WPS Government Health Administrators Draft Local Coverage Determination (LCD) Open Meeting Transcript

Moderator: Dr. Barry Whites

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

Dr. Barry Whites: This is Dr. Barry Whites, and I'd like to welcome all to this open meeting for six draft policies that – there – have been now publication and for consideration on the Medicare Coverage Database.

There's some housekeeping that we need to discuss, getting all callers will be placed on mute upon login. You probably already found that out. When it's time to speak, you just click the “raise hand” it is here, and when the facilitator calls on you to speak, make sure that your telephone or headset is not on mute. Also, be sure that your computer speaker are on mute when you're speaking so there is no echo.

This meeting is being recorded and transcribed as directed by CMS. To aid in the transcription, please introduce yourself before you speak. And also, if you would list any potential conflict of interest that you feel should be provided. The policycomments@wpsic.com is a very important email address to remember because all comments need to be addressed in writing to this mailbox to be considered. Comments that are not submitted over to the mailbox will not be considered.

Next slide please.

We’ll go ahead and get started with the proposed LCDs. The first one in order on your agenda is Allogeneic Hematopoietic Cell Transplantation for Primary and Refractory or Relapsed Hodgkin’s and Non-Hodgkin’s Lymphoma with B-Cell or T-Cell Origin; quite a mouthful. But what we've been requested by - particularly ASH and ASCO – to cover this, even though it has not been a problem with coverage, the hospitals certainly want to have some verification of coverage. This policy was an adoption of a policy from Palmetto in response to this – or these – requests.

The policy addresses additional local coverage for allogeneic stem cell transplantation as mentioned above meeting the statutory and CMS criteria for a reasonable and medically necessary coverage and reimbursement. The overall review of the evidence is consistently supportive of potential benefit. Patients who suffer from such diseases may have no other available therapeutic options for curative intent. Impact in such patients has been identified and counts for such inclusion in many national oncologic hematologic, clinical practice guidelines that are evidence graded. The development of reduced intensity conditioning, the adoption of maximum age increases for transplant

program patients and improved screening for and treatment of co-morbid conditions and older population supports the expanded therapeutic scope. Age is not to be considered as a contra-indication for this procedure.

We're fortunate to have Dr Joseph McGuirk, a professor of medicine, the University of Kansas City Cancer Center, to now give us a presentation on this topic.

Dr. McGuirk;

Richard Staley: Dr. McGuirk, I have placed you in the panelists and you can unmute at any time. And, we will have Mel set up your screen share.

Okay Dr. McGuirk, you should be able to click the unmute icon on your screen. There we go.

Dr. Joseph McGuirk: Okay, are you able to hear me?

Richard Staley: Yes, I can hear you.

Dr. Whites: Yes.

Dr. McGuirk: Thank you for the opportunity to present. This is Dr. Joseph P. McGuirk, I am the division director of hemo-malignancy and cell therapy at University of Kansas, as mentioned, and I have no conflicts of interest pertinent to our presentation today.

Allogeneic stem cell transplants represent a curative treatment approach for many patients with hematologic malignancies. Patients aged greater than – 65 years of age, or greater – with certain hematological malignancies, such as myelodysplasic syndrome myeloma, myelofibrosis or non-Hodgkin's lymphoma, with Medicare as primary insurance in the United States, historically, did not have coverage for allogeneic transplant, leading to disparities in access between those with private versus Medicare insurance.

Further, allogeneic transplant indications more recently had been approved for myeloma, myelodysplasic syndrome, myelofibrosis, sickle cell disease, having acquired CMS coverage. Coverage for allogeneic stem cell transplant in contrast for non-Hodgkin's lymphoma, in the United States, is limited to only those states that are in the National Government Services jurisdiction. Most patients, age – 65 years of age or greater in the United States received their primary insurance coverage through Medicare and most private insurance providers follow CMS guidelines. This means that

the vast majority of patients 65 years of age and greater with non-Hodgkin's lymphoma lack access to this potentially curative treatment modality.

As you can see in this slide the SEER national data from 2015 to 2019, representing all races and both sexes, the median age at diagnosis of non-Hodgkin's lymphoma is 67, and as you can see the distribution here, 58% of patients are greater – equal to, or greater than 65 years of age. The development of reduced intensity conditioning regimens and non-myelo[inaudible] regimens has resulted in increased utilization in older patients. Next slide please.

These data published by Shaw et al. in Blood Advances in 2018, reported on 1629 non-Hodgkin's lymphoma patients from 2008 to 2015, from the Center for International Blood Marrow Transplant registry. In this report, 446 patients were 65 years of age or greater and 1183 patients were 55 to 64 years of age. What you're seeing here in the left-hand side panel, on the upper part is non relapsed mortality, which is slightly greater, but statistically so, in the older population of patients. However, in subsequent multivariate analysis, this statistical significance was lost. In the lower panel, and the B panel on the left-hand side, is the relapse progression of disease and you can see those curves are superimposable and they are not different. On the right-hand side, very importantly, in A is progression free survival and B is overall survival. And there is no statistical difference between these two age groups. Next slide, please.

The same authors, Shaw and colleagues, reported in Blood Cancer Journal one year later, a CIBMTR registry analysis of 727 patients greater than 65 years of age undergoing allogeneic transplant and divided these patients by time period: 2000 to 2005, 2006 to 2010, 2011 to 2015. And what you're seeing here is on the left-hand side progression-free survival went from 17% in the earlier period to 31 and 30% in the second and third periods, and overall survival went from 21% in the initial period to 42 to 44% in the second and third period. What you don't see here, but it's reported it in this dataset is 30% mortality reduction from 2000 to 2005 to the 2011 to 2015 time period. And that's quite remarkable given that 50% of patients had significant comorbidities in a comorbidity index of three or greater. Next slide please.

Further, these are CIBMTR data demonstrating that the age of patients has been steadily increased over many years, year over year. So, if you look at the right-hand side, the number of – and percentage of – patients 65 years of age and greater has significantly increased and this has been made possible through reduced intensity non-myelo[inaudible] conditioning regimens and better supportive care post-transplant and patient selection based on fitness. Next slide please

In addition, the types of stem cell sources have changed over time, so that now the majority of stem cell sources for 60 – patients 65 years of age and greater, are represented by unrelated donors. Or increasingly haplo-identical family donors are mismatched, unrelated donors. Next slide please

The national efforts that we're talking about today has long been supported by the American Society of Hematology and the American Society of Transplant and Cell Therapy. An LCD submission to each MAC is planned by these societies. As mentioned, the Palmetto region is finalized and active. Noridian region, comment period is closed. The WPS, our own region, comment period is open, In the CGS region, comment period is open. This presentation has been organized by colleagues at University of Kansas and supported by our colleagues at Washington University, University of Iowa, and University of Nebraska. There's a great regional unmet need, as I described earlier, and sending patients outside of the region for allogeneic stem cell transplant presents real challenges for our patients. Next slide, please.

Those challenges are represented here by financial, travel, lodging, food, increased time away from work, all post significant financial hardships on patients to travel to a transplant center in a MAC jurisdiction with an LCD in place for allo-transplant. Social support critically important for our patients wellbeing is problematic in that the patient and caregiver must reside within 30 minutes of a transplant center for 100 days after transplant. That's a national standard. Caregivers required 24/7 for that 100 days post-transplant. Continuity of care is breached here. The patient must re-establish care with a new medical team, causing break in continuity and a delay potentially in transplant process. Further, there's lack of familiarity with the new team and area causing significant psychosocial stress potentially. And finally, frequent long-term follow up, which is required of these patients, life-long, patients must return at frequent, time specific intervals to complete post-transplant evaluation for a long – lifetime, and survivorship. Combining all of the above hardships, patients are less likely to comply with required followup, increasing risk of post-transplant complications and leading to missed early relapse detection and most importantly, loss of life, because many patients simply can't afford to travel long distances to a center and will succumb to their disease.

So, as mentioned earlier, age by itself is an insufficient and often inaccurate determinant of medical fitness for any specific treatment, including allogeneic stem cell transplant for lymphoma. Coverage for Medicare patients to receive allogeneic transplant for non-Hodgkin’s lymphoma is endorsed by the American Society of Hematology, the American Society of Transplant and Cell Therapy, and the National Marrow Donor program, or Be the Match. Our former American site-of-transplant and cell therapy, Dr John Dipersio, professor of medicine at Washington University in St Louis, will speak next and then we have a patient who is facing this very challenge who I believe plans to speak as well. Thank you for your time and attention.

Dr. Whites: Thank you very much. If any commenters would like to raise their hand and be recognized, please, at this time.

Richard Staley: We have a John Dipersio. I have just sent a request to unmute-

Dr. Whites: Please go ahead, sir. Thank you, thank you.

John Dipersio: Thank you very much, and I don't have much to add to Dr McGuirk's excellent review. I would just say that the data that he reviewed was registry data, encompassing many centers around the country. We're one of the larger centers in the Midwest, in our Medicare region, and our data that I sent to Dr. McGuirk – it's not in the slide presentation – is almost identical to what he showed, and I just want to emphasize that most of our patients of the 166 patients that we've transplanted since 2010, for non-Hodgkin's lymphoma have been over the age of 60, and 70% over the age of 65. And median, the overall cumulative survival over ten years, we have ten years survival data, Is 50%. And that, in transplant terms represents a substantial enhancement. Not only for the life of the patient, but also for the quality of life of all the family that are so close to these patients and have to care for them. So, I echo what Dr. McGuirk has said about the relative issues of age, and more important than age are comorbidities. And if the comorbidities are acceptable, age does not seem to be a significant risk factor for outcomes after allogeneic stem cells transplant, not only for non-Hodgkin's lymphoma, but for other diseases such as MDS and AML. And so, I echo his support for **t**his being approved for Medicare patients in our region.

Dr. Barry Whites: Thank you so much. Any other comments?

Richard Staley: I currently see no hand raises at the moment. If you are on a phone, you can press *3, and that will bring up the hand raise icon for me.

It appears there are no further comments at this time, Dr Whites.

Dr. Barry Whites: Thank you very much. The second item that we have is one of three molecular diagnostic testing, or Assays, and this is for cutaneous melanoma. It is DL39479. It is to assist dermatopathologists to arrive at the correct diagnosis of melanoma versus non-melanoma when examining skin biopsies. It will provide limited coverage for DNA/RNA assays that aid in the diagnosis or exclusion of melanoma from a biopsy when all of the seven clinical conditions are met, as listed in the policy; we'll not go over those just for brevity. I'm sure most of the dermatopathologists and the physicians treating cutaneous melanomas, certainly, hope you have reviewed the policy. The studies demonstrate that Medicare beneficiaries with diagnostic challenging lab results, or history, will have improved outcomes as defined by an increase in accurate diagnosis, appropriate clinical management, interventions and a reduction in burdensome and unnecessary treatments.

Are there any comments to this Draft policy?

Richard Staley: I do see a hand raise from a Lisa Mack. I am requesting unmute at this time.

Dr. Barry Whites: Please proceed.

Lisa Mack: Hi, [inaudible], but, good afternoon. My name is Lisa Mack and I'm a Medicare beneficiary from Kansas City, Missouri. First and foremost, I want to thank you and the K-Med team for giving me the opportunity to tell my story. I've been under the care of Dr. McGuirk and his amazing team since 2021. I was originally diagnosed with stage four mantle cell lymphoma at – in 2015, at 54 years old. I've had multiple lines of treatment, including R-CHOP an auto-transplant, Imbruvica®, CAR-T, and now Revlimid® and Rituximab. All doctors agree, this fifth line of treatment must be an allogeneic transplant, and it's my only curative option.

Unfortunately, I cannot proceed with this life saving treatment in Kansas City, due to the lack of clear coverage for the procedure in my Medicare area. So I'm traveling to Memorial Sloan Kettering in New York City to undergo my transplant. There's currently an LCD in place for that Medicare region. Specifically, allowing coverage.

Have I lost time because of this change? Absolutely. Time is my enemy now. Just so, you know, I don't wallow in my fight against this insidious disease. I walk three miles a day, I work out, and I have at least 30 medals of half marathons, 10Ks and 5Ks, while I executed either in remission or out of remission. With these factors in mind, I want to strongly advocate for the prompt approval of this LCD, for myself and all the Medicare beneficiaries in the WPS region. When, not if, Medicare rules or regulations allow, I ask you to please expedite approval and the effective date of the LCD in any way possible.

As a sidebar, I told Dr. McGuirk that the Palmetto jurisdiction was recently approved. His question was “how long did the approval take?” My answer was “Two to three months.” His answer was “Lisa, you don't have that time.” If this were in place today, I could safely transplant in Kansas City, eliminating many of the adverse factors mentioned. I can attest the traveling to New York for this transplant is a hardship, as Dr. McGuirk mentioned. The cost of travel, lodging, food and other incidental expenses will likely total roughly $30,000. This does not even take into account the financial cost my caregivers will face from time from work, family and their daily life. I don't have 24/7 caregivers in New York City. I do have significant and a close network of people here in KC, that would be with me for 100 days after transplant. I literally live five minutes from KU Med. The social and emotional stressors this places on my life can't be quantified as easily as the monetary stressors. Please imagine for a moment, leaving your friends

and family for this time period, to undergo a transplant several states away from the home. The psychosocial impact is immense. Since I already established care with my new medical team, and my disease requires the allogeneic transplant, My – Dr. McGuirk and his team expedited my referral to New York to minimize time lost during donor search and actual transplants. Truly, my objective is not about me, but for the hundreds, maybe thousands of Medicare patients in our jurisdiction, and perhaps across the country who are struggling with this disease. If I can help this team secure your approval It will be one of the greatest accomplishments of my life. Again, I ask you to please expedite your decision and the effective date of the LCD as quickly as possible. Thank you for your time.

Dr. Barry Whites: Thank you so much for your comments. I would, I would note that our limitations, as far as notice period, comment period, are fixed by law. I would also encourage you to speak back to Kansas City concerning the fact that this is a coverage policy that will be in effect, and as far as I am aware, Individual consideration is given to each and every patient on an individual basis by WPS, on patients who have undergone this procedure prior to the finalization of this proposed policy. So we're just asking them maybe they could review that because this, this may not really be that big of an issue for you. If individual consideration is granted. Again, each patient and individual consideration is based on their own history, their own review and, again, we do not have a non-coverage policy, we just don't have a policy period. So the fact that you – this policy of coverage is not out yet does not mean we have a policy decision that says you can't get it. Just remember that.

Any, any other comments on the first item - the allogeneic hemopoietic transplant – and again on, now on the molecular assay for cutaneous melanoma comments, any comments on that please?

Richard Staley: All right I see no hand raise icons at this time.

Dr. Barry Whites: Okay, thank you very much.

We will next go to the third item on the agenda, and that is for Biomarker Testing for Guide Targeted Therapy for Selection and patient Rheumatoid Arthritis. Currently, molecular biomarker tests for targeted therapy for rheumatoid arthritis are non-covered by this contractor, and all contractors, at least all MolDX contractors. This, again, is a MolDX policy that was derived from the Palmetto MolDX contractor. We are partners with them and therefore, and able to make some contributions to this decision, or we can choose not to take the policy. An evidentiary CAC was held by the – the subject matter expert was held. These experts were diffused from throughout the United States, not just in the MolDX jurisdiction. The panelists were not aware of any such tests that

have been rigorously validated for routine clinical use at the time of the evidentiary care advisory committee was assimilated. The – Also, any additional – any international, national societal guidelines, have not been endorsed for predictive; that is a response to therapy biomarker testing to date. And members of this evidentiary CAC committee, while agreeing in the value of testing, do not think that such a test, in their opinion, had demonstrated, had been demonstrated to warrant routine, clinical use. Therefore, the clinical validity and utility was not felt to have been established for the molecular diagnostic test for targeted therapy for rheumatoid arthritis. The contractor will continue to monitor the evidence and may modify coverage based on new information and the pertinent literature or societal recommendations.

Now, and we have a conductor, Jennifer Dines, the vice president of regulatory medical affairs, Scipher Medicine, who has a presentation for us. Would certainly appreciate if you would state, prior to the presentation, any conflict of interest that you may have.

Dr. Dines.

Dr. Jennifer Dines: Thank you very much. And yes, I have one conflict of interest, as I am a full-time employee at Scipher Medicine. We at Scipher Medicine are appreciative of the opportunity to present and look forward to working with WPS to further support our coverage application and thereby provide this vital test to Medicare beneficiaries. Very briefly, and on the next slide, I wanted to introduce myself as it relates both to precision diagnostics and clinical coverage.

As a clinical geneticist, I have focused my career on translating novel technology to the clinic to improve patient outcomes. With my keen interest in precision medicine at the University of Washington, I participated in the evolution of advanced sequencing technologies, integration into medical practice and saw an enormous impact on patient care as it has transformed probably better treat and diagnose patients in the field of oncology. At Adaptive Biotechnologies, I expanded from oncology to the use of auto in auto, immune and infectious diseases, and helped the company receive FDA's emergency authorization for new class of diagnostics, with a machine learning classifier based blood tests to combat the COVID pandemic. I am now leading similar efforts here at Scipher Medicine towards that end, on the next slide.

I will be providing a brief introduction and background to our company and PRISM RA, which has continued to gain adoption by the rheumatology community in parallel with the progression of studies that demonstrate its validity and utility in the clinic and will conclude with the urgent need for this test.

In the next slide, our company, Scipher Medicine, is focused on providing physicians with the right tools and solutions to deliver precision-based care to their patients. Doing so helps achieve the critical aims of improved outcomes, lower costs and more efficient health care delivery.

Specifically, in the next slide, PRISM RA, **t**he test you are discussing today is already experiencing large scale adoption across the country. Throughout the United States physicians and their practices as a whole have been ordering our tests, given its utility and necessity in the care of their patients, and is used by over 600 providers across 400 practices. Over 45% of our commercial tests come from patients covered by Medicare. And as such, our goal is to work collaboratively to improve access and coverage as we are doing today. Next slide.

This summarizes our clinical validity supporting PRISM RA integration in the clinic. PRISM RA has been clinically validated in both retrospective and prospective studies in over 800 patient samples and demonstrate consistent performance across multiple cohorts, with studies reporting close to 90% positive, predictive value, solidifying the value proposition of this innovative test. Most recently, in the aim study cohort at the far right of the slide, we evaluated the performance characteristics of PRISM RA in 369 patients. The resulting performance included a PPB of 88%, thereby demonstrating the continued performance in a cohort nearly three times larger than prior studies summarized on this slide. As 90% of patients with RA are treated with TNFI therapies as first line biologic targeted therapy, PRISM RA can accurately redirect patients with a molecular signature of TNFI non-response to an alternative therapy, increasing their likelihood of achieving targeted clinical outcomes, which I will go into more details after first clarifying a misinterpretation of our clinical utility data on the next slide.

Here, we believe this to be a misinterpretation of a key result related to the utility of the test. As was noted in the draft non-coverage decision and detailed at the bottom of the slide, the conclusion reached was surprising to us at Scipher, because an improvement over baseline and standard of care is exactly what we measured and achieved as a primary end point. As seen here on the left of the slide in table one, and highlighted, the absolute CDAI average among the predicted non-responders for those receiving TNFIs, and those receiving an alternative mode of action were both in the 30s. After six months, and shown in the second table on the right, of those predicted TNFI non-responders, only 10% of the group receiving a TNFI achieved an ACR50 while those aligned with the test results and on an alternative mode of action had more than three times, with 34.8% of patients achieving ACR50. P

I will now review the clinical utility data in more detail on slide eight. As I discussed previously, our test has been clinically validated in over 800 patient samples. Now depicted on this slide, prospectively evaluated for provider treatment selection and clinical outcomes in over 900 patient samples. It is important to note on this side are both the end values of our studies as well as the primary endpoints achieved. Additionally, and highlighted in the table at the bottom of this slide, we assess the patient numbers and demographics further to determine the representative value to Medicare beneficiaries. Across the interim analysis, 22 to 36% of patients for 65 years of age, or older with females representing 80 to 85% of patients and 25 to 32%.

Identifying as non-white and/or hispanic or latina in this age group. I will now go over the study primary endpoints in greater detail on the next slide.

From our peer-reviewed paper that brought our end value to 274 patient samples, that was published in this year, one key point, represented below the letter B, on the figure on the left; we see those with a molecular signature of non-response, treated with an alternative mode of action, therapy, had a 1.8 fold greater improvement in CDAI scores than those treated with a TNFI.

In the next slide, we have submitted for publication an additional clinical utility paper that is pending publication. Here, we not only increase the end value of patients tested and outcomes measured to 489 patients, but also show that treatment selection guided by our test results in 1.5 to 2.9 greater improvement in outcomes after six months of biological therapy initiation, compared to standard of care, external EMRI derived control group, where PRISM RA was not used to predict therapeutic non-response to TNFI therapy. Next slide.

And in response to MolDX draft LCD, we explore how robustly our test can predict TNFI non-response compared to clinical and serologic features in combination or alone. At Scipher medicine as well as key opinion leaders, including the members of the CAC, and at advocacy groups, we were surprised to hear that the contractor believes that tools and metrics are already available to practicing physicians and that the utilization of these metrics and values would provide predictive power comparable to PRISM RA. Here I am sharing from two analyses, comparing clinical, serologic and molecular features individually and in combination, we see that PRISM RA or MSRC shaded in gray is better able to predict TNFI non-response, more robustly across these two cohorts than any combination of clinical or serologic features alone.

In the next slide, we summarize physician and advocacy group sentiments that continue to provide support of our data, reaffirm the dire need to incorporate PRISM RA into their medical practice. Their support reaffirms the dire need, and this includes a devastating effects that occur as patients are trialed on different therapies until they find the right treatment to control their disease. Importantly, we know that patients who do not respond to their initial therapy are less likely to respond to subsequent therapies. Therefore, the utilization of PRSIM RA will help doctors make a more informed therapy choice and will improve patient outcomes as demonstrated in the body of the evidence we review today. Importantly, Medicare does not require TNFIs as first choice and second line therapy and PRISM RA is used in the clinic can be seamlessly integrated with decision impact with therapy decisions based on an individual patient's unique biology.

And I'll conclude with the final slide, which highlights and shifts focus solely on the patient and their journey. Here we see on the left-hand side and in gray, the patient's journey is long and arduous. Inadequate control of RA results in chronic inflammation which can lead to joint damage, permanent disability and poor health outcomes,

including shorten life expectancy. Prior to PRISM RA, management of patients with RA, included a trial and error approach. Since this approach often fails to efficiently identify the most effective therapy, RA patients suffer prolonged, poorly controlled disease, irreversible joint damage and an increased risk of cardiovascular disease cancer and death. As a physician myself, I fully understand the value of precision medicine tests, and the need to provide coverage for them so that they can be made available to patients. With PRISM RA, and illustrated on the right-hand side of the slide, patients can avoid treatment they are unlikely to respond to and start the right therapy sooner, leading to improve outcomes. We respectfully request that WPS support PRISM RA's LCD for this innovative test. As such, I will now conclude our presentation.

Thank you.

Dr. Whites: Thank you very much and any of the new data that you have out there that you would like for us to consider, please include that into the WPS policy comment Mailbox, if you would. And any and all comments we need, any documentation that you would like to please be sure it is in the mailbox to us, I would appreciate it.

Dr. Dines: Thank you. Will do.

Dr. Whites: Okay. Thank you. Any other any other comments on this MolDX policy?

Richard Staley: Once again, please press the raise hand icon or *3 on your phone if you would like to make a comment.

There are no comments at this time.

Dr. Whites: Thank you very much. The next one listed is Sacroiliac Joint Injections and Procedures. This is a 37-page redo of an LCD and – please let it be known, I am not going to go over all 37 pages. Just those who are doing the procedure, there are several limitations; a lot of different items; there are six items that are listed that must be present to consider it reasonable and medical necessary. The diagnostic joint injection have five criteria listed in the policy. The therapeutic has four criteria that all must be met. There are limitations on the number of procedures, the sessions that can be done, it is all based on a rolling 12 month average. Also, there's a section on radio frequency ablation, it is considered investigational and therefore is not reasonable and necessary. by this policy. The scales that are to be used to measure pain and disability must be documented in the medical record. Again that is pre-procedure as well as post-procedure, and that needs to be to be sure that's included to us because we can't guess

on that when we ask for information. That must be in both Pre- and post-. The requirements there are non-criteria to meet the coverage requirements that are in there and it has to be from the technical aspect to the medical, reasonably and necessary. There are 11 listed limitations in the policy. And this 37-page document, say again, this is filled with specific criteria and limitations and this would encourage anyone who is planning on doing the procedure to be sure to look at all of these items because they're very important. And this was a multijurisdictional policy; it has had a lot of input, and I think that's the reason for all of the various criteria, they're trying to nail this down as much as we can to be sure that the patients get the procedure that they need by the right individuals, right amount of time, and that again, you have comments or anything on this policy, not only are we opening comments to you at this time, but if you're listening and have comments that you need to get in, they need to be in by the 12th of November, but we need everything in writing.

Rich, is there any – if you would – any comment on this policy now?

Richard Staley: Once again, press the raise hand icon, or *3 on your cell phone.

And I see no indications of anyone wanting to make a comment at this time.

Dr. Whites: Okay, thank you very much. The next to the last item is Prognostic and Predictive Molecular Classifier for Bladder Cancer. Know that the Contractor has made a policy change at least in their own way of doing things and is trying to get into more foundational policies. And which means that they'll have a test for bladder cancer and under that will have the various tests that are to be considered, instead of having a different policy, or a different LCD for each test. This is being added to the foundational policy for bladder cancer, and it is a coverage policy with a beneficiary for bladder cancer which has certain criteria that will be met. And all of those criteria are very specific. They are listed in the policy and if you are performing this test or ordering this test, be sure that you have read these criteria that needs to be met, the coverage criteria are very important. They're very sensible. And also, that the test has been shown that you're requesting predicts response to therapy and accepted therapy options, based on nationally recognized, societal consensus guidelines, such as NCCN, ASCO, AUA and the Society of Urological Oncology.

We'll now entertain any comments on this proposed draft LCD L38684.

Richard Staley: All right, once again, the raise hand icon or a *3 on your phone, if you would like to make a comment.

And there are no current comments on this LCD.

Dr. Whites: Okay, number five on the list – number six on the list, excuse me, I guess I didn't know – five on the list is the predictive test for drug testing, and this is a test that came about because of the Department of Justice and OIG findings of inconsistency among the MACs as far as their LCDs were concerned, there were different verbiage. there was more in some, less in others, some contained one, some did not contain the other and vice versa; It would go back and forth. So, a workgroup was reconvened and a multijurisdictional policy were derived based on a lot of hard work by members of this workgroup, trying to be sure that the necessary parts of each policy were continued, and the superfluous items were removed. Also, new data was in, and we have had a significant conversation with CMS, as well as the legal – DOJ, the Department of Justice office of general counsel. And, to make this a policy that seems to be, I think, one of the better ones that I've been associated with. It is, again, it is a revised collaborative process for consistency and clarity of coverage. It contains several definitions, which were not present both for the presumptive and definitive tests, the limitations, reasonable and necessary criteria, and one of the major items is that 14 classes of drugs and this is urine testing, so we're not talking about blood tests. There's 14 classes of drugs to be the maximum number of classes considered for definitive testing based it on several references that are listed in the policy. In this policy, we've maintained the three groups of patients that were defined in, I think, every one of the previous policies, including those who are on chronic opioid therapy, and those who have been on substance abuse and those in acute **e**mergency room situations where consciousness or bizarre behavior has been noted as a third criteria. The changes that have been made to this policy are consistent with other MACs and help resolve issues as noted with the OIG determination, potential overpayment for definitive testing. We're not restricting any testing that has been present previously, but we are grouping our classification into 14 classes **o**f drugs, and which would include all of their metabolites and related drugs and one item.

Can I entertain any comments on this policy, please?

Richard Staley: It appears we have a question from Amy Turner.

Dr. Whites: Ms. Turner, please go ahead.

Richard Staley: Okay, I've requested unmute for Miss Turner.

Amy Turner: You said this is a multijurisdictional policy?

Dr. Barry Whites: Yes, it is.

Amy Turner: Okay. And all of the MACs will be participating?

Dr. Barry Whites: Yes, ma'am.

Amy Turner: Okay. Awesome. Thank you.

Dr. Barry Whites: Quite welcome.

That brings us to the end of our proposed LCDs, and this last LCD was, our draft policy is 34645 the drug testing. I would again ask that all verbal comments please be entered as well as any documentation. We do not want to have you just put what a reference is, we need a full copy of that reference, if you have it. I don't need summaries, I don't need abstracts, I don't need posters. I need peer reviewed items to review. The last day, again, for submitting comments is 11/12/22. After that, there will be a response to these comments written in part of the enrich in the Medicare Coverage Database under each one of these proposed tests, and they will then go with another notice comment for 45 days after our comments or out. So once the final is done.

Overall, are there any other questions for me, or mention that are – it looks like we have Dr Denise Nachodsky on today, Dr. Robert Kettler, and I'm trying to see we have a – Joelle, are you on at all? I don't see you on the – and we have a new CMD helping with our innovation project, and was scheduled to be on the call, but I see her on the list. I think everyone is familiar with Dr. Nachodsky and Dr. Kettler.

Richard Staley: She is on the list. I apologize. I'm, uh, moving her up to panelists right now.

Dr. Vlahakis, you should be able to unmute yourself now.

Dr. Whites: Yeah, see, yes, if you'd give us a brief summary of your training and what you've been doing, that would certainly be helpful, I think, to all of us who trying to get to know you better.

*6, there you are.

Richard Staley: Dr. Vlahakis, I see that you are not on mute at this point. Um, so you may have an audio connection issue.

Dr. Whites: Try *6 and see if that'll get you connected.

Okay, well, maybe next time, but she is part of our new CMDs, Internal Medicine has done a Hospice, has significant exposure to governmental regulations and will be welcome. Yeah, I hear you.

Dr. Joelle Vlahakis: You do? I'm so sorry about that I'm hearing-technically challenged [inaudible]. I'm Dr. Joelle Vlahakis, [inaudible] Hospice [inaudible] hospice setting [inaudible] Innovations project here at WPS, and I'm really excited to work [inaudible] especially in the [inaudible], so thank you for having me.

Dr. Barry Whites: Thank you very much. I think we still have a bad connection, but appreciate your being here and listening.

Any other comments? The meeting before we adjourn?

Rich, any other housekeeping, we need to do?

Richard Staley: Uh, we do have a request that you state or spell Dr. Vlahakis' last name and confirm that she's a new CMD.

Dr. Barry Whites: Are you going to spell your name for them?

Richard Staley: Yes, I apologize. It's Dr. Joelle Vlahakis, V-A-L-A-H-A-K-I-S.

I apologize. V-L-A-H-A-K-I-S, Joelle, J-O-E-L-L-E. She is the new CMD, covering the MAC Innovative Challenges for depression screening and chronic care management.

Dr. Barry Whites: Anything else?

Okay, we will call this meeting to be adjourned, thank you very much for everybody's attention. Thank you.