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

Moderator: Dr. Jill Sumfest

June 14, 2023

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

Dr. Jill Sumfest: Today's date is June 14, 2023, and the time is 1:00 PM central time. This meeting is scheduled for 2 hours. My name is Dr. Jill Sumfest, and I am one of the Contractor Medical Directors with WPS, and I will be moderating the meeting. The purpose of today's meeting is to take comments from stakeholders on draft LCDs. Before we begin, I will ask my colleagues at WPS to introduce themselves starting with who are on the call. If you can unmute yourself and please introduce yourselves.

Dr. Robert Kettler: This is Dr. Bob Kettler, one of the CMDs with J5 as my primary responsibility.

Dr. Juan Schaening: Hi, this is Dr. Juan Schaening. I am one of the Contractor Medical Directors with Jurisdiction in J5 and J8.

Dr. Denise Nachodsky: Good afternoon, this is Denise Nachodsky, one of the CMDs for J5/J8 and ALJ CMD with WPS, and welcome everyone.

Dr. Joelle Vlahakis: This is Joelle Vlahakis, I'm a CMD with WPS, currently working on an Innovations Challenge.

Dr. Sumfest: Thank you. Will the policy coordinators please introduce themselves?

Melissa Lietz: This is Melissa Lietz, one of the policy coordinators.

Emily Zehner: Hello, this is Emily Zehner, one of the RN policy coordinators.

Michelle McCary: I'm Michelle McCary, I'm one of the policy coordinators.

Stephanie Richmond: I'm Stephanie Richmond, one of the policy coordinators.

Dr. Sumfest: Thank you all. And do we have any other personnel on the call?

Linda Oliver: Hi Dr. Sumfest, this is Linda Oliver, clinical director of medical review and policy.

Dr. Sumfest: Okay, is that it? Thank you.

So, let me take the next several minutes to review a few procedural matters. This meeting is being conducted in accordance with CMS IOM Publication 100-08, Chapter 13, Section 13.2.4.4. Our purpose is to take public comment on the draft LCDs. That's the only business for today's meeting.

The meeting is open to the public. It's being recorded and will be transcribed. Both the recording and the transcription will be posted and available on our website in a few weeks. All callers are currently muted.

I will introduce the draft LCD up for comment and then invite comments. There are two types of comments that we will be taking today; formal presentations that have been submitted and registered in advance and any public comment that we may receive. If you wish to comment, please click on the raised hand icon. If you are calling in by phone press *3. When Mr. Staley calls on you, please make sure that your microphone is on at your end and that your speakers are silenced to prevent an echo. Before you comment, please introduce yourself, state your affiliation and – excuse me – and indicate whether you have a conflict of interest and if so, what that conflict is. When you make your comments, please be specific so that we can help – so that you can help us to improve the draft LCDs. If a previous speaker has already made your point, there is really no need to repeat it. If you do wish to go on record, you can simply say that you agree with the previous speaker. Each speaker will be allotted 10 minutes to give equal time to all who wish to comment. Mr. Staley will provide a two-minute warning and will close the microphone at the 10-minute point. If a speaker has a slide presentation, one of our WPS team will advance the slides to avoid technical difficulties. If we are unable to address all the presentations within the 2 hours of the meeting, we will ask that the presenters submit their comments in writing.

Our purpose today is to listen.

We typically do not respond to questions or make comments during this meeting, but we may ask questions of any speaker. Please be aware that only comments or questions submitted in writing to Medicarepolicycomments@wpsic.com will receive a written response. Please include the topic of the LCD on the email subject line and please attach supporting scientific literature in either a PDF or Word document format to your email. WPS cannot follow email links. All responses are for educational purposes only and do not establish Medicare or WPS policy. Comments will not be addressed individually but will be compiled and addressed in a response to comments document posted with the final LCDs.

The open comment period for these draft LCDs is from June 1, 2023, to July 15, 2023. And with that, I will proceed. Mr. Staley, are we ready?

I'm going to assume –

Richard Staley: Yes, we are.

Dr. Sumfest: Okay. Wonderful. So, the draft LCDs up for comment are listed in the agenda and if we are unable to address all the presentations within the two hours of the meeting, again, we ask that presenters submit their comments in writing.

The first draft LCD on the agenda is DL38682: Transurethral Waterjet Ablation of the Prostate. This is a reconsideration of an existing LCD. The lead CMD is Dr. Robert Kettler and the policy coordinator is Michelle McCary. Transurethral Waterjet Ablation of the Prostate is a minimally invasive alternative to transurethral resection of the prostate and open simple prostatectomy for treatment of benign prostatic hyperplasia. The changes are in Coverage Indications, Limitations and/or Medical Necessity and reflect eliminating the age limitation for individuals over 80 years of age. Are there any comments?

Richard Staley: If you do have a comment, again, raise hand icon or press the *3 on your phone.

There are no comments for this draft.

Dr. Sumfest: Thank you, Richard. The next draft on the agenda is DL34645: Urine Drug Testing. This is a reconsideration of an existing LCD. The lead CMD is Dr. Robert Kettler and the policy coordinator is Stephanie Richmond. This policy details the appropriate and allowed number of urine drug tests billed over time for safe medication management of prescribed substances in risk-stratified pain management patients and/or in identifying and treating substance use disorders. It designates documentation by the – excuse me – the clinician caring for the beneficiary in the beneficiary's medical record, of medical necessity for and testing ordered on an individual patient basis, and it provides an overview of presumptive urine drug testing and definitive urine drug testing by various methodologies. The changes are in CMS National Coverage Policy, Coverage Indications, Limitations and or Medical Necessity and Sources of Information, and Basis for Decision and are being made as part of a collaborative process for consistency and clarity of coverage across all MAC jurisdictions.

Are there any comments?

Richard Staley: There are no comments on this draft.

Dr. Sumfest: Thank you, Mr. Staley. So, let's go to the next draft LCD on the agenda, which is DL 39624: Amniotic and Placental-Derived Product Injections and/or Applications for Muscular Skeletal Indications, Non-Wound. The lead CMD is Dr. Robert Kettler, and the policy coordination coordinator is Melissa Lietz. This policy addresses amniotic membrane, amniotic fluid, or other placental-derived product injections and/or applications as a means of managing Musculo-skeletal injuries, joint conditions, and other conditions. This policy does not include discussion on burns, wounds, or ophthalmic conditions.

Are there any comments?

Richard Staley: There are no comments on this draft LCD.

Dr. Sumfest: Thank you, Mr. Staley. So, let's go to the next draft LCD on the agenda, which is DL 39614, MolDX: Molecular Biomarker Testing for Risk Stratification of Cutaneous Squamous Cell Carcinoma. The lead CMD is Dr. Denise Nachodsky, and the policy coordinator is Emily Zehner. This LCD outlines non-coverage for DecisionDX®-SCC, with specific details under Coverage Indications, Limitations and/or Medical Necessity. DecisionDX®-SCC looks at changes in gene expression of 34 metastasis associated genes and six control genes to identify patients with high risk of metastasis of squamous cell carcinomas of the skin.

We have 3 presenters who registered. The first presenter is Dr. Brent Moody. Is Dr. Moody on the call?

Dr. Brent Moody: I am here. Can you hear me?

Dr. Sumfest: Yes, we can.

Dr. Moody: Okay, yes, I'm here.

Dr. Sumfest: Melissa, do you have Dr. Moody’s slides?

And please, Dr. Moody, tell us your affiliation and if there's any conflict of interest.

Dr. Moody: Sure. My name is Dr. Brent Moody. I practice in Nashville, Tennessee; the Skin Cancer Surgery Center, part of a multidisciplinary skin cancer team and I'm not an employee or shareholder of the company in question. I have served them as a speaker in the past. I'm not being compensated for my time today.

Dr. Sumfest: Okay, thank you. Since Melissa is running your slides, please let her know when to switch to the next one.

Dr. Moody: Okay, well, I think I've already introduced myself, so we can go to the next slide. Please.

So, I just wanted to give some of my perspective as a clinician who treats this disease frequently, some of the challenges I face when encountering cutaneous squamous cell carcinoma. The first problem is that our current staging systems have poor positive predictive value and that many people are put into a high-risk category when, in fact, the vast majority of those people will not experience a poor outcome. They will not have a metastasis. So, we tend to over-stage people.

A second problem with the current staging is they're binary. They're not continuous variables. You either have the factor or you do not. What do I mean by that? Good example would be PNI; perineural invasion. The threshold for actionability in the NCCN guidelines is a nerve size of 0.1 millimeters and so a nerve of 0.09 is treated as the same as a nerve of 0.01, or no perineural invasion at all when looking at AJCC and Brigham Women's Hospital Staging System. So, we have this issue of non-linear variables that we are considering. The second problem is that all the variables are treated the same; all factors weighted equally in the staging systems when some are indeed more important than others. Also, a lot of times we have incomplete clinical pathologic reports. We don't have all the information we need at times. Some clinicians use these formal staging systems, but a lot of people just do the factor-based approach. So, I think, one thing that I use this test is to help me better risk stratify my patients. Next slide.

And this is the NCCN staging system, another one that I use. It just highlights that, again, we just are looking at factors. You're just picking the factors. But again, many times they're bimodal, yes or no, rather than a continuous variable. Next slide

And looking at NCCN guidelines for a high-risk cutaneous squamous cell carcinoma, I, as a clinician am given a lot of options in to how frequently I see that patient. What's my total assessment? Is it just clinical? Should I image these patients? Should I do a sentinel node biopsy? So, what am I going to do? And then, adjuvant therapy, it ranges from nothing just surgery and be done all the way to adjuvant radiation, adjuvant chemotherapy or adjuvant immunotherapy. So, you look at these guidelines and they give you this broad swath of options, and they can sometimes be hard to apply without better risk stratification. Next slide please.

I think a key decision that we have to make is after surgery, and this is still primarily a surgical disease, is should this patient have radiotherapy? And that's where that 0.1 perineural invasion cut-off comes into play. 0.1 is the general threshold for that. But again, there's lots of factors we consider and even if you have all these factors, it just says “Consider.” You know, we're not giving very explicit guidelines.

Let's go to the next slide, please. And this is a real patient for my practice. It was an 80-year-old gentleman with a cutaneous squamous carcinoma on the scalp. The tumor extended beyond the subcutaneous fat. I had to go down to bone to get clear surgical margins and he had perineural invasion and the nerve measured 0.11, which again, is that sort of actionable threshold. So, looking at the pathway for this patient per NCCN guidelines, surgical removal was

done, and I am part of a multidisciplinary team where we discussed these patients. And one thing would be considering adjuvant radiation therapy and then what are we going to do with the nodes in this patient, as well? So again, high risk patient, but again, very broad guidelines as to what to do; everything from nodal palpations to Sentinel Lymph Node biopsy could be considered. Next slide please.

So, this is where I do employ the test in question, because it allows me to further risk-stratify a patient, even within a traditional staging category, whether it's Brigham Women's T2B, or AJCC T3, or NCCN very high risk. I can further subdivide my patient's risk using the biomarker in question. Next slide.

You can see what that does to their risk of metastasis based on again, traditional risk factors. And then adding in this test is a complementary task. You can see it -the GEP result adjusts their likelihood of metastasis. Next slide.

So back to my patient, so he had those risk factors, which traditionally we would consider adjuvant radiation therapy. However, there were some social factors here; the patient was elderly, had transportation difficulties and his daughter who came with him, simply explained that having 20, 30 radiation treatments would be, while not impossible, would be very difficult for him. So I checked this test, the DecisionDX® Squamous Cell Carcinoma. He came back a favorable Class One result. So, based on that objective piece of data, I discussed it with the patient and the family and in a shared decision-making capacity, we decided to de-escalate care, and we avoided imaging and adjuvant radiation therapy. And I've been following him now for 15 months, and so far, so good. Let's hope that continues. But they were very happy with this idea that we can de-escalate their care and the GEP result gave me an objective piece of data to help me guide those patients – the patient – in their decision making. Next slide.

And I'm not the only one using this to help risk-stratify and alter patient care decisions. There are publications to this effect as well, that a class one or a favorable result generally can lead to a de-intensification of care. Whereas a high-risk result leads to the need for more advanced care and that would be radiation or imaging, or even sentinel lymph node biopsy at times. Next slide.

And looking at this, some other studies, you – really – one in four instances where the test was employed, management changed. That's the top figure there. And in fact, 85% of the time, the management either changed or validated the current thinking. So, it was valuable to that extent. And also in the same study, another data point that came out that when clinicians such as myself are deciding which factors drive our clinical decision making the GEP data was nearly as important as tumor size and more important than other risk factors as well. So, it's become, for those of us who use this test, a really important risk factor that we consider. Next slide.

So, we're comparing the test in question, the 40 GEP test, and management changes, as we said, one in four times it’s going to lead to a management change. And this is consistent with other currently approved GEP tests as far as ability to influence management. So, I think this is similar to currently approved and currently actionable tests. Next slide.

And this is my final slide. I just want to emphasize that this really allows me, as a clinician, to use my traditional staging factors that I've used for years; to use it in addition to, not instead of. So, it's complimentary. It augments it, amplifies what I'm able to do. I'm comfortable using this. It's been well validated in over 1000 patients. Clinical utility studies have shown that people are

using it the way I do; to escalate or de-escalate care. And the bottom line is without this objective tool, if I get a patient that my traditional staging says is high risk, regardless of what staging system use my -

Richard Staley: [Inaudible]

Dr. Moody: I'm sorry. I didn't hear that.

Richard Staley: I said, I'm sorry I said two minutes remaining.

Dr. Moody: Oh, thank you. Thank you, Richard. My hand is really forced. I'm kind of forced to do things when, with, with an objective piece of data this is okay, this is a lower risk situation. I can many times safely de-escalate that care when it's clinically appropriate to do. So, I would hope this test will be something that stays available for these cutaneous squamous cell carcinoma patients. And that's my last slide and sort of all I wanted to say today.

Dr. Sumfest: Thank you. Dr Moody. Are there any questions from the CMDs at WPS?

Dr. Schaening: I have no questions. Thank you for your presentation. [inaudible].

Dr. Moody: You're very welcome.

Dr. Nachodsky: I, too, thank you very much for your very detailed and thorough presentation. We will take this, you know, this is part of the MolDX program and so this information will be shared with the team members and MACs in the MolDX program. Once again, thank you.

Dr. Moody: Okay, well I'm going to go back on mute.

Dr. Sumfest: Thanks again. So, the – our next presenter is Dr Ally-Khan Somani. Dr. Somani, are you on the call? and I think you're unmuted so - We need you, just again, to state your affiliation and if you have any conflicts of interest.

Richard Staley: I show that doctor Somani is on the call and his line is unmute. However, we are not able to hear you at this time, Dr. Somani.

Dr. Sumfest: Okay, he's back on mute. Rich, do you want to work with him? Or Dr. Somani, and then –

Richard Staley: Yes, and we can move on to the next presentation.

Dr. Sumfest: Perfect. The next presentation is Dr. Matthew Goldberg. Is Dr. Goldberg on the line? I see him. Okay.

Richard Staley: I've just promoted him to a panelist. You can unmute yourself.

Dr. Matthew Goldberg: Hello, can you all hear me here on the line?

Dr. Sumfest: Yes, we can.

Dr. Goldberg: Okay, great. So, at the outset, you'd like me to state my affiliation and conflict of interest?

Dr. Sumfest: Yes.

Dr. Goldberg: Is that Dr. Somani?

Dr. Ally-Khan Somani: You guys want me to go on? I'm back on.

Dr. Sumfest: Rich, what would you like to do? Have Dr. Somani proceed or have him wait?

Richard Staley: We will allow Dr. Goldberg since his presentation is up, and Dr. Somani, I apologize, but you will go after Dr. Goldberg.

Dr. Somani: Okay, Sorry about that, thank you.

Dr. Sumfest: No problem. Thank you.

Richard Staley: You're welcome.

Dr. Goldberg: All right, so before I begin here, Richard, my name is Dr. Matthew Goldberg. I'm the senior vice president of medical here at Castle Biosciences, where I'm an employee and stockholder for relevant disclosures. Is that – can I begin the presentation here?

Dr. Sumfest: Yes, please go ahead and just remember to let Melissa know when you want a slide advanced.

Dr. Goldberg: Okay. Thank you.

All right, well, first off, thank you for the opportunity to speak at this public meeting. My comments here this afternoon on behalf of Castle Biosciences, support our assertion that DecisionDX® – SCC has met the criteria of medical reasonableness and necessity for Medicare coverage, and should be included as a covered test in the draft LCD DL39614. Next slide please.

The DecisionDX® – SCC test addresses limitations of risk stratification approaches that are currently used by skin cancer experts and help physicians navigate the wide range of management options that are available to all patients with high-risk SCC. Risk stratification approaches that are reliant on the presence or absence of clinical or pathological risk factors alone misclassify a significant number of patients with squamous cell carcinoma. And at least 30% of patients who go on to experience a regional and distant metastasis or are low stage at initial diagnosis. And not all patients who present initially with high stage disease will actually go on to experience poor outcomes. And DecisionDX® – SCC is a clinically validated solution to these well-known limitations. Next slide please.

The draft LCD contains statements that reflect an incomplete understanding for how high-risk squamous cell carcinomas are managed today by skin cancer experts. At a high level, the LCD contains multiple inaccuracies that invalidate the conclusions of the draft policy. And these include misconceptions that high-risk squamous cell carcinomas are treated slowly in an academic center, and misses the fact that patients are also treated in community practice across the US where methods of risk stratification and risk assessment vary widely from practice to practice due to their limited accuracy. And it's critically important to note that the test should be used with available staging and risk assessment systems and does not seek to replace these systems as suggested in the LCD. The LCD also demonstrates misunderstanding of adjuvant radiation therapy, or ART, which is indicated for patients who have a high risk of metastasis with a demonstrated improvement in their health outcomes. What's more, ART is currently recommended and considered for a broad range of high-risk SCC tumors, all of which are currently covered by Medicare. The problem is that skin cancer experts don't know based on clinical and pathologic factors alone, which patients have the highest risk of metastasis and will therefore benefit the most from ART. So, this presentation will focus on the perspective of

clinicians treating patients with squamous cell carcinoma today and with a focus on, again, a specific management decision that's informed by DecisionDX® – SCC test results and it has a demonstrated improvement in health outcomes when provided the patients with the high risk of metastasis. Next slide, please.

We'll, of course, submit formal comments that address the MolDX request for additional clinical validity data during the open comment period. These do not impact the conclusion that the test is medically reasonable and necessary, and I won't be discussing these in this brief presentation. Please move two slides ahead, if you will.

In an independent validation study within a group of 420 patients with squamous cell carcinoma and one or more risk factors, the DecisionDX® – SCC test identified three discrete risk groups. The Class 1, Class 2A and Class 2B. And what's consistent across validation analysis, and here, is that Class 1 results are associated with half the risk of metastasis as the overall cohort and the Class 2B results associated with nearly three times the risk of the overall cohort. Next slide, please.

A multivariate analysis demonstrates the ability - the statistical independence of the Class 2A and Class 2B results from risk factors that are incorporated into staging. DecisionDX® – SCC, in this way, adds prognostic information that's not obtainable from risk factors or staging, and can be added to other known risk factors for a more complete assessment of a patient's metastatic risk. Next slide.

Continuing that thought, this data shows how DecisionDX® - SCC stratifies risk within the NCCN High Risk and Very High-Risk patients. This is from a cohort of over 900 – of 954 patients, and it adds information to current NCCN risk assessment. Next slide, please

In multivariate analysis with all other staging systems that are currently used in the US, the DecisionDX® -SCC test provides independent prognostic information. And here are the Class 2A and 2B results are statistically independent of the metastatic risk described in each of these stratification approaches. The search – the assertion in the draft LCD that it is unclear how the test adds value to clinical and pathological information is simply unfounded in the face of this clinical validation data. Next slide, please.

To unpack a bit more how the test adds information to current risk stratification, this table provides accuracy metrics. When DecisionDX® – SCC is used in the context of the BWH staging system. Here, the test significantly improves the accuracy and addresses current limitations. For example, all low stage patients are not truly at low risk. The lowest risk Class 1 patients, within the T1, T2A tumors have an improved negative predictive value and all patients who are identified by Class 2 result, Class 2B result, are missed by staging. On the other hand, all high stage patients do not benefit from higher intensity management and the positive predictive value of the Class 2 result is excellent within the Brigham Women's C2B Tumors. Next slide, please.

To emphasize this point further, incorporating DecisionDX® – SCC results with BWH staging allows stratification within stages as seen in this arrow chart on the left and the test enhances but doesn't replace the staging approach. When adjuvant radiation – when we focus on adjuvant radiation therapy decisions specifically you can see in the bar graph on the right that management changes are not made in a vacuum as the LCD suggests, but in the context of

clinical and pathological risk factors that are in each of these real-world cases from this validation – from this utility study. Next slide, please.

On a high level, adjuvant radiation therapy is considered as a therapeutic option for all patients within our intended use population and is covered by Medicare beneficiary – and is covered by Medicare when it's provided to those patients. This is a costly and potentially morbid treatment, and there is no – there is really a need to better identify patients that are most likely to benefit from adjuvant radiation therapy that balances the risk benefit ratio for each patient. Next slide, please.

One study that's not referenced in the LCD literature demonstrates that ART is associated with a 50% reduction of poor outcomes in patients with a high risk of regional and distant metastasis. In this cohort of patients with high-risk SCC, there's a benefit seen in ART provided to the entire cohort on the left graph and all these patients are considered for ART today. And importantly, the greatest benefit from ART is seen in the highest risk tumors in the center graph. And, in fact, these higher-risk tumors actually fall outside of our proposed intended use for the DecisionDX® – SCC test. However, on the figure on the right, which includes patients within our intended use population, the benefit from ART is more modest: 5% improvement in metastatic rate. However, the DecisionDX® – SCC test result is an independent risk classifier, which can accurately risk-stratify patients within similarly high-risk cohorts such has been shown in multiple validation studies and therefore, can accurately identify the patients who have the highest risk of metastasis within this group and who will benefit from adjuvant radiation therapy. Next slide, please.

In this next slide, the combination of Brigham and Women's Staging and DecisionDX® – SCC test results impacts the predicted metastatic risk and crosses thresholds for clinical accessibility. Using staging alone, only T2B tumors cross the threshold for adjuvant radiation therapy. And here, specifically, when you add gene expression profiling, you can identify patients with a Class 1 result who fall below the threshold and patients with the Class 2B result who rise above the threshold across all tumor stages. Next slide, please.

And this is also true for an approach that counts NCCN risk factors. Next slide.

So, we looked next at a combination cohort of 954 patients, a combined cohort with a matched control analysis to evaluate the test's ability to identify patients who will benefit from adjuvant radiation therapy. Well, all of these patients are eligible for consideration of ART based on –

Richard Staley: Two minutes.

Dr. Goldberg: Thank you. The DecisionDX® – SCC test is able to find the group of patients who will significantly benefit. When you look at the Class 2B graph on the right, adjuvant radiation therapy is associated with a marked improvement in survival, as seen by the blue curve on the bottom right. And this aligns with published literature that adjuvant radiation therapy benefits patients most when they have an elevated risk of regional and distant metastasis. Notably, there's a steep rise in the red curve of metastatic events in the Class 2B cohort, corresponding to the rapid rate of metastasis in these patients not treated with ART. And

this highlights the urgency to act in the Class 2B result, where most metastatic events are seen within the first two years. Next slide.

It's important to emphasize that skin cancer experts ordering DecisionDX® – SCC are appropriately using the test for the intended use population. Most clinically tested patients have an average of 2.7 risk factors with a predominance of T1 to T2B tumors by staging, and clinicians are ordering this test in patients where they can make risk aligned management decisions after surgery, including whether or not to recommend adjuvant radiation therapy, or consider it. Next slide. Please

For prognostic tests, clinical utility is demonstrated by improvement in risk stratification that informs proven treatment modalities, and DecisionDX® – SCC has met this of evidence. Next slide, please.

So, in some, the draft LCD should take into consideration how high-risk squamous cell carcinomas are currently managed in the US today and clinicians treating SEC tumors are skin cancer experts, adept at incorporating multiple clinical, pathological, and genetic risk factors to inform risk on treatment plans. They've demonstrated both in practice and clinical utility studies that test results are being used appropriately with staging information to make individual patient management decisions.

DecisionDX® – SCC can be used to guide adjuvant radiation therapy decisions that have a proven impact on health outcomes for patients with a high risk of regional and distant metastasis identified by the test. And therefore, improvement in the accuracy of risk stratification for patients with squamous cell carcinoma has an inherent improvement in patient outcomes as this direct those with a high risk of metastasis to a therapy known to improve outcomes. And finally, the broad clinical adoption of DecisionDX® – SCC stands in stark contrast to the analysis of evidence in the draft LCD. Over 3600 clinicians, experienced in treating patients with high-risk SCC, have determined to test to be medically reasonable and necessary for Medicare. Beneficiaries –

Richard Staley: 10-minute mark.

Dr. Goldberg: Yep, I have my last sentence here if that's okay, Richard.

And we urge MolDX to reconsider the rationale for determination and finalize the LCD with coverage of DecisionDX® – SCC, as clinicians are using this test to inform their management decisions in a risk aligned manner.

I thank you for your time and apologies for going slightly over.

I can't hear any sound here. If there's any questions, I lost the sound feed for a moment.

Dr. Sumfest: I forgot to go off mute. Do any of the CMDs have questions for Dr Goldberg?

Dr. Schaening: I have no question Thank you.

Dr. Nachodsky: No questions at this time. Thank you.

Dr. Goldberg: Thank you very much.

Dr. Sumfest: Thanks again, Dr Goldberg, for your comments, for your presentation. So, let's move forward with Dr Somani. If you can let us know your affiliation and if you have any conflicts of interest.

Dr. Somani: Thank you. So, thank you for your time today. My only conflict of interest is that my institution has carried out validation and prospective studies for Castle, where I have been the PI, and also on an ad hoc basis, I have been a speaker for them. Furthermore, I'm not being compensated today for my time and I'm here to give my clinical perspective on the gene expression profile test that helps me better manage my patients. My affiliation is that I'm the Director of Dermatological Surgery and Cutaneous Oncology. I'm also an Assistant Professor of the Department of Dermatology and an Adjunct Assistant Professor of Otolaryngology-Head and Neck Surgery. And I also am a fellowship director for the Mohs micro-graphic surgery in the country. One of them. So, in that regard, I have the privilege of training future dermatologists and Mohs surgeons, and it is definitely important imperative that we utilize evidence-based medicine and provide the best care possible to our patients.

I believe that the decision gets should be a covered test under Medicare and I disagree with the conclusions of the current draft LCD. The big picture for my presentation this afternoon is that I believe that my patient should have access to the test. Because when my colleagues and I encounter patients with a potentially dangerous skin cancer, I hope you will appreciate how DecisionDX® – SCC helps us better manage patients. Next slide please.

So, as a brief background, I use risk stratification systems in my practice that are based on clinical and pathological factors, as was earlier mentioned. And this means that I take stock of the risk factors that every patient has, engage my patient's risks for, risk of poor outcomes based on the presence, or absence of these factors. But there are well known limitations to the accuracy of these systems that result in a significant number, 35% of patients being under staged, and 75% being over staged, respectively, as seen here in this table. So, in the right clinical context, I can reasonably justify adjuvant radiation therapy, or ART for short, for a patient with a lower stage tumor by questioning the need to aggressively manage every patient who presents with the higher stage tumor. Even though I use a factor-based risk stratification of AJCC and BWH staging, I must consider the full broad range of management decisions for each patient individually. Next slide please.

Here are two cases from my published case series. These cases clearly demonstrate the limitations of our current staging systems and the types of management decisions we offer to patients with high-risk SCC. Both of my patients had poorly differentiated SCC tumors on their left temple, and both are immunosuppressed transplant recipients. Our staging considers these

patients to have low risk tumors. This simple fact illustrates a limitation of staging because in my professional estimation, I did not think that these tumors are both low risk. And I was most concerned clinically with a gentleman on the left side of the screen. In fact, this patient was presented at our multidisciplinary tumor board and was formally offered radiation therapy by our treatment team, which the patient declined himself. Interestingly, the patient on the right side of the screen underwent a technically straightforward Mohs surgery. And my post-Mohs treatment plan did not include adjuvant radiation therapy or multidisciplinary tumor board referral. In practice, these two Medicare patients were nearly identical on paper. I could have considered adjuvant radiation therapy in both patients. And in fact, I only offered ART to the patient on the left. Most surgeons, like myself, are looking for independent risk stratification to inform specific decision in patients just like these ones. Next slide, please.

I won't belabor this to fix the statistics on this next several slides but suffice it to say that the 40-GEP test has been clinically validated in large cohorts of patients with high-risk SCC and is statistically independent of the approaches that we used to risk stratify or stage our patients. Whether you use NCCN risk groups or BWH, or AJCC H staging, the 40-GEP test results adds independent prognostic value to what we currently use. Next slide.

As a Mohs surgeon, I'm particularly interested in the outcome of patients treated with this effective surgical approach. And the independence of the 40-GEP results from staging system continues in this subset of patients who were all treated with Mohs surgery. The statistical independence seen in this cohort highlights the use of the 40-GEP to improve the care of our patients who will be treated with Mohs surgery by enhancing the accuracy and precision of our prognostic assessments. Next slide, please.

So, it's critical to understand how conditions integrate results from the GEP test with the staging risk information that we already have for our patients. This slide shows that our current approaches to risk stratify patients, whether it be BWH, AJCC or NCCN, as shown in this graph here, using either an academic setting like my own, or in the community, provides important risk stratification seen with positive hazard ratio in each column as shown by the gray bars. But when I layer the accuracy of the 40-GEP in the context of the known risk factors or staging of the tumor, which provides me a more comprehensive, individualized risk assessment. By integrating the clinical pathologic and the GEP results, I can improve the accuracy of my risk assessment as you can appreciate here in the blue and red bars in each column. Next slide please.

So, this slide looks at the data from another perspective, and using likelihood ratios, confirms that including 40 gene expression profile tests in metastatic risk prediction, significantly improves the prognostic accuracy of the AJCC 8 and BWH staging systems. This data is important because my colleagues and I never use the test result in isolation. But rather in the context of the risk factors, or clinical stage of the patient's tumor. So, when risk stratification from clinical and pathological factors used together with the test results from the GEP test, this significantly refines the metastatic risk prediction that we can offer to our patients and better informed our management decisions. Next slide, please.

So, that brings me back to my two patients who, again, are both considered low stage by AJCC and BWH. However, the GEP test results in clinical outcomes for risk align, but the staging results were divergent for these patients. And the patient on the left returned a Class 1 result and the patient on the right returned a Class 2 result as shown on this table, who ended up

getting a recurrence in the metastasis. In my practice edition of this independent risk information, informs specific management changes. And I would have considered recommending ART to the patient on the right, and I would not have recommended radiation to the patient that I was worried about on the left. This test has allowed me to appropriately refer my patients for not only ART, but also for nodal imaging and multidisciplinary chair. Next slide please.

So, like my cases, when my colleagues have seen similar patients, such as the third real world case from the study highlighted on this slide, the Class 2B results will lead to an overall increasing management intensity is shown on the first graph on the bottom left. And specifically, an increase in consideration as shown on the second graph adjacent to the first. This corroborates the approach to risk stratification that I just discussed in my own patients and can be found in the published clinical utility study from Hooper and colleagues, and I believe Dr. Moody also presented this paper. Next slide.

So, I want to conclude with one last clinical challenge that Mohs surgeons face in another area with the validity and utility of the 40-GEP test stands out in my practice. Most surgeons, like myself, worry that we're missing patients with low stage disease who actually have a significant risk of metastasis. Anywhere from 30% to 50% of the eventual metastatic events will come from patients who initially staged as low risk. I have been involved with this research and what we have found is that the 40-GEP was able to significantly risk stratify our patients with those stage tumors and importantly, identify the subset within this core that carries significant risk of metastasis. Next slide.

Richard Staley: Two-minute mark.

Dr. Somani: Thank you. This pie chart here drives this point home because again, 100% of these patients are classified as having low-risk tumors by either AJCC 8 or BWH, and yet there are significant number of metastatic events. The Class 2 results identify 67% to 70% of the metastatic events in the score. As shown in the red slices. This is where the clinical validity data leads to clinical utility in my practice. You know, I hope you can appreciate where the GEP test results help us identify patients who have lower risk by staging, who have significantly higher risk of metastasis after integrating the GEP test result. And I think I'm on my last slide now, please.

So, in summary, I think that the known limitations of staging and the two cases I presented, underscore the need to improve the accuracy of our risk stratification for patients with high-risk SCC. Limiting access to this test by failing to cover it in the LCD will have a substantial negative impact under care of Medicare beneficiaries, and I strongly urge you to consider a reversal of this draft policy. Being at a very large academic tertiary center, I take care of many of these patients who are even transplant patients is we're one of the big centers and this test has afforded us a really great way to risk stratify them. The 40-GEP is the only test that helps accurately identify cases that are deemed low risk by staging and has been validated in multiple cohorts, including cohorts treated with Mohs surgery. The test and informed risk align decisions, such as adjuvant radiation therapy, as in the two cases I discussed today and the treating clinicians ordering this test, like myself, are skin cancer experts. And we can integrate in a

meaningful way, the GEP test results into our existing risk assessment to help make better informed decisions for our patients. So, in that, I'm going to conclude. Thank you for your time.

Dr. Sumfest: Thank you very much. Rich, do we have any – or are there any comments from the CMDs on the line?

Dr. Schaening: No comments, thank, you.

Dr. Nachodsky: No comments and thank you for your presentation.

Dr. Sumfest: Yeah, thank you very much. And to the three presenters, I just want to remind you that these presentations will be shared with the MolDX program and any written comments from them will be incorporated in our responses. So, again, thank you for your time and your interest in this LCD.

We'll move on to the last LCD – draft LCD on the agenda, which is DL39620, Micro-Invasive Glaucoma Surgery otherwise abbreviated as MIGS. I am the lead CMD and the policy coordinator is Stephanie Richmond. This LCD addresses a group of new surgical procedures for glaucoma referred to as Micro-invasive Glaucoma Surgery. A multijurisdictional contractor advisory committee meeting was held on January fifth of this year, hosted by Palmetto, CGS NGS, and Noridian, and to discuss the evidence for the development of this policies. Transcripts are available on the Palmetto website. The LCD outlines limited coverage for this service with specific details under Coverage Indications, Limitations and/or Medical Necessity.

We have six presentations, and we'll start off with Dr. Raymond Kong – excuse me – Mr. Raymond Kong, with New World Medical. I'm assuming he's on the line. I see his name and it looks like Rich unmuted you. Mr. Kong, please state your affiliation and any conflicts of interest.

Raymond Kong: Yes, Hi. First, I'd like to thank you, Dr. Sumfest, and the other WPS medical directors, CAC members and staff for the opportunity to present today. I do appreciate the number of requests that you must get, and I do not take this opportunity and responsibility to represent ophthalmology lightly. My name is Raymond Kong, I'm the chief commercial officer for New World Medical. New World Medical is a glaucoma surgical device manufacturer based in Southern California. One of our flagship products, the Kahook Dual Blade®, is used in the procedures we're discussing today. So, in the spirit of conflict-of-interest disclosures, I am employed and representing that company. Today, I would like to share our perspective on the proposed MIGS Draft LCD. I know that there are other presenters who will focus more broadly on all other procedures, so my presentation and comments will focus solely on the goniotomy procedure and specifically excisional goniotomy with the Kahook Dual Blade®. Next slide, please.

In the interest of time, I'm sure that we all have a very healthy understanding of the disease and the mechanism of the structures of the eye. So, I'm going to propose to skip this slide and move to the next slide, please.

Before getting into the key points, I thought it was important to share with you a quick overview of the product that will be referenced in most of the clinical data being presented; that being the Kahook Dual Blade®. We have seen significant advances in techniques and technologies in the space over the last 10 years, and the KDB is one of those. The KDB is designed to perform a complete excision of the diseased trabecular meshwork, provide an access from the anterior chamber to the canal and distal collector channels. This is unlike goniotomies described using an MVR blade or other unsophisticated instruments like bent needles used in some of the studies referenced in this proposed LCD. The studies and results referenced in my presentation will all be consistent with true excisional goniotomy. Next slide please.

To begin with my first point, the draft LCD cited incomplete evidence for goniotomy, which in my opinion, is neither experimental nor investigational. Goniotomy has been performed to treat glaucoma patients for over 80 years and the procedure safety and efficacy has been exhaustively documented as evidenced by over 90 peer-reviewed publications on goniotomy alone, including Level 1 randomized clinical trial data. The draft LCD being discussed sites only a sliver of the clinical evidence related to goniotomy that is currently available. The citations include a listing of multiple studies with different goniotomy procedures and/or devices, and this listing shows, both the comingling of different procedures and devices as well as the age of the references which certainly impacted the conclusions drawn. The age of these references are of particular importance, considering the KDB device was launched in 2015 and the body of evidence continues to grow even as we speak today. The LCD also refers to a lack of RCTs, which I will address in the next slide. Next slide, please.

I'd like to point the audience to the existence of a prospective, multicenter randomized controlled trial comparing goniotomy with the KDB and eye stent implantation at the time of cataract surgery in mild to moderate glaucoma patients. I'd like to pause for a minute here to emphasize the point that the comparator in the study, trabecular meshwork stent implantation, is covered in – is supposed to be covered under the NPS proposed LCD. Results of this level on study were published in the Journal of Cataract and Refractive Surgery, one of the most prestigious journals in Ophthalmology, and the study included 82 open angle glaucoma eyes in each arm or 164 in total and procedures were performed across nine clinical practices. The study success definition was Intraocular pressure reduction greater than 20% – greater than or equal to 20% – or medication reduction greater than or equal to one. Next slide, please.

You can see the results from this study in this slide. The investigators found that at 12 months, 93.7% of the eyes in which goniotomy with KDB were performed met the success criteria, versus only 83% in the eye stent arm. This difference in outcomes was statistically significant. There are also a number – as mentioned earlier – a number of peer reviewed prospective – retrospective studies or publications that confirm these conclusions in the real world. Next slide, please.

The next four slides are a listing of all available data on excisional goniotomy which I previously noted. And as of today, over 90 published peer reviewed studies have been found on excisional goniotomy alone. Let's go ahead and skip to slide 11, please. Next slide, please.

Right there, thank you. Moving on to my next point, goniotomy is a well-accepted procedure among ophthalmic surgeons in treating adult patients. What you're looking at here is an industry report conducted by market scope, a well-recognized market research group in ophthalmology. What you can see here is that non-implant procedures, such as goniotomy and canaloplasty continue to gain popularity, providing significant benefits to more patients. In Q1 2023, the total MIGS procedures were split almost evenly between implants, which includes iStents and Hydrus, and non-implants, which include procedures like goniotomy and canaloplasty and 55% to 45% showing a significant surgeon adoption and acceptance. I would argue that an investigational procedure would not have this level of adoption from well- respected surgeons who've all taken an oath to do what's only in the best interest of patients. Next slide, please.

In addition to the real-world acceptance data shown on the previous slide, at a society level, goniotomy has also receive broad based support. The world glaucoma associations 11th consensus report on glaucoma surgery recognizes goniotomy with the KDB as an acceptable procedure and states: "KDB can be used as a standalone or combined with cataract surgery in early, moderate or severe open- or closed-angle glaucoma to reduce IOP, hypotensive medication burden, or both." You can also see that goniotomy is also well accepted by the American Academy of Ophthalmology. And finally, I'd like to point out that in the Palmetto multi-jurisdictional CAC meeting that was mentioned earlier, convened in January and referenced in this LCD, the members were very clear about the need for not only goniotomy, but multiple options to be able to treat this terrible disease. And you can see some of those comments here.

Richard Staley: Two-minute mark.

Raymond Kong: Next slide, please.

My final comment is related to financial considerations. And while I realize that this is not the primary focus, there are implications of a non-coverage decision for CMS and more importantly, Medicare beneficiaries. A non-coverage decision for goniotomy and canaloplasty would force surgeons to substitute trabecular meshwork stent implantations for these procedures, which require leaving a foreign body in the eye. While the procedures may go away due to non-coverage, the patients will not. These substitute stents have a markedly higher facility fee in an ambulatory surgical center setting, where the majority of ophthalmic procedures are performed. By forcing care in this direction, a non-covered decision would increase Medicare costs and more importantly, the financial burden born by the beneficiaries in the form of copays. Next slide, please.

Dr. Sumfest: Mr. Kong, I think that was your last slide?

Melissa Lietz: Yes, it was.

Raymond Kong: All right. Yeah, the last slide was just a summary, so we are good there.

Dr. Sumfest: Any questions from the CMDs on the phone, or on the line?

Dr. Schaening: Thank you for your presentation.

Dr. Nachodsky: And thank you very much for your very informative presentation. No questions.

Raymond Kong: Thank you.

Dr. Sumfest: Our next presenter is Dr. Amanda Bicket, and I see that she's on. So, if you would just state your affiliation and if you have any conflict of interest, and then let Melissa know when to advance your slides.

Dr. Amanda Bicket: Certainly, thank you. Good afternoon. My name is Amanda Bicket, and I'm a glaucoma specialist at the University of Michigan. I want to first think the conference organizers for the opportunity to present to you on this impactful proposal by WPS to limit coverage for some of our surgical treatment options for glaucoma. I'm here on behalf of the American Academy of Ophthalmology, the American Glaucoma Society, and the American Society of Cataract and Refractive Surgery, as we make our case that this determination would substantially impair our ability to care for patients with glaucoma; a chronic progressive vision-threatening family of diseases. Next slide, please.

I have no financial conflicts of interest to disclose. Next slide, please.

Glaucoma patients require continual, often escalating therapy from diagnosis through the end of their lives. This is often 15 years or more, and in some cases decades. Eye drops are often used as first line therapy, but many patients have great difficulty using them and using multiple drops markedly decreases adherence. For each individual patient, a target pressure below which progression of vision loss is not expected defines his or her goals of care. Refractory glaucoma refers to intraocular pressure remaining above target despite the use of multiple classes of medication, or fewer medications when tolerability or effectiveness limit the use of certain drug classes. Please note, that this definition does not include an arbitrary IOP cut-off, as many patients progress at an IOP of less than 21. For patients who are progressing, or are likely to progress at their current IOP, a carefully tailored surgical treatment approach is often the next best step in saving their vision. Next slide, please.

A brief review of the surgical approaches being discussed today will help frame this discussion. Goniotomy refers to incision, excision, or cleavage of the trabecular meshwork, which overlies Schlemm’s canal, the most proximal structure in the angle, the eyes natural outflow pathway. Techniques in this class include what was previously called ab interno trabeculectomy with the Trabectome, ab interno trabeculotomy, using gonioscopy assistant transluminal trabeculectomy or other devices and other techniques, including those listed here. Canaloplasty refers to the

direct dilation of Schlemm's canal, via cannulation or injection of an ophthalmic viscoelastic surgical device in a technique known as ab interno canaloplasty. The list of devices are among those that are used in this way. It feels appropriate at this moment to thank WPS and Palmetto for their coverage of trabecular bypass stents, which also address this anatomical point of outflow resistance in the drainage angle. Given the mention of cyclophotocoagulation, or application of laser energy to the ciliary body, in the language of the draft determination as well as the CPT code for iridoplasty, or application of energy to the peripheral Iris, those definitions are also relevant. Next slide, please.

As you know, and as others may discuss later, goniotomy has been a mainstay in the management of glaucoma in young people, in whom high pressure often results from outflow resistance at the angle, since the 1960s and '70s. Goniotomy is also a necessary treatment for adults with glaucoma. Subconjunctival bleb forming and external filtering surgeries, such as trabeculectomy, tube shunt implantation and XEN gel stent insertion are effective for dramatic IOP lowering but come with attendant morbidity and long-term risk of infections and other complications. Patients with glaucoma refractory to medical management, who require only modest IOP reduction need safer options, among which angle surgeries like goniotomy and canaloplasty have become standard of care. Moreover, many patients are poor candidates for filtering surgery and for the trabecular bypass stents that are currently covered. Surgically, goniotomy does not require dissection of conjunctiva, which may be damaged or scarred from chronic topical medications, systemic disease, or prior surgery. And, lastly, angle surgery is often performed at the time of cataract removal, which all on its own provides inadequate IOP reduction in the majority of glaucoma patients and may even cause a transient IOP spike, and which also lowers the success rate of simultaneously performed external filtering surgery. Next slide, please.

We will highlight high quality evidence underpinning the use of goniotomy in adults as standard of care. Mr. Kong nicely reviewed this first publication, so I will be brief here. A prospective randomized clinical trial comparing cataract removal by phacoemulsification plus goniotomy to phaco with trabecular bypass stenting was published in August of 2020. More phaco/goniotomy eyes than phaco/stent eyes met the clinically significant primary outcome of greater than 20% IOP reduction or reduction of medication burden by greater than or equal to one drug at 12 months. And this result was statistically significant. Next slide, please.

Furthermore, you can see again that this trend held at all postoperative time points, demonstrating that goniotomy combined with cataract surgery is at least as effective as trabecular bypass stenting. Next slide, please.

The literature supporting goniotomy in adults with glaucoma stretches back to the early 1990s. And we will briefly present results from a review and meta-analysis of outcomes of goniotomy or ab interno trabeculectomy published between 2008 and 2014. From this first forest plot, you can appreciate that the weighted mean difference of the reduction in IOP between baseline and final measurements was significant for both standalone and combined cases. Next slide, please.

Furthermore, the same meta-analysis supports the fact that goniotomy reduces medication burden in adult patients with glaucoma. Next slide, please.

Canaloplasty has also been extensively studied in adults and here I'll briefly touch on 12-month results of a study of ab interno canaloplasty or ABiC™ and combined Phaco/ABiC™. Here, blue bars represent preoperative eye pressure and orange bars eye pressure 12 months after

surgery. The asterisks indicate that this change was statistically significant for all eyes: both those undergoing standalone ABiC™ and those undergoing combined surgery. Next slide, please.

Lastly, cyclophotocoagulation, or application of laser energy to the ciliary body to reduce aqueous production is a necessary tool in our armamentarium to treat glaucoma. We're somewhat puzzled by its inclusion in the draft LCD because this approach has been saving vision since the 1930s, and its safety and applicability only improved with the introduction of endoscopic cyclophotocoagulation and micro pulse delivery. While it is used judiciously, typically, as a treatment of last resort for eyes that are poor candidates for incisional surgery or have limited visual potential. It is an effective and important piece of our standard care – standard of care for glaucoma. Next slide, please.

In summary, patients with glaucoma, which I should mention, disproportionately affects Black and Hispanic persons, need access to a range of surgical procedures, reflecting their individual anatomical and disease features. For many patients, even when treatment with medications is inadequate, their glaucoma is not yet severe enough to merit more morbid filtering procedures. For these patients, minimally invasive glaucoma surgery like the angle-based procedures discussed today, preserve quality of life and reduce total costs to the health care system. We urge you to ensure that Medicare Beneficiaries with glaucoma continue to have meaningful access to these transformative procedures by providing coverage for minimally invasive glaucoma surgeries, including goniotomy canaloplasty and cyclophotocoagulation. Thank you very much for your time and attention.

Dr. Sumfest: Thank you, Dr. Bicket, for a very informative presentation. Any CMDs have questions?

Dr. Schaening: No questions, thank you for your excellent presentation.

Dr. Nachodsky: Yeah, no questions, and once again, much appreciated your detail and time taken to present to us.

Dr. Sumfest: Hey, our third presentation is Dr. Andrew – and I'm not sure if I'm going to pronounce his name correctly – Pouw. Is Dr. Pouw on the line?

Dr. Andrew Pouw: Yes, I'm here and you are pronouncing it very correctly.

Dr. Sumfest: Okay. Perfect. Thank you. Will you please tell us your affiliation and if you have any conflict of interest, and don't forget to let Melissa know when you're ready for the next slide.

Dr. Pouw: Thank you. My name is Andrew Pouw. I am a glaucoma surgeon and a clinical assistant professor at the University of Iowa. Today, I'm representing my colleagues at the University of Iowa as well as our state society, the Iowa Academy of Ophthalmology, and our community of referring eye care clinicians across our Iowa region. I have no disclosures. I do not have any financial or consulting relationships with entities, other than my employer, which is the University of Iowa, and I am not being compensated for my time here today. Many thanks to Dr. Sumfest, Mr. Staley, and WPS for allowing me to comment during today's session. Next slide please, then.

Most of my comments are also with regard to the LCD draft language, specifying the following micro-invasive glaucoma surgeries as investigational. I agree with my colleague Dr. Bicket, whom you'd heard from just earlier about the existing evidence for the procedures listed here. And I won't repeat Dr. Bicket's points exactly, but I would like to underscore the general point that most glaucoma surgeons would agree that these procedures are now part of the surgical glaucoma standard of care in the appropriate circumstances. Next slide, please.

There is, as Dr. Bicket had mentioned, an abundance of evidence that support at least the efficacy and utility of these procedures for glaucoma. And while all surgeons will agree that the evidence is certainly less strong than we would like that evidence is forthcoming with multiple randomized controlled trials in the works. Dr. Bicket referenced some of them. Again, I won't duplicate her points, but I'll add by mentioning my concerns specifically; that if insured coverage becomes unavailable for these procedures, then I'm concerned that clinical investigators may be compelled to seek support from biomedical industry sponsors to provide resources for these procedures so as not to leave patients with large bills for the sake of research data. And, of course, this might have the potential to introduce further conflicts of interest that may affect the resulting data. Next slide, please.

This slide, and the next one, are just two representative examples of data in the existing literature. Which again, while not high quality, randomized, controlled trials, still show that the procedures are helpful to some degree in lowering intraocular pressure. These results are referencing the GATT procedure and the Goniotomy procedure done with the Kahook Dual Blade®. Next slide, please.

And this slide shows reduction in the number of medications used after those same procedures. Next slide, please.

And here, I'll emphasize that while we know that the quality of evidence for these MIGS procedures is so far less robust than that for traditionally covered surgeries, like trabeculectomy and glaucoma tube shunt procedures, these MIGS procedures still have a valuable place in our surgical tool kit due to their lower risk profile. This citation illustrates a case where a Kahook Dual Blade® goniotomy was done in a patient's one good eye. And the patient also had mucous membrane pemphigoid. If this patient had been treated with a subconjunctivally based trabeculectomy or tube shunt procedure, the pemphigoid would have guaranteed a poor outcome. In my own experience, I have treated one patient who similarly only had one good eye, which itself was in a tenuous position relying on a corneal transplant to see well. The gap procedure that I did for him yielded a good outcome. But if I had put in a trabeculectomy or a tube shunt, either one would have led to more rapid failure of his corneal transplant and additionally would have limited contact lens refractive options, which for many corneal transplant patients are medically necessary and not able to be substituted by spectacle correction.

I'll lastly mentioned briefly. My own personal family experience, where my own father underwent three trabeculectomy procedures while I was growing up. He experienced complications and now has limited vision, which I know to be a direct consequence of clinically significant hypotony after his surgeries. This hypotony complication is one that MIGS procedures are intended to avoid, and they largely do. While I myself, as a surgeon, now do the same trabeculectomy surgeries that my father underwent, and I advocate for their important role in our toolkit, I do always wish that my father had had the benefit of having less invasive procedures, like these MIGS, available to him when he had needed them. Next slide, please.

And again, the last few points here, like, as similar to Dr. Bicket's, are with regard to cyclophotocoagulation, which I believe was perhaps mistakenly included in this draft language, as it is a procedure that has been done for decades. Next slide, please.

Specifically, or so I thought, the procedure had been done since 1987, though I may be mistaken, as Dr. Bicket had mentioned it's been done since the 1930's. I'll have to revisit my history textbook. Next slide, please.

Consequently, we have at least three decades, perhaps more of data about how well this procedure does work to lower intraocular pressure with one representative review paper referenced here summarizing many of these studies. Next slide, please.

I do wonder whether the draft language meant, instead, to identify a recently created variation of the CPC procedure, the micro-pulse cyclophotocoagulation procedure as investigational instead. As a recently introduced procedure with its own distinct and specifically required equipment, this micro-pulse version of cyclophotocoagulation does suffer from a paucity of quality evidence. However, as with – as is the case for the other MIGS procedures we've been discussing, this lack of evidence is slowly changing, and randomized controlled trials are beginning to percolate in the literature for this procedure as well. With one study here referenced from our colleagues at Hopkins.

And this final slide concludes my presentation, and I would like to again thank WPS, Dr. Sumfest and Mr. Staley for the opportunity to speak with you all today. Thank you.

Dr. Sumfest: Thank you for an excellent presentation. Anybody on the line have a question for Dr. Pouw?

Dr. Schaening: No questions. I just want to thank him for his excellent and very thorough presentation.

Dr. Sumfest: Okay.

Dr. Nachodsky: Thank you very much. Very well presented. I'm learning a lot from all of you.

Dr. Sumfest: So, our, our next presenter is Dr. Michael Siegel and I see he's on the line. Rich has just unmuted him. So, if you can start your presentation, let us know your affiliation and if you have a conflict of interest.

Dr. Michael Siegel: Thank you. I appreciate you all having me here. It's an honor to speak to you all. My name's Michael Siegel, I'm a glaucoma specialist in the Detroit metropolitan area. I'm a partner and owner of the Glaucoma Center of Michigan, which is a private, independently owned private practice with four glaucoma fellowship trained surgeons. And I also run the teaching glaucoma service at Oakland University, William Beaumont School of Medicine. I have no financial disclosures. I don't work for – I never have worked for – industry, and I've never been a paid speaker. I'm not being paid for this talk as well. Next slide, please.

So, we've all been discussing this proposed LCD and I wanted to discuss how it's just again reiterating that it's preventing us from performing necessary and effective procedures. We all know the procedures that are being listed and discussed, but what I did want to mention here that has not been discussed is that the MIGS stents, which have ample evidence and are used widely by many, and are great devices, are limited in their indication. Where we step in and use or have the ability to use goniotomy and canaloplasty across a broad swath of glaucoma types, and I'll get into that in a second. And, next slide, please.

We've looked at the pictures of the anatomy already, and I won't belabor the point. But, to get to the point of the types of glaucoma; glaucoma is not just glaucoma. There are a multitude of variants of glaucoma. Most commonly people think of primary open angle glaucoma, where this trabecular mesh work is visible, it's accessible and it just may not work well. And that is what the stents are indicated for. There's a few variants of that, but there are numerous diagnoses of complexities that we cannot use those stents for, even if we wanted to. And many of us choose to use excisional goniotomy and canaloplasty and ab interno trabeculotomy for those variants and cutting out the ability to do that would hinder our ability to treat numerous types of glaucoma, forcing us into utilizing more invasive procedures, which I'll get to in a second. Next slide, please

Just to underscore here what happens in glaucoma, this is what our patients are experiencing; a tunnel vision effect if you will. And it's extremely drastic, causes complete loss of function and ability and our goals are always to prevent this from happening in the least invasive way possible. And that is where a lot of these procedures have changed the game. Next slide, please.

As you can see, across the treatment spectrum here, minimally invasive – [inaudible interference]

Hello? Hello? Is there an echo? Sorry?

As you can see across the spectrum here, the mixed procedures fit into a wide range of patients, keeping us from utilizing more involved techniques like trabeculectomy and tube shunts. Next slide, for me, please.

Just an example, as I know most of you aren't operating on eyes. Our conventional treatments. The first picture on the upper left is a bleb formation from trabeculectomy. You can obviously see that that is not normal look to an eye. It's a, a trabeculectomy is, for better or worse, really

just a glorified hole that we create, a flap. It's incredibly invasive. It's been done successfully for 30 to 40 years and has an important place in what we do, but obviously we try to avoid this. The lower picture is the original version of an ab interno canaloplasty, of which we've now moved on from, utilizing devices like OMNI® to utilize a more internal technique, which doesn't involve cutting down on the outer tissues of the eye, the sclera, and the conjunctiva. On the right side is an example of a tube shunt, which you can obviously see, itself, is quite large. It's under the muscles of the eye, or there's other variants that don't, but they're all large tubes that externally implant on the outside and then you put a tube into the eye directly to shunt fluid off. So, in essence, we're basically plumbers, right? And we're trying to figure out a better way to do our plumbing and that's where these MIGS procedures come into play. Next slide, please.

Most of them are obviously targeting this internal drainage system, whether it's excising them, stenting them, or, in a sense, canaloplasty is sort of like doing a roto-rooter or flushing out the drain with the ability of also opening up and excising the trabecular mesh work as well when utilizing something like an OMNI® or the ABiC™ procedure. So, you can see just the picture on your right is just our approach to doing this canaloplasty versus the prior picture, the external canaloplasty, and just how less invasive of an approach it is. Next slide, please.

I just wanted you to see some examples on the next slide of these are complications we have when we are doing trabeculectomies and tube shunts. They create a very robust pressure lowering, which is, of course, our goal in many of these patients. However, that comes with a massive slew of challenges. And again, obviously, we know we have to use these procedures. We still use these procedures, but we try to avoid them at all costs, and that's where the MIGS step into play. Next slide, please.

Tubes are not benign either. Tubes expose; they’re foreign bodies on the eye. They shouldn't be there, but they need to be there in some instances. They cause corneal failure, double vision, and obviously erosions that lead to endophthalmitis, and infections and loss of the eye. So, again, just trying to help you understand what we're avoiding here by utilizing these procedures. Next slide, please.

So, my sort of thought when this came into play, was that how was there not evidence that this doesn't – these procedures don't work? And obviously, you're being provided with ample evidence of that. But I just wanted to explain in this manner that this is a graph showing our reduction of trabeculectomy surgery from the late ‘90s till about 2012. I'd like to point out that most of these procedures we are talking about weren't even quite into play yet until about 2012-13. And the reason is, we were utilizing ECP®, which is endoscopic cyclophotocoagulation and trabectome, which is basically another type of – another device to do an excisional goniotomy. And you can see, even with those two procedures, the counts of trabeculectomy were coming down judiciously from the late ‘90’s to 2012. Next slide, please.

I took the data from my own practice over the last five or six years, skipping 2020 of course, because those numbers are sort of jaded. But, this is really since the implementation of our practice, and we do all of these procedures from endocyclophotocoagulation through excisional goniotomy, canaloplasty with ab interno trabeculectomy and the stents, and you can see the profound reduction of trabeculectomies. We're close to 200 in 2015, and the last couple years we've dropped down below 150, so nearly a 25% to 30% reduction in having to put holes in eyes, and that is a success to us. You can see the tube shunt numbers as well and the reason, you know, there are certain patients that just need tube shunts no matter what. But once

trabeculectomies fail, you end up moving to a tube shunt most of the time, and therefore if you're doing less trabeculectomies, there's less tube shunts. Next slide, please.

So, what are the implications of less minimally invasive glaucoma surgery? It results in more risky filtration surgery. Next slide, please.

And the reality, what defines success? Obviously, keeping our patients from going blind. But less filtration surgery – it results in better patient outcomes, less postoperative visits, less time these patients have to come to the office and deal with transportation issues, less complications, more access to care and just most importantly saving our patient's vision. These minimally invasive procedures, specifically goniotomy, canaloplasty and cyclophotocoagulation, allow our most vulnerable patients better chances, and a safer way of maintaining vision. Next slide.

As has been mentioned and I will reiterate, a disproportionate prevalence of glaucoma affects African Americans. And as somebody who practices in Detroit, where it's nearly 80% African American, we obviously see this burden daily. About half of our patients are African American, and about 70% of our patients are on Medicare. Not having –

Richard Staley: Two-minute mark.

Dr. Siegel: Yeah, thank you. Not having these procedures in our armamentarium would directly result in us having to move towards filtration and trabeculectomy in our most vulnerable patients. The pigmented patient population also just tends to be the toughest to do filtration surgery on. They scar. They have all sorts of challenges, and I just can't even describe how these procedures have become our standard of care and moved us away from doing these procedures on our most vulnerable patients. Next slide, please.

Next slide, thanks. So, denying access to effective MIGS worsens our disparities for our minority patients, and those less able to afford ongoing medications. Many patients already face a mounting medication burden, and these procedures help reduce that. As you'll hear later, I'm sure, the Gemini study talks about OMNI® and canaloplasty reducing these IOP fluctuations and resulting in lower medication burdens. And as previously mentioned, the randomized control trial comparing goniotomy and eye stent show lower IOP and less medications with excisional goniotomy. Remember, less medications is better compliance, which equals less filtration and less complications. Next slide for me, please.

So, in summary, patients in our WPS area, including my practice in metro-Detroit, need access to these procedures, patients are unresponsive to medications or are unable to administer eye drops, these minimally invasive procedures offer us a safer option than our filtration surgery. Progression from medications to minimally invasive surgical procedures have a much safer profile with less adverse side effects. And really, as has been mentioned, MIGS like canaloplasty with ab interno trabeculotomy, goniotomy, excisional goniotomy, ECP®; they are our standard of care and have been for at least the last five to seven years. Next and last slide, please.

So, in closing, I request that WPS establishes coverage, not deny it. Preserve our patient access to these nonstandard procedures, so that our Medicare patients in Michigan are not denied the access to these proven treatments. I appreciate the opportunity to present here, and we hope that this input will change your minds, as it will impact thousands of Medicare patients in our jurisdiction, and in my practice. Thank you for your time.

Dr. Sumfest: Thank you very much Dr. Siegel. Any questions from our CMDs?

Dr. Schaening: No questions. I just want to say, thank you for an excellent presentation, and I congratulates you for your advocacy on behalf of your patients.

Dr. Siegel: I Appreciate it.

Dr. Sumfest: Okay, well, we'll move forward. The next speaker is Dr. Anita Campbell. And, is Dr. Campbell on the phone?

Dr. Anita Campbell: Yes, I'm here.

Dr. Sumfest: Okay, thank you.

Dr. Campbell: So, next slide please. So, I'm Dr. Anita Campbell, I'm a glaucoma and cataract specialist in Wichita, Kansas. And I am one of the three glaucoma specialists west of Kansas City and the entire state. So, we see a wide attachment of patients with all sorts of glaucoma from mild to severe. My disclosures are that I am a principal investigator for several of the trials that I will be discussing here, and those were funded by Sight Sciences, who makes OMNI®. Next slide, please.

So, today I'm going to primarily discuss what is OMNI® canaloplasty and trabeculotomy and discuss the high-quality clinical data that supports the OMNI®'s efficacy and safety in our patients, and really reiterate what many have discussed so far; that Medicare beneficiaries must have access to these types of devices for long term treatment success. Next slide, please.

So, we all understand the physiology, but specifically talking about the OMNI® surgical system, how does it interact here? So, the blue, red, and green layers are the trabecular meshwork and behind them is Schlemm's canal, which leads to the outlet channel, or the collector channel. Canaloplasty washes out Schlemm's canal, and the distal collector channels, allowing those proteins to be washed away in that roto-rooter sense that Dr. Siegel mentioned. And the trabeculotomy allows the aqueous fluid directly flow to Schlemm's canal. So, these are MIGS approach for patients with early, moderate, and advanced glaucoma. So, a wide variety. Next slide, please.

The LCD referenced only three clinical studies when discussing goniotomy. While I'm going to present results from well-designed studies that were published in top tier, peer reviewed journals. And this published evidence shows that the procedures using OMNI® are effective. They consistently lower patient's intraocular pressure. They reduce the medication burden and are safe for our patients with few adverse events. The results are comparable to the implant procedures that are currently covered under the proposed LCD, and the evidence supports coverage for OMNI® procedures to provide patients with this comprehensive, effective, non-implant glaucoma treatment option. Next slide, please

Looking at the data, specifically for OMNI®, there have been publications from 2020 to present. And these slides are just naming several of those and showing that they are in reputable, peer-reviewed journals. Next slide, please. And next slide again, please.

These landmark studies that I'm going to focus on are long-term multi-centered, peer-reviewed trials. The first one listed here is GEMINI. It is a prospective trial. It had a medication wash-out period, and it was multi-centered, in 15 practices across 14 States. It was single arm because the historic arm was used for cataract surgery, which is where data has been generally accepted on intra-ocular pressure alone. The follow up periods included one month – or one year, which was already reported in the 24 month or two-year results are pending. It included 149 patients, and we used the cataract surgery with the OMNI® surgical device combined. The ROMEO study is a second landmark study. It was retrospective, also multi-center and had a single arm looking at the OMNI® interventions. This one included OMNI® device canaloplasty and trabeculotomy, both combined with cataract surgery and standalone, and there were 129 eyes included. The one month – or one-year results have been reported and the two-year results are also reporting. Next slide, please.

So, let's start by discussing the GEMINI trial. So, this trial, as I mentioned, was prospective, we were able to enroll 149 patients with mild to moderate open angle glaucoma in which was performed in combination with cataract surgery. The initial follow up period was one year, and the inclusion criteria was 20-22 years or older, meaning the adult population, patients who had medicated intraocular pressures less than or equal to 33 millimeters of mercury and on one to four medications. That was important because we wanted to include patients who would be safe to be able to participate in this type of trial. And we also looked at diurnal intraocular pressure after medication wash-out, so the medication was not a factor in those diurnal measurements and eye pressure, similar to blood pressure, fluctuates through the day. So that's an important factor that can affect progression in glaucoma and loss of peripheral vision. Our exclusion criteria included prior incisional glaucoma surgery of any kind. So, next slide, please.

[Inaudible] – for decrease in intraocular pressure and decrease in medication burden for our patients. The total patients reported on at one year were 120. You can see on the graph to the left that at screening when the patients were still taking their anti-hypertensive glaucoma drops, that their pressure average 17.1 at baseline. After a medication was performed, they were at 23.9. One year out, again after performing that medication washout, the pressures landed at 15.6 on average. That means that 8.2 millimeters of mercury pressure reduction was achieved. That's very impressive in the world of glaucoma and that can save vision for hundreds of patients. 87% of patients had a greater than 20% reduction in pressure and our previous trials in glaucoma show that 20% reduction in pressure is a great primary starting point for a patient when they're first diagnosed. So that's why that's an important end point for this study. And finally, 34% reduction in pressure. When we look at medications, just like Dr Siegel and Dr.

Bicket had mentioned, that 82 – that medication burden is difficult on patients and for numerous reasons it can lead to non-compliance. So, 82% of eyes actually achieved medication freedom at one year. So that's an entire cohort of patients that no longer have to worry about the cost, convenience or timing of eye drops and 78% of that number and amount of eye drops that were used for patients were decreased by the end of the study. When we're talking about populations that are greater at risk for having damage from glaucoma, we're talking about African Americans and Hispanics, and there was a cohort study for the Hispanic patients who are a subset of this GEMINI trial. In that population, it showed similar decrease in IOP reduction, which was 7.9 points, and a 1.85 number of medication reduction. So, it is OMNI® with Canaloplasty, 360 degrees, and 180 degrees of trabeculotomy is effective even in this minority population, which tends to have damage from glaucoma. Next slide, please.

So, to focus on that subset of Hispanic patients, it was a population specifically from El Paso, Texas, 39 patients – Hispanic patients – were included, and the results mirror the results of the larger GEMINI study. Next slide, please.

So, before I go on to ROMEO, I do want to mention how the individual patient groups are really what we see as clinicians, and really put up our antenna when we have a patient with a subset of glaucoma. For example, normal tension glaucoma, which means their pressure may run from 10 to 21, which is considered normal, but it's still causing progressive damage in their eyes and optic nerve. So, one of the points I had mentioned was the diurnal pressure that we check with GEMINI, and it showed that there was a 34% reduction in diurnal fluctuation. For me, being the most difficult patients when we're talking about being a specialist in a large catchment, when those patients walk in the door and, you know, they've already been tried on numerous other treatments by their primary eye provider, and now you're saying, well, what can we do to keep this person from going blind? And you have a study that shows that there is technology like OMNI® and trabeculotomy and canaloplasty that can blunt the intraocular pressure at 34%, that's the difference between this person maintaining usable vision and functional vision for day-to-day life or turning into dark vision and losing their job and their functionality and being stuck at home, depressed and a burden on their family and society.

Dr. Sumfest: Dr. Campbell, I apologize. I think Rich was unable to let you know that you passed the two-minute mark. So, if you're about ready to summarize your presentation, please.

Dr. Campbell: Oh, I'm sorry. Okay. Yes, I believe I only have two slides left so that should be just perfect. Thank you.

So, with the ROMEO study that looked at OMNI® in real world setting, and by that, we mean it was a retrospective study, it included patients who had cataract plus OMNI®, or just OMNI® stand-alone. And next slide, please.

And with the ROMEO study, it showed similar results, meaning IOP reduction, the groups were separated into patients in that normal tension group, like I mentioned, patients with primary open angle glaucoma. And both groups had significant number of patients who were medication free and significant and intraocular pressure that's statistically significant. So, the ROMEO 1 study extended to one year. ROMEO 2 study expanded the initial study with additional patients

and study sites and there was a 24 month follow up. So, the results demonstrated continued and stapled control of intraocular pressure and medication usage similar to that one year. And both of these facts were significantly lower than the pre-surgical baseline. Next slide, please.

Okay so the most recent and relevant evidence demonstrates that this OMNI® surgical procedure with canaloplasty and trabeculotomy delivers consistent, long term, improved outcomes, including intraocular pressure reduction and medication reduction for glaucoma patients. And when considered with prior studies, and recognition by AAO and American Glaucoma Society, consensus treatment guidelines, the weight of the evidence supports Medicare coverage of the OMNI® procedure to ensure patients can access this technology as an alternative to more invasive procedures or implantable MIGS stents. It's critical that Medicare Beneficiaries and clinicians in the WPS jurisdiction continue to have access to the range of effective MIGS options demonstrated to improve health outcomes. Next slide.

Dr. Sumfest: I think, Dr Campbell, you're done.

Dr. Campbell: And I thank you for the opportunity.

Dr. Sumfest: Perfect timing. Thank you very much. Any questions from the CMDs?

Dr. Schaening: No questions, just want to thank you for your presentation.

Dr. Sumfest: Thanks again, Dr Campbell. Our last presenter is Mr. Paul Badawi, and he's on video, and his slides are up. Just let us know your affiliation, and if you have any conflicts of interest and let us know when you want your slides advanced, thank you.

Paul Badawi: Sure. Well, thank you. My name is Paul Badawi, and I am a Co-founder, President, and Chief Executive Officer of Sight Sciences. So, I'm an employee and shareholder, obviously.

I want to first thank all of you at WPS for taking the time out of your busy schedules to learn more about Sight Sciences and our OMNI® surgical system glaucoma technology. For background, I started Sight in 2006 with my brother, Dr. David Badawi, an ophthalmologist. Our original goal was to develop better treatments for glaucoma. We wanted to make sure that patients never go blind from this disease. Over the past decade, we painstakingly researched developed and created a new technology; the OMNI® technology; with the aim of delivering the safest and most effective, minimally invasive surgical procedure for the treatment of glaucoma. And it has all been worth it. With OMNI®, we have equipped glaucoma surgeons across the country with a better, more comprehensive, and more effective surgical glaucoma technology. And in so doing, we've made a real impact on the treatment of glaucoma. Next slide please.

We've been able to transform how glaucoma is treated by developing technology that is implant free and allow surgeons for the very first time to access the entire 360-degree diseased aqueous outflow pathway. The technology allows them to perform what has been referred to as two outflow procedures canaloplasty followed by trabeculotomy. But OMNI® does more; it allows surgeon to address all three sources of resistance in the aqueous outflow pathway. Surgeons can thereby reduce intraocular pressure and reliance on IOP lowering eye drops, which are difficult to administer, suffer from compliance issues and have varied absorption, such that IOP may vary significantly over a 24-hour period, also affecting disease progression. Prior to OMNI®, only partial or minimalist outflow solutions had been available. OMNI®'s a more complex procedure. It's harder to master. It requires more training. It requires more practice. But it's absolutely worth it for the comprehensive procedure profile and differentiated efficacy it provides. Next slide, please.

As an innovation and teaching partner to thousands of glaucoma surgeons who use our technology as their standard of care, we were extremely disturbed to see OMNI® listed as investigational. We fear this could lead to beneficiaries and surgeons losing access to this procedure in WPS's region, and disproportionately impact patients with limited financial resources. We think that the proposed policy mistakenly discounts OMNI® as a standard of care and overlooked several important, peer-reviewed studies, further demonstrating OMNI®s, efficacy. We expect a full review of the clinical evidence will show that OMNI® is as effective as the stents WPS has proposed to cover. Next slide, please.

MIGS is an effective intermediate treatment between daily eye drops and lasers, shown on the left, and far more invasive surgery that comes with lifelong risks of complications, shown on the right. Prior to OMNI®, the only MIGS solutions were stents and goniotomy, and these treatments target just one of the three sources of outflow resistance, the trabecular meshwork. Stents and goniotomy do not target and treat Schlemm's canal and the distal collector channels, which are also implicated in glaucoma. OMNI® is the first and remains the only technology and procedure that comprehensively treats all three sources of resistance. If finalized as proposed, the LCD eliminates this implant-free, comprehensive outflow restorative surgical option from the glaucoma treatment algorithm, creating a significant treatment gap for patients seeking to avoid permanent invasive implants and filtering procedures. Next slide please.

Unlike all other devices, instruments and procedures deemed investigational on this proposed policy, OMNI® is the only technology that has an FDA cleared indication for use in lowering IOP in adults with primary open angle glaucoma. OMNI® received an expanded indication in March 2021, based on a rigorous FDA evaluation of results from our ROMEO multicenter pivotal trial. OMNI® has gone through a rigorous clinical trial and FDA regulatory assessment of safety and efficacy, a process that payers should expect. In addition, the AAO identifies OMNI® as a MIGS option in is preferred practice patterns, with no limitations on scope of treatment and no limiting statement on the level of evidence for OMNI®. Next slide please.

I appreciate all the efforts put forth to assess all the clinical evidence for the various procedures and technologies in the MIGS category. However, in this case, important clinical evidence for OMNI® was overlooked in the draft policy. For example, I encouraged to review the one-year results from the GEMINI study. The prospective GEMINI study was modeled after the three prospective MIGS stent studies that were used to support coverage for those stents. Also, only three studies of OMNI® were cited in the draft policy, but at least 18 additional peer-reviewed

papers with one-to-two-year outcome information have been published. I expect that these additional peer reviewed publications will fill the need for longer term data. Next slide, please.

Here we see the compelling clinical outcomes from the GEMINI trial in almost 150 patients, a landmark, prospective multi center medication washout trial at 15 sites in the US. The GEMINI study protocol used eligibility criteria almost identical to the eligibility criteria in the stent trials, thereby allowing the use of consistent control arms from those trials as a historic cataract control. One other important aspect of the GEMINI trial was that it had prespecified success criteria. Importantly, OMNI® met its success end points at 12 months and showed a clinically and statistically significant improvement in IOP lowering and medication reduction beyond the cataract surgery alone historical control. By addressing all three areas of outflow resistance with the most comprehensive MIGS procedure, OMNI® delivers consistent, positive clinical outcomes, including meaningful IOP reductions; a vast majority of patient to achieve a greater than 20% IOP reduction at one year; IOP reductions that are stable 24/7 and consistent reductions in daily prescription eye drop use. Next slide, please.

Again, we see remarkably consistent clinical outcomes with OMNI® technology across all of our studies and in everyday practice, similar to the GEMINI results. We believe the comprehensive nature of the OMNI® technology and procedure is what enables it to clinically perform as good or better than the covered MIGS implants. Next slide, please,

We provide a brief summary of some additional peer-reviewed studies involving over 630 patient eyes. Within these publications are a variety of clinical data that capture OMNI®'s consistent effectiveness and its broad indication for use. To highlight a few examples in addition to GEMINI and ROMEO, the retrospective studies by Klabe as well as Brown also showed very consistent results. The Klabe study reported a 40% reduction in IOP and a 64% decline in medication usage. Next slide, please.

Here's the continuation of our peer-reviewed publications on over 630 eyes treated. And again, I would just highlight both the number of studies, and the consistency with which positive treatment affects have been identified. For example, the Williamson study was a continuation of the ROMEO pivotal study and extended a period of analysis out to two years post-surgery. The paper demonstrates that the one-year efficacy seen in ROMEO were maintained for two years. So, it shows clinically and statistically significant reductions in both IOP and medication use. From the OMNI® procedure out to two years. Next slide, please.

Richard Staley: And we are at the two-minute mark.

Paul Badawi: Okay, thank you.

Together with the surgeons you've heard from today, we are here to help better treat glaucoma and improve the lives of patients who suffer from this blinding disease. There is no greater joy than being in a clinic the day that a patient returns for a post-op day one checkup, and hearing the surgeon report that the post-op reductions in IOP and medications are even better than expected. Our goal is to continue to provide patients and surgeons with the technology they need and they rely on to keep this disease from progressing and to help them avoid blindness. This open meeting process is a critical opportunity to ensure that the Medicare coverage criteria

take account of OMNI®'s standard of care in glaucoma surgery and provide continued access to critical technology, like OMNI® in the WPS region. Next slide, please.

In closing, we believe the full scope of the clinical evidence and expert input supports the efficacy of the procedure labeled as OMNI®. To ensure Medicare Beneficiaries suffering from glaucoma have access to OMNI®, we request that the proposed LCD be revised to recognize that the procedure performed with OMNI® described as canaloplasty followed by trabeculotomy is reasonable and necessary to reduce IOP in adults with primary open angle glaucoma. We intend to continue our discussions with the AAO and CMS involving coding for OMNI®.

I'd like to personally thank everyone at WPS for your time, interest, and consideration of our mission and our purpose. I'm happy to address any questions. Thank you all.

Dr. Sumfest: Thank you Mr. Badawi. Any questions from the CMDs?

Dr. Schaening: I have no questions. Thank you for your presentation.

Paul Badawi: Thank you.

Dr. Sumfest: So, I just want to thank everyone who attended this meeting, and particularly the presenters who kept to the ten-minute time limit, which allowed us to get to all the presentations. I was amazed how smoothly it went.

I do want to request that anyone who has literature – peer-reviewed literature, studies that we did not consider in the collaborative work group to please submit them to us electronically on the medicarepolicycomments@wpsic.com. We do need them either in a PDF format, because we can't follow any email links.

I do also want to thank my colleagues here at WPS for participating and particularly Mr. Richard Staley, who is the one who makes all these events possible.

This concludes our meeting and thank you very much and have a good afternoon. And so, we are adjourned at 3:54 Central time – excuse me – 3:54 Eastern time. So, convert that to Central, it's too late in the afternoon for me to do that. But thank you again for everyone, and please submit the documents so that we can share them with the collaborative work group.

Okay, we're done.