# Jurisdiction 15 Open Draft LCD Meeting

| Meeting Details | |
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| **Meeting Date:** | July 11, 2023 |
| **Facilitator:** | Dr. Meredith Loveless |
| **Location:** | Teleconference |

Dr. Loveless briefly introduced the Proposed Polices that are to be discussed:

## Dr. Meredith Loveless (0:00:00)

### DL39575 Amniotic and Placental-Derive Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound

- This is a NON-Coverage policy for all amniotic membrane, amniotic fluid or other placental-derived production injections and/or applications as a means of managing musculoskeletal injuries, joint conditions, and all other conditions within the policy.
- This guidance does NOT include burns, wounds, or ophthalmic conditions.
- Definitions of these products is within the policy.
- There is a lack of evidence to support the role of amniotic and placental derived products for these musculoskeletal indications.
- Throughout the policy, there are the different musculoskeletal applications that have been reported in the literature with an evidence review for each one of those covering the current knowledge that we have in those conditions. And there is a possibility of evidence in in a large number of those conditions, as well as a lack of high-quality evidence and outcome benefits for the Medicare population.
- The other challenge with this literature is a lack of consensus in the technique volumes. How these two would be delivered, measuring follow-ups long term data. So, they're just as quite a bit that we do not know or understand regarding these products and those benefits as with any non-coverage position, if new literature is developed that would warrant a potential change to the non-coverage position that can be submitted through the reconsideration process for reconsideration.

### DL38378 Fluid Jet System in the Treatment of Benign Prostatic Hyperplasia (BPH)

Minor revision include:

- The age limitation of less than 80 was removed.
- Additional published literature that utilizes this technology over the age of 80 supports potential improvements in long term outcomes with the less invasive approach in this population.

 

## DL39585 MolDX Molecular Biomarker Testing for Risk Stratification of Cutaneous Squamous Cell Carcinoma

### Non-Coverage Policy

The rationale for this non-coverage is that while this test is capable of metastatic risk stratification, it's still uncertain how these results can consistently or accurately be interpreted in the context of baseline clinical pathological risk.

We're still not sure how these results will translate to clinical practice and patient management. We know the test gives us that information but how it can be used is not established. If that becomes established, then that can be reconsidered within the policy.

## DL37578 Micro-Invasive Glaucoma Surgery (MIGS)

There were two reconsiderations for this policy.

The first reconsideration addresses a new stent that has been on the market for utilization of the stent outside of cataract surgery.

In the initial policy placement of a stent was limited to be done during cataract surgery, which was how the stents had been studied and consistent with the published literature. This was supported by new literature that was published this year in January that led to the reconsideration and is addressed in the new policy.

The second reconsideration addressed the performance of goniotomy procedures.

Performance of these procedures at the time of stents and this led to research and investigation on this on this of surgical procedures for cataract surgery and this was determined to be investigational based on the current body of literature to support these surgeries.

The policy states that there would be coverage for the management of refractory glaucoma with a prior failure of a filtering or cilioablative procedure, an uncontrolled intraocular pressure defined as progressive damage and mean diurnal medication intraocular pressure greater than 20 on maximally tolerated medical therapy In those cases, the be stent would be covered for placement outside of cataract surgery.

This was based on systematic review and meta-analysis and randomized controlled trials with positive results in that patient population.

The following procedures are considered investigational in patients over the age of 18 for glaucoma management:

a.) Goniotomy or ab interno trabecular bypass surgery

b.) Excimer laser trabeculostomy

c.) Viscocanaloplasty

d.) Canaloplasty in combination with trabeculotomy ab interno

e.) Gonioscopy-assisted transluminal trabeculotomy.

f.) Ab Interno Canaloplasty

g.) Transculiary Fistulization

h.) Cyclophotocoagulation

Each one of these procedures are reviewed separately with the body of evidence that was evaluated for that decision discussed. In addition to a summary of that evidence, the limit strengths and limitations of evidence are reviewed within those sections.

The concern with the with these procedures is that while there is certainly an unmet need for additional interventions for glaucoma. Some of them have very little literature to support them and others are supported by low quality literature. There's almost an absence of any randomized control trials. There's a very little long term outcome data.

Optimal patient selection has not been consistent across the studies. There also are no studies to compare these surgical procedures to optimal medical management to understand benefits of surgery as compared to current standard of care treatments and when patients may best benefit from additional interventions.

There's a concern, as far as terms of the role of goniotomy in the adult population.

This procedure was well established in the pediatric population, but there is not a lot of literature to understand the role of it and the adult population.

Pediatric congenital glaucoma has different pathophysiology than adult glaucoma. That's where that can be challenging to not have a lot of research and understanding the role of the surgical procedure with the different pathophysiology of the disease that's being treated.

Large Cochrane review reviewed the evidence of this and concluded a need for properly designed studies and the American Academy of Ophthalmology Glaucoma preferred practice. While they don't state that you know not to be able to do these procedures. It does acknowledge the scarcity of evidence for several of these procedures.

In addition, we don't fully understand the role of the lowering of interocular pressure and how that impacts progression of glaucoma.

So these procedures reduce interocular pressure based on the studies that have been done, but in many cases it's a modest reduction into the mid-teens and it's not clear how that impacts the progression and long term management of glaucoma and if it is indeed beneficial to have that modest reduction early on, it does reduce the need for the number of medications for many patients, but again, without having a comparison to patient outcomes with these procedures compared to optimal medical management, that's difficult to know what that translates to in terms of long term benefits.

There are also again the variations in patient selection. Patients may have different degrees of glaucoma, so someone might be very mild, moderate, severe.

What we're trying to find here from the literature is who is the right patient for the procedure? What's the right timing for the procedure and how is this going benefit the patient long term? Are there any potential harms from surgical intervention early that could impact more definitive surgical procedures later on and the current body of evidence was unable to clarify those questions for us and therefore it is considered investigational while we look towards establishing further understanding and literature support the procedures and right on time.

## Paul Badawi, Sight Sciences, Inc. (40:13)

My name is Paul Badawi, and I am a co-founder, President, and CEO of Site Sciences.

Therefore, I'm an employee and the shareholder. I started Site Sciences in 2006 with my brother, Dr. David Badawi, who is an ophthalmologist. Our 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, to facilitate 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, safer, more comprehensive, and more effective surgical glaucoma technology; and in so doing, we have made a real impact on the treatment of glaucoma.

We have been able to transform how glaucoma is treated by developing technology that is implant free and allows surgeons for the first time to access the entire 360-degree diseased aqueous outflow pathway via an AB interno approach.

The technology allows surgeons to perform what has been referred to as too sequential and comprehensive aqueous flow procedures canaloplasty followed by Trabeculotomy, but OMNI does more.

It allows surgeons 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 and have characteristic peak trough effects that can lead to patients IOP varying significantly over a 24-hour period which, can also affect disease progression. OMNI is a more complex procedure, it is harder to master and requires training and practice, but it's worth it for the differentiated efficacy it provides.

As an innovation and teaching partner to thousands of glaucoma surgeons who use our technology, we are extremely disturbed to see OMNI listed as investigational. We fear this could lead to beneficiaries and surgeons losing access to this procedure in the Medicare jurisdictions you oversee and disproportionately impact patients with limited financial resources.

OMNI is now a standard of care. I think that the proposed policy mistakenly discounts OMNI, perhaps because the proposed LCD overlooks several important peer reviewed studies demonstrating OMNIs efficacy.

I expect that when you do a full review of the clinical evidence, your LCD will change and indicate that OMNI is as effective as the stents that are covered under the draft LCD.

This slide intends to illustrate where MIGS fits in the glaucoma treatment paradigm.

Between daily eyedrops that have their various limitations on the left and more risky and invasive surgery on the right. For some time, MIGS involve stents and goniotomy, and these treatments work for some, but these surgeries target just one of the three sources of aqueous resistance, the trabecular meshwork. Goniotomy do not improve the aqueous outflow through Schlemm's canal and the distal collector channels, which are also implicated in glaucoma. OMNI is the first and the only technology that enables a procedure that comprehensively treats all three sources of aqueous resistance and does so without leaving an implant behind. For these and other reasons that I will address, the MACs should not eliminate coverage for OMNI.

Doing so would create a significant treatment gap for patients seeking to avoid permanent implants and more risky glaucoma surgery.

Regarding regulatory and medical specialty society support, the FDA cleared indication for use for OMNI is to lower IOP in adults with primary open angle glaucoma. The FDA expanded OMNIs indication in March of 2021 based on its evaluation of clinical results from our Romeo multicenter pivotal trial.

The American Academy of Ophthalmology identifies OMNI as a MIGS treatment and its Preferred Practice Patterns. The AAO has never hinted that more evidence was needed to demonstrate the clinical value of OMNI.

While I appreciate your efforts to assess the clinical evidence for the various MIGS procedures. However, in OMNI's case, important clinical evidence was overlooked in the draft policy, for example, the one-year result from the Gemini study. The key point regarding the Gemini study is we model the study protocol, patient criteria and success endpoints after the three implantable MIG stent studies that have been used to support coverage for those stents.

Also, only three studies of OMNI were cited in the draft policy, but at least eighteen 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.

Briefly here you can see the compelling clinical outcomes from the landmark Gemini trial in almost 150 patients at 15 sites in the United States. As I mentioned, the prospective multicenter medication washout Gemini study was modeled after the prospective multicenter medication washout stent trials.

The Gemini trial had a prespecified endpoint and success criteria based on the consistency of the cataract historical control.

The results from Gemini showed that OMNI met its success end points at 12 months and showed a clinically and statistically significant improvement in IOP lowering and medication reduction beyond that of the cataract surgery alone historical control.

The data is clear, OMNI delivers consistent, positive clinical outcomes, lowers IOP 24/7 and reduces the need for IOP, lowering medications.

I want to highlight here that we see remarkably consistent clinical outcomes with the OMNI technology across all these studies and in everyday practice similar to the Gemini results. We believe the comprehensive nature of the OMNI technology is what enables it to perform as good or better than the MIGS implants you intend to cover.

OK, we've provided brief summaries of some additional peer reviewed studies involving over 630 patient eyes within these publications, or a variety of clinical data that capture OMNIs broad effectiveness and broad indications for use.

Here's a continuation of our peer reviewed publications on over 630 eyes treated and before closing, I want to point out that many private insurers cover MIGS and OMNI procedures. For example, Cigna very recently updated its mixed policy to cover canaloplasty both ab internal and external reported with CPT 66174.

I don't understand why Medicare is heading in the opposite direction, denying coverage for MIGS. Medicare beneficiaries should not be deprived of these minimally invasive procedures, especially OMNI and canaloplasty.

I am honored to work with surgeons that are working to better treat glaucoma and improve the lives of patients who suffer from this blinding disease and there's no greater joy to all of us at sight sciences for delivering on our mission.

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 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.

Thank you for your time and interest and consideration of our mission and our purpose.

I'm happy to address any questions. Thank you.

### Dr. Fred Chu (49:44)

Good afternoon. My name is Fred Chu and I'm a glaucoma specialist at the Cincinnati Institute. I want to thank our conference organizers for the opportunity to present to you on this impactful proposal 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 the determination would substantially impair our ability to care for patients with glaucoma, which is a chronic progressive vision threatening family of diseases.

I have no financial disclosures.

Glaucoma patients require continual, often escalating therapy from the diagnosis of glaucoma through the end of their lives. Eyedrops are often used as first line therapy, but many patients have great difficulty using them. Using multiple drops markedly decreases adherence for each individual patient a target pressure is determined below, which progression of vision loss is not expected.

Refractory glaucoma refers to intraocular pressure remaining above the target despite the use of multiple classes of medications. For these patients, minimally invasive glaucoma procedures and laser procedures can be beneficial.

A brief review of the surgical approaches being discussed today will help frame the discussion. MIGS is an acronym for Micro Invasive or minimally invasive glaucoma surgeries. These tend to have the characteristics of being safer, more predictable and less time consuming than traditional conjunctival based surgeries.

Goniotomy refers to incision, excision, or cleavage of the aqueous meshwork, which overlaps Schlemm's canal. The most proximal structure in the angle, the eyes natural outflow pathway. Canaloplasty refers to direct dilation of Schlemm's canal via cannulation or injection of ophthalmic viscoelastic surgical devices.

So iridoplasty and cycle photocoagulation are also defined here as the language of the draft determination indicated alterations to these CPT codes as well.

As you know, Goniotomy has been a mainstay in the management of glaucoma in young people in whom high eye pressure often results from outflow resistance at the angle since the 1960s and 1970s. Goniotomy has also been found to be necessary in the treatment of adults with glaucoma, subconjunctival, bleb forming and external filtering surgeries such as trabeculectomy, tube shunt, and Xen gel stent insertion are effective for dramatic intraocular pressure 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 intraocular pressure lowering need safer options, among which angle surgeries like goniotomy and canaloplasty have become standard of care. Moreover, patients who are poor candidates for filtering surgery and for trabecular bypass stents are excellent candidates for these procedures. Surgically goniotomy does not require dissection of the conjunctiva, which may be damaged or scarred from previous topical medication use, previous surgeries, or systemic disease. Lastly, angle surgery is often performed at the time of cataract removal, which on its own provides inadequate intraocular pressure reduction for the majority of our glaucoma patients.

We will highlight high quality evidence underpinning the use of goniotomy in adults as a standard of care approach. This is a prospective randomized clinical trial comparing cataract removal with facial modification plus goniotomy with patients who received trabecular bypass stenting with cataract surgery, and this was published in August of 2020.

In this study, more patients who underwent phaco with goniotomy then patients who underwent phaco with bypass stents met the clinically significant primary outcome of greater than 20% IOP reduction or reduction of medication burden by greater than or equal to 1 drug at 12 months and these results were statistically significant.

Furthermore, you can see 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, along with cataract surgery.

The literature supporting goniotomy and adults with glaucoma stretches back to the early 1990s, and we will briefly present the results from our review and meta-analysis of outcomes of goniotomy or ab interno trabeculectomies published for studies published between 2008 and 2014.

These forest plots in this slide in the next demonstrate a reduction in intraocular pressure and drop burden for patients undergoing goniotomy.

Canaloplasty has also been extensively studied in adults, and here we briefly touch on 12-month results of a study of Ab interno canaloplasty or ABiC and combine phaco with ABiC.

Here the blue bars represent preoperative eye pressure and medication use, and the orange bars represent 12-month postoperative intraocular pressure in medication use. The asterisk indicates that in all of these data points that the standalone ABiC and those undergoing combined phaco with ABiC were statistically significant.

Cycle photocoagulation or application of laser energy to the ciliary body is a necessary tool in our armamentarium to treat glaucoma. This approach has been saving vision since the 1930s.

While it is judiciously used, typically as a treatment of last resort for eyes that are poor candidates for incisional surgery or have limited vision potential, it is effective and important piece of our standard of care for glaucoma. Additionally, with the advent of endoscopic cycle Photocoagulation and Micropulse delivery, it has become more broadly applied.

In summary, patients with glaucoma 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, they're glaucoma is not yet severe enough to merit 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 healthcare 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 for your time and attention.

## Rick Fischella (58:47)

My name is Rick Fischella. I am the director of medical payer strategy for ophthalmology at Abbvie and wanted to discuss the LCD for MIGS devices. I am a full time employee at Abbvie.

On behalf at Allergan and Abbvie, the manufacturer of ZEN, the glaucoma treatment system, I wanted to really thank you for the opportunity to provide comments on the proposed LCD and we were respectfully would like to ask you for your consideration for the proposed LCD and would only request one additional word change.

Well, in the statement that is in the current proposed LCD you have highlighted and/or which we do appreciate because it expands that population of our glaucoma patients, but also in addition to that, when we you say uncontrolled intraocular pressure defined as progressive damage and it says and a mean diurnal medicated IOP more than 20 millimeters of mercury, we would suggest that and changed to or for more comprehensive and actually takes in consideration many of our patients who are controlling or progressing on their glaucoma with intraocular pressures less than 20 millimeters of mercury.

By the way, I just wanted to mention there are similar language known not only in your current LCD on Page 3 but also on page 17.

Clarification of refractory glaucoma and I know we had talked about this a little previously, some of our presenters, the American Glaucoma Society, has defined maximally tolerated medical therapy and ? glaucoma as ambiguous terms.

And that may be confusing when you integrate those into clinical practice and also not only in practice guidelines, also policy statements. So, I won't read the whole definition here for you.

Well, one other consideration is refractory glaucoma is really simply glaucoma, that is difficult to treat or poorly controlled by current therapy.

And so that's regardless of the stage of the disease of at this point in time, this does not mean, by the way, a specific intraocular pressure has to be more than 20 millimeters of mercury.

There's often refers to a patient that's continuing to progress and not related necessarily to that specific IOP.

I just wanted to give you an example here of some of our XEN publications that include patients that are considered refractory, non-refractory and progressing based upon the clinical decision that further intervention was necessary to prevent detrimental long-term outcomes.

Namely, as we're all well aware, sight loss or blindness, and that also goes in conjunction with what some of the previous speakers have mentioned too, that it depends on the clinical decision on whether that patient is progressing or not. The examples that we have here is the XEN gel stent has been implanted in many patients with moderates, is very glaucoma based on baseline intraocular pressures less than 20 millimeters mercury.

And we have multiple studies here that have actually demonstrated that. We also have comparative trials evaluating clinical outcomes and Zen was compared against trabeculectomy in those clinical trials and that is considered the gold standard for glaucoma filtering surgery, notably baseline patient characteristics in these studies also cited often include intraocular pressure less than 20 millimeters of mercury.

A recent publication that just came out this year in 2023, a systematic review looked at the XEN literature, and this included 59 different studies and reported on overall range of medicated baseline intraocular pressures of these patients and they range from 15.3 to 36.1 millimeters of mercury, obviously, less than 20 millimeters of mercury and of recently published again just this year, perspective randomized clinical trial on the effectiveness and safety of XEN compared to Trabeculectomy demonstrated that patient baseline characteristics included intraocular pressures that range from 15 to 44 millimeters of mercury.

We would just like to thank you for the opportunity to provide comments to the proposed LCD.

We respectfully submit for consideration the request for removal of the and with replacement or for that statement of the management of refractory glaucoma, defined as prior filtering, failure of filtering or cilioablative procedure and or uncontrolled intraocular pressure defined as progressive damage or mean diurnal medicated IOP more than 20 millimeters of mercury and maximally tolerated medical therapy.

We will respond in writing to the presentation today and we will also make sure that we forward all the references that we have discussed today. Hopefully I'm giving some time back to the folks appreciate your consideration.

### Dr. Loveless (1:04:36)

Thank you very much and for sending in the literature and comments as well, and it looks like we have Dr. Bafna’s audio issues corrected. So, we welcome you to the floor.

We'll pull your slides up.

### Dr. Bafna (1:04:51)

Awesome. Thank you so much. OK, I was on a Mac and that was the issue.

So I think I'm fine. Thank you very much for giving me the chance to speak.

I'm a practicing ophthalmologist that's part of Midwest Vision Partners, which is a network of over 140 providers across five different states.

We provide a full suite of vision care services, including makes another glaucoma procedures and treat a high proportion of Medicare patients that come from patients from minority communities.

So ultimately, the main goal with glaucoma is that we have high pressure inside the eye and that ultimately causes damage to the optic nerve ,and so our goal is basically to try to figure out how can we go ahead and lower this eye pressure inside of patients.

One of the best ways that we found to be very effective at lowering pressures is to the utilization of MIGS, and for myself, I perform about 200 MIGs procedures every year.

Out of those 200, probably about 50% of them represent stent procedures and the other half represent various modality procedures such as canaloplasty, goniotomy things of that.

And ultimately what I like to do is try to look at each patient to try determine in my hands what I feel is going to work best for that patient. We basically can treat all stage of glaucoma with MIGs.

And the beauty about MIGS it demonstrates a favorable safety profile with quick recovery. The key MIGs benefits is that it lowers interactive pressure. It reduces the need for IOP lowering medications and #3 reduces the chance for more invasive surgical procedures.

So I think this is a very important slide from my perspective. I mean, ultimately, we've got three areas of resistance whenever we deal with any patient, it can be at the trabecular meshwork. It can be a Schlemm's canal, and it can be at the distal collecting channels and it's very difficult as a provider to try to determine where exactly is the resistance that takes place.

When we're going ahead and using stents, and I use stents very extensively. We're basically making the assumption that the resistance is that the trabecular meshwork and we'll be able to bypass that. But many times, patients may have resistance at Schlemm's canals or at the Distal collector channels, and depending upon where that is, that may determine how effective a stent may or may not be. And so ultimately, it's very critical to have devices available where one can go ahead and treat all these various 3 point of resistance.

Like I mentioned earlier, stents do not address all of these three-pointer resistance and by utilization of canaloplasty and trabeculotomy, we've got the ability of going ahead and addressing these other areas of resistance.

There's multiple areas of evidence that's basically of supported. the coverage of OMNI as well as well as various other devices for canaloplasty and trabeculotomy. The results of these well-designed studies were published in peer reviewed journals and showed that OMNI procedures are comparable to the stent type procedures that are covered under the proposed LCD.

The LCD actually only references 3 clinical studies. There have been multiple additional studies which have already been demonstrated by the other speakers that are relevant to CGS's review, and besides the studies which I think are very, very critical as a provider myself, I can speak to as a very high-volume provider.

The efficacy of these various procedures that are being considered, "investigational", but in reality, in my mind is not investigation at all.

Basically, I've highlighted 2 particular studies. One is a Gemini and the Romeo. One was prospective, one was retrospective, clearly demonstrated the efficacy of OMNI.

These and other studies show that MIGs technologies like OMNI are at least as effective, if not more effective than certain stent procedures, depending upon the patient that we're dealing with and are covered under the proposed LCD.

So, in conclusion, there's plenty of recent and relevant evidence that demonstrates a MIGs procedures like the OMNI procedure can deliver consistent long term improved outcomes for glaucoma patients. If you look at the American Academy of Ophthalmology as well as the American Glaucoma Society's consensus treatment guidelines, the weight of evidence supports Medicare coverage for these procedures to ensure patients have an alternative to implantable makes sense over more invasive surgeries.

I personally feel that stents work extremely well, but there's plenty of times when the utilization of these other devices can be very effective as far as going ahead and morning pressures, and if one was to go ahead and eliminate them, I think it's being a big disservice to a big population of our patients that could be very effectively treated by these other modalities.

So, my request is to ensure that Medicare beneficiaries and clinicians in the CGS jurisdiction continue to have access to these effective mix options that improve healthcare options. Thank you very much for your time.

### Raymond Kong (1:10:36)

First, I would like to thank the CGS medical directors, CAC members and staff for the opportunity to present in today's meeting. I do appreciate the opportunity to not only represent New World Medical but also the ophthalmology community and ultimately the patients which we all serve who benefits most from these technologies and procedures.

My name is Raymond Kong and I serve as the Chief Commercial Officer of New World Medical and in the spirit of full disclosure, one of our flagship products, the Kahook Dual Blade will be referenced in my presentation today.

Today I'd like to share our perspective on the proposed MIGS draft LCD. I know that other presenters of have already spoken broader about other procedures and so my comments will focus solely on the goniotomy procedure and specifically excisional goniotomy with the Kahook Dual Blade.

In the interest of time, I think we're all familiar now, so we'll go ahead and skip this slide as well.

Before we get into the key points, it's important to share just a quick overview of the product that I will be discussing. The Kahook Dual Blade, I think the medical director initially made a very

good point regarding the difference in pathology between pediatric and adult glaucomas, and we've certainly seen significant advances in techniques as well as technologies over the last 10 years and the KDB is one of those.

This device is designed to do a complete excision of the disease trabecular meshwork.

Unlike the procedures that we had seen with pediatric glaucoma, which involved incisions off the trabecular meshwork and the studies that I will reference today are all relative to Excisional Goniotomy performed in adult patients.

To begin my first point, the draft LCD cites incomplete evidence for goniotomy which we believe 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 94 peer reviewed publications on Excisional Goniotomy alone, including the existence of a Level 1 randomized clinical trial.

The draft LCD sites, only a sliver of the clinical evidence related to GONIOTOMY and the citations, includes a listing of multiple studies with different goniotomy procedures and or devices. This listing shows both the commingling of different procedures and devices, as well as the age of the references, which certainly impacted the conclusions that were drawn by the LCD.

The age of these references in particular are important, considering that the Kahook Dual Blade device was launched in 2015, and this body of evidence continues to grow.

I did the same presentation three weeks ago to the WPS Medical directors where we had at that time 88 peer reviewed publications and today three weeks later, we were over 94. So we continue to see new publications being introduced in the in the literature.

I won't spend a lot of time here because Dr. Chu is already presented this as part of the AAO and AGS presentation, but this really highlights my second point, which is the availability of a prospective multicenter randomized clinical trial comparing the Kahook dual blade during cataract surgery to the eye stent during cataract surgery.

And it's important to emphasize here that the comparator, the eye stent, trabecular meshwork stent, is being covered by the current Proposed LCD.

The results, as already explained by Dr. Chu, you can see at 12 months 93.7% of eyes that underwent goniotomy with the Kahook dual blade met the success criteria versus only 83% of the eye stent arm, and again, this was deemed to be clinically significant.

This evidence, by the way, was published in one of the most prestigious journals in ophthalmology, that is the Journal of Cataract and Refractive Surgery, and so although it was a company sponsored trial, was well accepted by very prestigious journal.

The next four slides are a listing of all available data on excisional goniotomy, which I previously noted there to be over 94 today. I urge the medical directors to review some of the most updated data we have provided this to you in a letter with a listing of all of these, all of these available data, and I urge you to review these prior to drawing your conclusions on the safety and efficacy of this procedure.

And we can go ahead and skip the slide 11, I believe as this is just the continued listing of all of the available literature that's out there.

Now moving to my third Point, we believe goniotomy is well accepted as you've heard so far by all of the ophthalmologists that have either written letters or spoken today.

What we're looking at here on this slide is an industry report conducted by market scope, a very well recognized market research up thermology market research group and ophthalmology, and you can see here that non-implant procedures such as goniotomy and canaloplasty continue to gain in popularity, providing significant benefits to more patients.

I believe there was an error in the LCD mistakenly citing a decrease in trabeculectomy procedures when referencing goniotomy's and you can see here that goniotomy procedures continue to grow in popularity.

Looking at Q1 2023, total MIGS procedures were split almost evenly, very consistent with what Dr. Chu just stayed in in his own practice between implants, being eye stent, Hydrus, and non-implant MIGS, IE canaloplasty, goniotomy and other procedures showing a 55-45% split which shows significant surgeon acceptance and adoption.

I would argue that a procedure that was considered investigational would not have this level of adoption from well-respected surgeons who have all taken an oath to do what is in the best interest of their patients.

The Goniotomy is well accepted. We've talked about that already by the societies, and even in your own Palmetto CAC meeting, there were significant support from surgeons on the need for multiple options for patients.

So in summary, I'd like to we'd like to ask the MAC to consider goniotomy as a covered procedure. We believe Goniotomy is neither investigational nor experimental based on the broad level of evidence. There are 94 clinical peer reviewed publications available, and we urge you to look at all of those, including our RCT data.

We're well accepted by the societies and finally a non-coverage decision would increase CMS expenditures as well as the financial burden on Medicare beneficiaries based on the increase in copays for stent-based procedures. Thank you very much for your time and we appreciate your consideration for our procedure.

### Dr. Douglas Rhee (1:20:32)

I'd like to start by thanking you guys, the LCD group and the MAC to solicit comments. So, my name is Douglas Rhee. I'm a professor and chair of the Department at University Hospitals in Cleveland Ohio and Case Western Reserve University School of Medicine. I'm also the immediate past president of the American Society of Cataract and Refractive Surgery. I have over 2 decades of experience, and I've been in practice prior to when MIGS procedures were developed and where we are today.

I'm here representing our patients and your beneficiaries, and I will stick to the slides and kind of go through them. But I believe that we all wake up wanting to do good for the people that we have the responsibility and the privilege of caring for and protecting.

And I will just say that in large summary that the policies proposed in this LCD will not help people. It will probably do the opposite of that, so let me go into sort of the why that may be.

When you say patients with glaucoma, it's a wide spectrum. Even if you just restrict it to open angle, they can be complex or high-risk glaucoma cases, rare clinical syndromes, as well as the more common forms and early-stage disease.

Our surgeons employ a range of surgical procedures, selection of appropriate treatment is based on physician discretion and must be patient specific to treat their underlying condition and optimize their individual quality of life, and it's very difficult to say one size fits all because it doesn't.

There is a higher prevalence of glaucoma in persons of Latin and African ancestries, and persons of African ancestry are more likely to go blind from glaucoma even after controlling for social determinants of health.

So lowering intraocular pressure is the only modifiable risk factor to control glaucoma progression and I do want to urge the MAC and the LCD team to understand that the evidence that controlling intraocular pressure is beneficial for glaucoma and prolonging vision is extraordinarily strong. And so, when you have medications or lasers or surgical procedures and germane to this is the MIGs procedures that lower intraocular pressure, you are making a positive impact on the patient’s quality of life as well as their disease progression.

Half of all people with glaucoma will eventually require incisional surgery, so in that other half, we're just talking meds and lasers, but half of them over 20-year period will go on to develop the need for surgical intervention.

Procedure utilization data validates that all procedures identified within this LCD are beneficial and are widely used, and my prior speakers have done a wonderful job summarizing literature and even some incredibly technical aspects of the condition and the treatments.

So, the patient access implications of the proposed LCD policy changes are very significant. Surgeons will have to go to trabeculectomy in tube shunts much faster, and while these two procedures have been shown to be highly effective in level one evidence, but these very same studies demonstrate higher rates of immediate and long-term side effects and complications compared to these MIGS to devices and procedures. Trabeculectomy and tubes on patients have lower quality of life scores and I think I'm hopeful that this LCD would likely consider that it would have a disproportionate effect on traditionally disenfranchised groups of people.

So in conclusion, I urge CGS to please ensure that patients continue to have access to effective glaucoma treatment options that are necessary to treat their disease. Medically necessary MIGS procedures identified within this LCD should be covered consistent with the technologies FDA indication. You have a critical job as you consider whether to classify these as experimental or not. The evidence is there, it's been presented, you have some of it. What you didn't have the opportunity to look at has been well presented by my prior speakers and

in some cases the companies that that they represent, but I'd urge you to continue to give our surgeons and our patients access to these procedures which are very beneficial to the disease progression and very importantly to their quality of life. Thank you very much for allowing me to speak.

### Dr. Loveless (1:25:55)

Thank you for your presentation and we're going turn things over to Dr. Mackey.

But because we're at the original time and we do plan to go over to complete our presentations, I do want to remind all of our speakers and all of our participants on the call to submit their comments in writing and accompany that with the PDF's of the peer reviewed publications for any literature that that was not referenced in the LCD and now I'll turn things over to Dr Mackey.

### Dr. Mackey (1:26:46)

Alright, fantastic. Thank you, my name is Dr Mackey.

I live in a rural area in Kentucky, so I guess from a different perspective.

I live about 80 miles from a tertiary care academic center in in a very poor, socioeconomically region of the country.

So here this is the summary of my practice. I've been using many different MIGs procedures over the years. I see a ton of glaucoma down here and I end up practicing and treating a ton of glaucoma. There's just not a glaucoma specialist near us, and MIGS has been a really a godsend since it's come around.

Obviously, and I haven't been on the meeting, I've been seeing patients, but I don't know if some of this is repetitive, but you know the great thing about MIGS is it covers a lot of different severities of glaucoma, and we see a lot of that in rural Kentucky. So, you can use MIGS, and I'll show you a couple of examples later in a lot of different scenarios. So, it makes it a really, really, really nice group of procedures.

So yeah, this LCD, when I heard about it, I think would be devastating for my patients.

I perform my first external canaloplasty over 10 years ago and I just don't understand the whole experimental thing. I've probably performed over 100, at least of these.

Goniotomy's were approved by the FDA, I think based on very solid evidence and from what I saw in an earlier presentation, I think all that's been covered, but I'm going to give you some anecdotes to kind of show that these studies are real and this these things affect real people. So, I would just request that my patients have access to these things because they are sight saving.

So I could have probably listed five or six slides almost off the top of my head, but this is a couple of examples. This 93-year-old gentleman had multiple laser procedures, prior cataract surgery and he was on 3 glaucoma drops. His lowest pressure was 25 on the three medicines and he was obviously losing vision based on OCT and visual field studies. He was 93, he's in good shape at 93, but he didn't want to go through the major glaucoma procedure and so I told them we could try a goniotomy procedure because you know goniotomy was approved for outside of cataract surgery. And so, I thought if I really didn't know if it would have a big effect on this much older gentleman, but I was shocked. We performed the goniotomy and his pressure and vision are stabilized. He's at pressure of 14 for months after the procedure, so on 3 medications, he was 25, and after a goniotomy he was fourteen. And he sustained that pressure, I think it's been about a year now.

Another 73-year-old female with pressures of 32 and 22 on multiple meds, gradually worsening vision had already had cataract surgery years prior. We did canaloplasty last year and her vision has since stabilized, and pressures are at 11 and 9.

You know, these procedures really work on real people, and they save vision over time, and this is just a couple of examples I could give you more.

Drops don't always work, a lot my patients obviously as well don't like to use drops, can't use drops. You get a patient older with Rheumatoid arthritis and asked them to put drops in their eye and that not a good formula for success. Long term medication use is just challenging, especially where I practice it.

It's very important to have a standalone MIGS option for patients without concomitant cataract surgery and this Ab interno stuff with goniotomy canaloplasty is just much less invasive than other surgical options.

You know there are absolutely benefits of 360 canaloplasty+trabeculotomy and you know OMNI comprehensively treats that out for all the resistant outflows.

There's some clinical evidence, I think this has been gone over before, so I don't want to be redundant but there a lot of literature out there to support and the FDA approval for these procedures and their efficacy.

So to summarize we need this, I mean patients need this, people with glaucoma need these procedures, this is going to be devastating to real people with real glaucoma, and I would strongly recommend that you reconsider this draft policy not to preserve the coverage of OMNI and a lot of other MIGS procedures.

### Dr. Loveless (1:32:28)

Thank you and thanks for all of our MIGs presenters for taking time out of their busy schedules to present and share this information with us today and we'll look forward to the comments and publications, and I'm going to turn things over to our final two presenters. The first will be Dr Goldberg and so Doctor Goldberg, the floor is yours.

### Dr. Goldberg (1:32:52)

I just want to first thank the CGS for the opportunity to speak at this public meeting here today. My name is Dr. Matthew Goldberg. I'm a senior vice president of medical at Castle Biosciences, where I'm an employee and shareholder. We understand that as part of the MolDX, Palmetto GBA has drafted the policy that I'll speak about today, the DL39585 and my comments this afternoon on behalf of Castle are to raise your awareness to significant flaws and limitations within the LCD's that you can make sure they are addressed in the finalized LCD. The decision DX gene expression profile test, or GEP, has met criteria of medical reasonableness and accessory for Medicare coverage and should be included therefore, as covered test, in the final policy, please skip ahead to slide three.

The draft LCD contains statements that reflect an incomplete understanding for how high-risk SCCs or squamous cell carcinomas are managed today, and multiple inaccuracies that invalidate the conclusions of the draft policy. At a high level, it's critically important to note that the test should be used with available staging and risk assessment systems and does not replace these approaches as it suggests in the LCD. The draft LCD also demonstrates misunderstanding of adjuvant radiation therapy or ART, which is indicated for patients who have a high risk of SCC metastasis with a demonstrated improvement in their health outcomes. So, this presentation will focus on the perspective of clinicians treating patients with SCC today with a focus on ART and decision to SCC clinical utility evidence. Please skip ahead to slide six, please.

In an independent validation study for the decision Dx-SCC test within a group of 420 patients with cutaneous SCC and one or more risk factors. The test identifies 3 discrete risk groups, class 1, 2A and 2B, and what is consistent across validation analysis, class 1 results are associated with half the risk of the tasks as the overall cohort and the class 2B result is associated with nearly three times the risk as the overall cohort. This full decrease in increased respectively in risk compared to baseline is consistent across validation cohorts in various subset analysis. Please skip ahead to slide eight.

Decision-DX-SCC validation studies have shown comparisons to every current clinical and pathologic based risk stratification approach. The Kaplan Meyer curve shown here demonstrate how DecisionDX-SCC stratifies risk within the NCCN high risk and very high-risk patient groups adding information to current NCCN risk assessments.

In multivariate analysis, with all other staging systems, DecisionDX-SCC provides independent prognostic information. The Class 2A and Class 2B results are statistically independent of the metastatic risk described in each of these risk stratification approaches. The assertion and 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 published clinical validity data.

Please skip ahead to slide 11. Here in this arrow chart on the left from Ibrahim et al, all the DecisionDx test provides stratification within the Briggman women's staging system, again emphasizing that the published clinical validation of the test is to enhance the accuracy of staging but does not replace staging approaches. The prospective multicenter clinical utility study from Salibi et al. demonstrates that DecisionDx-SCC leads to a change in management in 24% of tested patients comparable to other Medicare covered molecular tests for cancer patients and when focusing on ART decisions specifically, the bar graphs on the right from the Hooper et al. clinical utility study confirmed that clinician management changes are not made in

a vacuum, but in the context of the clinical and pathologic risk factors in each real-world case. This analysis from Hooper et al. was not included in the LCD draft. Next slide, please.

So based on broad management strategies for high-risk SCC patients, ART can be recommended or considered as a therapeutic intervention for all patients in our intended use population and ART is covered by Medicare for these patients. This is a costly and morbid treatment and there is a need to better identify patients most likely to benefit from ART that balances the risk benefit ratio for each patient. Next slide please.

Another study, not referenced or considered in the draft LCD from Ruiz et al. is highly relevant for this discussion and demonstrates that art is associated with a 50% production of poor outcomes in patients with a high risk of SCC disease progression.

The study demonstrates that ART is beneficial in patients with elevated metastatic risk, as shown in the three Kaplan Meyer curves on this slide. Hoover also concluded that the benefit of art is greatest in cohorts with the highest risk of a test is the Kaplan Meyer curve in the center of the figure, and that there is a need for improved or stratification in the Kaplan Meyer curve on the right, which includes patients within the intended use population for the DecisionDX-SCC test. Next slide please.

While all high-risk SCC patients are considered for eligible for Azure radiation therapy.

TBB? patients are considered to have enough risk at the? to strongly recommend ART. Because Decision Dx-SCC provides independent risk stratification.

The addition of GEP results can identify patient populations not found by clinical and pathologic factors alone that have similar or higher risk of metastasis to TTP patients. Addition of GEP? can also identify patients with a significantly lower risk of metastasis across all stages of tumors seen here in the bar graphs on the right in red and on the left in green. Let's skip ahead to slide 16.

Yep, in a match cohort analysis in a combined cohort of 954 patients, all eligible for consideration of art based on guidelines, when looking at the class 2B graph on the right, ART is associated with a marked reduction in metastasis assigned by the blue curve on the bottom right and if you put this ART discussion together, the ART is known to improve patient outcomes when directed to patients with the highest risk of metastasis, and for high risk SCC clinical and pathological risk factors alone are insufficient to guide ART decision making accurately, and the DecisionDX-SCC test provides clinically actionable risk stratification information that identifies SCC patients in any stage.

You can be considered for any benefit from ART. Next slide, please to slide 18.

For prognostic tests, clinical utility is demonstrated by improving at risk stratification that informs proven treatment modalities similar to GEP tests with positive Medicare coverage and prostate and breast cancer and DecisioDX is clearly met this level of evidence. Lastly, if you can move ahead 2 slides, please.

So, in conclusion, the draft LCD should take into consideration how high-risk SCC is currently managed. The draft LCD should take into consideration how high-risk SCC is currently managed in the US where clinicians treating SCC or skin cancer experts adapted, incorporating multiple clinical pathologic and now genetic risk factors to inform risk online treatment plans.

Finally, the broad clinical adoption of DecisionDx-SCC stands in stark contrast to the analysis of evidence contained in the draft LCD DL39589. Over 3600 clinicians experienced in treating patients with high-risk SCC have determined the Decision DX-SCC is medically reasonable and necessary for more than 7000 patients with SCC and were more risk factors to inform their management decisions.

We therefore urge CGS medical directors to work with Palmetto CMDs to reconsider the rationale for determination and finalize the LCD with positive coverage of Decision Dx-SCC. DecisionDx-SCC can be used to guide ART decisions that have a proven impact on health outcomes for patients with a high risk of regional and distant metastasis and therefore the improvement and accuracy of risk stratification for patients with SCC has inherent improvement in patient outcomes as this directs those with a high risk of metastasis to a therapy known to improve outcomes. Again, I appreciate your attention today and the opportunity to provide these comments.

### Dr. Loveless (1:40:17)

Thank you for your presentation.

And I'll turn the floor to our final presenter, Robert Cook.

## Dr. Cook (1:41:13)

Terrific. Thank you. Thank you all very much for the opportunity to present our comments about LCD DL39585. My name is Bob Cook. I'm the senior vice president of research and development with Castle Biosciences. As Dr. Goldberg reviewed DecisionDX-SCC as a prognostic gene expression profile test, or GEP that can provide independent information about the likelihood of a cutaneous squamous cell carcinoma tumor to metastasize regionally or distantly in patients with a high-risk feature for that disease progression, as defined by the NCCN criteria. Next slide please.

One goal for this presentation is to provide insights about the test, validation, and statistical approaches to clarify inaccuracies in the LCD regarding the performance of DecisionDx-SCC. These statements suggest that the alignment with clinical features negates the prognostic information provided by DecisionDx-SSC. In fact, it would be concerning if validation studies demonstrated a dramatic difference from previously identified and validated risk factors. We will submit these responses as written comments, but in the interest of time, I'm going to skip this section and move to slide 7 for the request for additional validations for the LCD that support clinical actionability and validation criteria, if we could skip to slide seven, please.

With slide seven, I'll address the first analysis that was requested within the LCD and demonstrate that DecisionDx-SSC value in the context of available high risk clinical factors using a multivariable model. Results from the request to modify the multivariable model to include tumor diameter perineural invasion of greater than .1 millimeter and tumor location are shown in the table on the right side of the slide.

Columns labeled without GEP indicate that tumor thickness, diameter, differentiation, location on the head and neck, and immunosuppression are all associated with a higher risk of metastasis for these patients as indicated by the significant P value of less than 0.05. In the columns labeled with GRP, we have done that same analysis, but have included DecisionDx-SSC results as a variable while the same clinical factors continue to provide prognostic value, so that the Class 2 and Class 2B results are significant contributors to the multivariable model, and importantly the Class 2B result is associated with the highest risk of metastasis over 6 fold of all those factors evaluated. So it should be noted that a patient who is tested due to the presence of one of the clinical factors listed would have their risk multiplied by a factor of 2.41 if they receive a class 2A result and by a factor of 6.22 if they have a Class 2B result What that means is that the risk of metastasis for a tumor that was tested due to the presence of poor differentiation, for example, and subsequently received a class 2B result, has a metastasis risk 16 times greater than a tumor with no concerning features. Next slide, please.

So, I'd like to next demonstrate that risk stratification by the DecisionDx-SSC test occurs across all BWH stages that bring in them women's staging system. In general, BWH stage T1 tumors are thought to have a low risk of metastasis because there's no evidence of for clinical factors that contribute to BWH staging, which are diameter greater than or equal to 2 millimeters for differentiation invasion below the subcutaneous fat and paranormal invasion. In this population of 200 patients reported in Ebrahim ET al. who all had T1 tumors, 19 patients had a recurrence or metastasis, which reflected in NPV or negative predictive value of 91% and then event rate of 9.5%.

Layering the results from DecisionDxSCC testing on top of the Brigham and women staging allows clinicians to identify a low risk class one group in the 2nd row with a metastasis rate of only 3.3 3% compared to class 2A and class 2B rates of 18.2% and 44.4%.

These are significant adjustments for cohort that would be deemed low risk according to this staging system and notice also the improved NPV of 96% when including GGP results. Next slide please.

Similar evaluation BWH T2A and T2B stages also reflect important risk stratification following GEP testing. T2A tumors on this slide have an elevated risk within the context of BWH staging because they're characterized by one of the risk factors that I listed earlier. Within this cohort, the overall event rate is 15.2%, but we can identify class one patient with an event rate of 9.3% compared to Class 2 or Class 2A or 2B patients with significantly different event rates of 22% and 42.9%. Next slide please.

Finally, the same risk stratification can be observed when adding DecisionDx-SSC test results to Brigham and Women's stage T2B clinical results, and again here the Class 1 patient has very low risk profile compared to Class 2A and 2B patients who weren't intensified management protocols to monitor for or treat metastatic disease. Next slide.

In conclusion, I've shown results from an expanded multivariable analysis performed as requested within this LCD and those results demonstrate independent risk prediction by the

test. I've also shown that the test result provides meaningful information that identifies levels of risk consistent with higher and lower BWH stages, which is clinically actionable and informs the demonstrated clinical utility of the test result. And just in final closing, based on these and other published data, DecisionDx-SCC, we believe meets the standards established for medical reasonableness and necessity and supports coverage of the DecisionDx-SSC test and incorporation to the LCD prior to its finalization. So, thank you very much for your time.

### Dr. Loveless (1:48:21)

Thank you very much for your presentation. I wanted once again thank all of our presenters for the time and education we feel this is a very important step in LCD process to ensure that we hear from providers and stakeholders and this meeting will be transcribed and recorded for transparency.

This is the process for comment submission. Our preferred method is to utilize our online comment form that can be submitted to the email address CMD.Inquiry@cgsadmin.com that's located on the website with the information on comments as well, they can also be faxed or mailed and on the next slide it just directs you to where on our website the comments go. Draft LCD Comment Submission Form (A/B MAC Jurisdiction 15) (cgsmedicare.com) The most effective way to utilize comments is to provide PDF copies of the literature and provide supporting literature for your comments because policies are required to be evidence based, it is most important that that we have the literature to accompany the comments for the most effective results of comments that are submitted. We cannot accept publications that are or literature that is not yet published. That includes literature that has been submitted but not accepted. If it has been accepted, then we can look at that, but we cannot take anything that's does not peer reviewed published. We cannot consider abstracts and so that I think we have one final slide. I think that we conclude our meeting today and we thank everybody for your attention.