steven Allen. Your line is open.

Dr. Steven Allen: Thank you. I just wanted to point out that you had a serious typo in the JAK2V617F statement about genotyping. It says it's considered medically necessary in the initial diagnostic workup of BCR-ABL-negative, JAK2-negative adults, but you don't know if somebody's JAK2-negative until you test for it.

Dr. Olatokunbo Awodele: Indeed, thank you very much. Dr. Allen. Thank you very much. If you could please just send it to us in writing just as backup as well. I would really appreciate it. Thank you. Dr Allen.

Dr. Steven Allen: Okay. Thank you.

Dr. Olatokunbo Awodele: Any other comments, (Courtney)?

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

Dr. Olatokunbo Awodele: Thank you very much, (Courtney). At this time, this ends the portion of the meetings for DL35000, Molecular Pathology Procedures, and we'll move on to the next draft LCD, which is DL33394, Drugs and Biologicals, Coverage of, For Label, and Off-Label Uses. We are bringing this LCD back to the conference to the open meeting.

Based on a reconsideration request, this LCD has been revised to allow off-label use of bevacizumab in hereditary telangiectasia with atrial venous malformations, also known as AVMs, causing gastrointestinal bleeding. So, (Courtney), could you please – we had no request for presentation on this, but (Courtney), could you please ask our attendees if anyone would like to make an oral comment?

Coordinator: Please press Star 1 if you would like to make a comment. Again, please press Star 1 if you would like to make a comment. I'm showing no comments at this time.

Dr. Olatokunbo Awodele: Thank you very much, (Courtney). And at this time, I would like to hand over to Dr. Noel to continue the meeting.

Dr. Ella Noel: Thank you, Dr. Awodele. I will be discussing Draft LCD 37606, the Genomic Sequence Analysis Panels in the Treatment of Hematolymphoid Diseases. We received a reconsideration request because the prior version of this LCD did not align with the World Health Organization or International Consensus Committee diagnostic criteria for acute myelogenous leukemia.

We decided at that time that we were also going to look at the other parameters discussed in this LCD, which include myelodysplastic syndrome and myeloproliferative neoplasms. There's some additional information about the changes that were made to the LCD. There were no requests for any presentations today. So, we will be asking for comments from the audience on this LCD. Can we have the operator check to see if anyone wishes to say anything?

Coordinator: Please press Star 1 if you'd like to make a comment. Again press Star 1. We have a comment from Dr. Steven Allen. Your line is open.

Dr. Steven Allen: Okay, thank you again. So, on Page 5, under limitations, it says repeat genomic sequential analysis panel testing is not reasonable and necessary in MDS after initial diagnosis and risk stratification. But I was wondering if it might be considered helpful sometimes as patients are progressing, the information we get from NGS testing may show clonal evolution, which may

help guide treatment decisions. Is that something you would reconsider?

Dr. Ella Noel: Please put that request in writing. We'll have to take a look at it. As you know, with NGS testing, there are certain parameters that need to be met for repeat testing. And among those, I think a change in - considering for a change in clonal makeup would qualify. But please send it in so we can look at it in detail.

Dr. Steven Allen: You'll be giving instructions how to do that?

Dr. Ella Noel: Yes, as soon as we finish up with this section, Dr. Awodele will be going over how to get those into us. She has a slide with everything written out on it. Do we have any other comments?

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

Dr. Ella Noel: All right, well, I thank our commenter on the question that he has, and I will turn the meeting back over to Dr. Awodele so she can inform everybody how to get those comments to us.

Dr. Olatokunbo Awodele: Thank you very much, Dr. Noel. All right, so I would like to once again thank all our presenters and thank all our commenters, and thank all the attendees for coming to our draft LCD open meeting for J6JK. And at this point, I want to point our attention to the screen and say that - to give some information.

The comment on the proposed LCD during the official comment period, which is from 10-3-2024, and we have already started receiving comments in writing, and we want to thank those who have been sending comments in, and this comment period ends 11-16-2024. That's the 16th of November 2024.

There are a few ways that you can send in these comments.

One way would be to click on Public Comments button on the proposed LCD in the Medicare Coverage Database. So, if you were to go to CMS, go to the Medicare coverage database, and you were on the proposed LCD, there will be a public comments button. You can click on that. You can simply send us an email directly to PartBLCDcomments@anthem.com. And you can also send us a letter addressed to National Government Services, Inc., LCD Comments, P.O. Box 7108, Indianapolis, Indiana, 46207-7108.

Before we finish, I would like to put a plug in for NGS and just request anybody on the line who would be interested in being a subject-matter expert to help us out as we do - you know, write these proposed LCDs, but more importantly, during CAC meetings, which we usually constitute for LCDs or proposed drafts that we feel might be controversial.

We would really appreciate if you could respond to us and be on the lookout because we are going to be posting requests for such subject-matter experts to please - who would like to partner with us and help us to more succinctly be able to address different needs of our stakeholders and our community. We would really appreciate that.

So, please just be responsive. Things will come through Listserv. If you're not on Listserv, please register on Listserv or frequently visit the comments, the policy area of our NGS Medicare website. We would really appreciate that, because we look forward to working with you, and we can't really do it without you. We want to be responsive to you as our stakeholders.

So, with that being said, I would like to thank everybody for insightful presentations and participation today. We do appreciate your input and the

productive discussion, and we look forward to your continued engagement and feedback. Have a great rest of your day. Thank you very much. Operator, you may now disconnect. Thank you.

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

Dr. Olatokunbo Awodele: Thank you.

END