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National Government Services, Inc.

Moderator: Dr. Ola Awodele

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12:00 p.m. CT 1:00 ET

Coordinator: Welcome and thank you for standing by. At this time all participants are in a listen-only mode until the public comment section of today's conference.

I would like to inform all parties that today's conference is being recorded. If you have any objections, you may disconnect at this time. I would now like to turn the conference over to Dr. Awodele. Thank you. You may begin.

Dr. Olatokunbo Awodele: Thank you. Good afternoon. My name is Dr. Olatokunbo Awodele, and I'm one of the contractor medical directors at National Government Services. I'd like to welcome you to our proposed local coverage determination open meeting today, July 13, 2023.

The purpose of this meeting is to give you an opportunity to provide input into the development of proposed local coverage determinations. These local coverage proposed policies must be based on published evidence as required by the 21st Century Cures Act.

Today's meeting will be conducted in accordance with the guidelines established by the Centers for Medicare and Medicaid Services. The process will be as follows.

The meeting is an open forum for receipt of your comments regarding only the proposed policies. Please be assured that all comments provided will be considered by the medical directors in the policy development process.

Please state your name, affiliation and disclose any conflict of interest before speaking. And finally, all written materials related to your comments must be submitted to partblcdcomments@anthem.com or LCD Comments, P.O. Box 7108, Indianapolis, Indiana 46207-7108 or by clicking on the public comments block, which is located on the top left-hand corner of the proposed LCD on the Medicare coverage database.

The official comment period extends from June 22, 2023, which is when the drafts were made available online, through August 5, 2023 for amniotic, UDT and MIGS. For transesophageal, the comment period ends on August 12, 2023. Your comments are most welcome.

Today, we have four policies, or draft policies, to present. The first is DL39139, and it's titled, Amniotic and Placental Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound. The second one is DL39611, titled, Urine Drug Testing. The third is DL33579, titled, Transesophageal Echocardiography, also known as TEE for short. And the last, but not the least, is DL37244, titled, Microinvasive Glaucoma Surgery, also called MIGS, for short.

We are honored to have six speakers today who will comment on MIGS. No speakers have registered for the other three proposed LCDs. Given the number of registered speakers and the tight schedule, we can only allow 10 minutes per presentation.

Therefore, in the interest of time, if you have similar comments as the previous speaker, please only speak to the unique comments. Thank you for understanding.

So, moving right along, we'll receive comments on the proposed policies. Please introduce yourselves and note any conflict of interest. So the first policy that we have is DL39139, Amniotic and Placental Derived Product Injections and/or Applications for Musculoskeletal Indications, Non-Wound.

This LCD is a non-coverage policy for all amniotic membrane, amniotic fluid or other placental-derived product injections and/or applications as

a means of managing musculoskeletal injuries, joint conditions and all other conditions not stated in the LCD.

The LCD guidance does not include burns, wounds or ophthalmic conditions. Due to the paucity of randomized controlled trials, poor study design, small sample sizes, lack of comparators, lack of long-term efficacy and safety data and high risk of bias in the current body of literature, there is insufficient evidence to demonstrate the efficacy of any amniotic and placental-derived product in the treatment of specific musculoskeletal conditions, whether injected or applied intraoperatively.

In addition, there is lack of knowledge of intermediate or long-term safety data derived from human clinical trials. There is insufficient evidence-based literature to support coverage of amniotic and non-amniotic placental -derived products injected or applied both non-operatively and intraoperatively to treat musculoskeletal conditions or pain-related to said conditions and any other conditions that is not burn, wound or ophthalmic treatment.

So I will now, like I said earlier, there were no registered speakers for this draft. So we'll now call on the attendees. So, operator, are there any comments from anyone who has called in?

Coordinator: I'm showing no comments so far.

Dr. Olatokunbo Awodele: So as there are no further comments being offered today, comments related to DL39139 are now closed, and I will hand over to Dr. Boren for the next couple of LCDs. Dr. Boren?

Dr. Stephen Boren: Thank you very much, Dr. Awodele. My name is Dr. Stephen Boren. I'm also a medical director here at National Government Services.

The policy we're discussing now is DL39611, Urine Drug Testing. This is quite similar to a previous urine drug testing policy. The policy details, the appropriate indications and allowed number of urine drug testings built over time for safe medication management of prescribed substances in a risk-stratified pain management patient and/or in identifying and treating substance use disorders.

It designates documentation by a clinician taking care of the beneficiary in the beneficiary's medical record of medical necessity for and testing ordered on individual patient basis. It provides an overall view of presumptive urine drug testing and definitive drug testing by various methodologicals.

We do not have - well, I will add this is revised as part of the collaborative process for consistency and clarity in the coverage across all MACs. The urine drug testing changes in DL39611 in billing coding article. The parent drug and metabolite charts has been deleted. CPT codes G0482 and G0483 have been added to the billing and coding article.

Dr. Olatokunbo Awodele: Operator, can you open up the floor for comments?

Coordinator: Please press star 1 if you'd like to make a comment.

Dr. Stephen Boren: There are no comments. Is that correct?

Coordinator: I'm showing no comments.

Dr. Stephen Boren: Okay. Well then we will close the discussion on this and go on to the next draft policy. Thank you.

The next draft policy is also a policy of mine. This is DL33397, transesophageal echocardiogram, TEE. It's a reconsideration request.

Intraoperative TEE can be considered medically necessary when performed by a qualified cardiologist, cardiac surgeon, anesthesiologist or other physician, but only when performed as a diagnostic test, not for monitoring purposes.

We have no speakers who have signed in for this to speak. Operator, do we have anyone online who wants to speak on this?

Coordinator: I'm showing no comments.

Dr. Stephen Boren: Okay. Well thank you very much. And the comment discussion on this policy is now closed. Thank you.

Dr. Olatokunbo Awodele: Thank you. We'll now hand over to Dr. Noel for the next draft policy.

Dr. Ella Noel: Good afternoon. I'm Dr. Ella Noel. I'm one of the CMDs at NGS, and I would like to present the collaborative draft policy on MIG. It's DL37244, microinvasive glaucoma surgery.

This was prompted by the receipt of two reconsideration requests. The proposed local coverage determination and billing and coding article were revised to reflect an update to the existing policy based on new technologies for minimally invasive glaucoma surgery.

Next slide. The Contractor Advisory Committee meeting on microinvasive glaucoma surgery was held on January 5 of this year, hosted by Palmetto, CGS, NGS, Noridian and WPS. Transcripts are available at jurisdiction J, Part A, Multi-Jurisdictional Microinvasive Glaucoma Surgery Contractor Advisory Committee meeting with the date of January 5, 2023, at the Palmetto GBA website.

Next slide. NGS considers one iStent, iStent inject, iStent inject W or Hydrus device per eye medically reasonable and necessary for the treatment of adults with mild or moderate open-angle glaucoma and a cataract when the individual is currently being treated with an ocular hypotensive medication and the procedure is being performed in conjunction with cataract surgery.

Next slide. One XEN45 device per eye is covered for the management of refractory glaucoma, defined as prior failure of a filtering or cilioablative procedure and/or uncontrolled intraocular pressure, defined as progressive damage and mean diurnal medication and intraocular pressure of 20 millimeters of mercury on maximally tolerated medical therapy.

The XEN45 insertion must be performed by an ophthalmologist with experience with trabeculectomy and bleb management.

Next slide, the iStent Infinite device receives 510k clearance with an indication for use to reduce the intraocular pressure of the eye for adult patients with primary open-angle glaucoma and it is considered reasonable and necessary to be performed in conjunction with cataract

surgery or as a standalone procedure in whom previous medical and surgical treatment has failed.

Next slide. The following were considered investigational in patients over the age of 18 for glaucoma management and I will let you look at the list. And to save time for people to comment, we will not read through this list at this time.

Next slide. We will now have our first speaker start. As a reminder, you are allowed 10 minutes to speak. I will try to warn you 15 to 30 seconds before your time is up to summarize so that the next speaker has an opportunity to talk.

We're going to start with Rick Fiscella, PharmD, master's in public health. Rick, please present. Is Rick on the line? Can someone please open up Rick's line? I see he is in attendance.

Dr. Rick Fiscella: Hi.

Dr. Ella Noel: Hi, Rick. Thank you. Go ahead and start.

Dr. Rick Fiscella: Okay, thank you. Hi. My name is Rick Fiscella. I am the Director of Medical Payer Strategy for Ophthalmology at AbbVie. I wanted to comment on the proposed LCD. I am also by the way a full-time employee of Allergan.

Next slide, please. And the one right after this, please. On behalf of Allergan and AbbVie Company, the manufacturer of the XEN Glaucoma Treatment System, thanks for the opportunity to provide comments on the proposed LCD.

And we respectfully thank you also for one more consideration for a single word change in the component. It mentions there one XEN45 (ricin) infinite device per eye covered management of refractory glaucoma, defined as prior failure of filtering or cilioablative procedure.

And you highlighted the and/or, uncontrolled intraocular pressure, defined as progressive damage. And we would suggest instead of and to replace that with or because it would be mean diurnal IOP more than 20 millimeters of mercury.

And the reason for this change, we'll explain in just a minute. But I wanted to explain that patients sometimes have progressive damage with intraocular pressures less than 20 millimeters of mercury. By the way, this statement in your proposed LCD also has similar language not only on page four, but also on page 13.

Next slide, please. Clarification of refractory glaucoma and its implications within clinical practice. According to the American Glaucoma Society and their MIGS position paper, I just wanted to mention in the first one, maximally tolerated medical therapy and refractory glaucoma are ambiguous terms.

They may be confusing, especially when integrated into clinical practice guidelines and/or policy statements. And in particular, refractory glaucoma is simply glaucoma that is difficult to treat and poorly controlled by current therapy.

This really does not mean a specific intraocular pressure has to be more than 20 millimeters of mercury. And in fact this often refers to a patient that is continuing to progress and not necessarily related to a specific IOP.

Next slide, please. I just wanted to mention, too, XEN publications include patients that are refractory, non-refractory and progressing based upon the clinical decision that further intervention was necessary to prevent detrimental long-term outcomes, namely sight loss and/or blindness.

And this is the really important aspect. Clinicians will make their decision not necessarily based upon just a specific intraocular pressure. And to give you some examples of that, the XEN45 gel stent has been implanted in many patients with moderate or severe glaucoma based upon the intraocular pressures less than 20 millimeters of mercury. And there are multiple references attached to this statement.

Also, comparative trials evaluating the clinical outcome, XEN was compared against trabeculectomy, which is often considered, obviously, the gold standard for glaucoma filtering surgery. Notable baseline

patient characteristics in these studies often include intraocular pressures less than 20 millimeters of mercury.

And a recent systematic review that was just published this year of XEN, including 59 various studies, reported an overall range of medicated baseline intraocular pressures between 15.3 and 36 millimeters of mercury.

And then another publication that was recently published this year again is a prospective randomized clinical trial where XEN was compared against a trabeculectomy. And in the baseline characteristics, they included intraocular pressures ranging from 15 to 44 millimeters of mercury.

So as you can see, many times these pressures are often less than 20 millimeters of mercury when it is judged by the clinician that the patient is progressing and needs an active intervention to prevent sight loss.

Last slide, please. Thank you again for the opportunity to provide comments on the proposed LCD. We respectfully submit for your consideration the request for the removal of and with the replacement of or from the statement, management of refractory glaucoma, defined as prior failure of filtering ciliobladed procedure and/or uncontrolled intraocular pressure defined as progressive damage or mean diurnal medicated IOP more than 20 millimeters of mercury.

We will be responding in writing and of course forwarding all the references that we have included in this discussion. Thank you again and more than willing to take some questions.

Dr. Ella Noel: We won't be asking any questions of you at this point in time. I appreciate the fact that you're going to be sending that to us in writing as well. And I thank you for your presentation.

Dr. Rick Fiscella: Thank you very much.

Dr. Ella Noel: You're very welcome, sir. May we have the next slide? Next, we have Geoffrey Emerick speaking to us from the University of Connecticut School

of Medicine. Please open up the line for him so he may start his presentation.

Dr. Geoffrey Emerick: Hello, good afternoon. Can you hear me?

Dr. Ella Noel: Good afternoon. Yes, I can hear you great.

Dr. Geoffrey Emerick: Great. So, hi, my name is Geoff Emerick and as mentioned I'm a glaucoma specialist in private practice in Connecticut. I have faculty appointments at UConn and the Yale School of Medicine.

And I'd like to thank the meeting organizers for the opportunity to present on this draft LCD which would limit Medicare beneficiaries' access to important glaucoma treatment options.

I'm speaking on behalf of the American Academy of Ophthalmology, the American Glaucoma Society and the American Society of Cataract and Refractive Surgery as we make this case that this determination would substantially impair our ability to care for patients with glaucoma, a chronic vision-threatening group of diseases and the leading cause of irreversible blindness in African Americans.

If you could go to the next slide, please. And then the next one. So I have no financial conflicts. I do volunteer with the EGS as the patient care committee chair.

Next slide, please. So patients with glaucoma require continual, often escalating therapy from diagnosis through the end of their lives. This is typically 15 years or more and in some cases decades. Eye drops are often used as first line therapy, but many patients have great difficulty in using them. And using multiple drops markedly decreases adherence and can cause additive side effects.

For each individual patient, a target pressure, below which progression of vision loss is not expected, defines his or her goals of care. And refractory glaucoma refers to intraocular pressure remaining above target despite the use of multiple medications or fewer when tolerability or effectiveness limits their use.

So this definition does not include an arbitrary pressure cutoff as Dr. Fiscella pointed out as many patients progress at pressures of less than 21. For patients who are progressing, or are likely to at their current pressure, a carefully tailored surgical treatment approach is often the best next step in saving their vision.

Next slide, please. A brief review of the surgical approaches addressed in the draft LCD will help frame the discussion. Goniotomy refers to incision, excision or cleavage of the trabecular meshwork, which overlies the canals of Schlemm, the eye's natural outflow pathway.

Goniotomy techniques include what was previously called ab interno trabeculectomy, using gonioscopic-assisted transluminal trabeculotomy or other devices and other techniques such as those listed.

Canaloplasty refers to dilation of the canal by cannulation or injection of viscoelastic. The listed techniques are among those used in this way.

Given the mention in the draft LCD of cyclophotocoagulation, or application of laser energy to the ciliary body, as well as mention of the CPT code for iridoplasty, which is application of energy to the peripheral iris, those definitions are also relevant.

Next slide, please. Goniotomy has been a mainstay in the management of glaucoma in young people for many decades. And goniotomy is also a necessary treatment for adults with glaucoma, as we have seen with over 20 years of clinical experience and strong clinical evidence.

Blood forming and external filtering surgeries 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 currently covered. Surgically, goniotomy does not require dissection of conjunctiva, which might be damaged or

scarred from chronic topical medications, systemic disease or prior surgery.

Lastly, angle surgery is often performed at the time of cataract removal, which on its own provides inadequate IOP reduction in the majority of glaucoma patients or may even cause a transient IOP spike and which lowers the success rate of simultaneously performed filtering surgery.

Next slide, please. We will highlight high-quality evidence supporting the use of goniotomy in adults as standard of care. A prospective randomized clinical trial comparing cataract removal by phacoemulsification plus goniotomy to phaco with trabecular bypass stenting was published in August 2020.

More phacogoniotomy eyes than phacostent eyes met the clinical 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. This result was statistically significant.

Next slide, please. 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.

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. Next slide, thanks. Canaloplasty has also been extensively studied in adults. And here we briefly touch on one study

which is 12 months results of a study of ab interno canaloplasty, or ABIC, and combined phaco ABIC.

Here blue bars represent preoperative eye pressures and orange bars eye pressures 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 were a bit puzzled by its inclusion in the draft LCD because this approach has been vision saving since the 1930s and its safety and applicability have been only improved with the introduction of endoscopic and micropulse delivery.

While it is used judiciously, typically as a treatment of last resort for eyes that are poor candidates for incisional surgery or who have limited visual potential, it is a very effective and important piece of our standard of care for glaucoma.

Next slide, please. In summary, patients with glaucoma, which disproportionately affects Black and Hispanic people, 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 riskier filtering procedures. For these patients, minimally invasive glaucoma surgery, like the angle-based procedures discussed today, preserve quality of life and reduce total cost 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.

We will follow up with more extensive written comments and PDFs of the relevant literature. Thanks very much for your time and attention.

Dr. Olatokunbo Awodele: Thank you very much for those comments.

Dr. Ella Noel: Oh, I'm sorry, I forgot to take myself off mute.

Dr. Olatokunbo Awodele: Okay. That's all right. Go ahead.

Dr. Ella Noel: Can we queue up the next presentation? And can we open up Raymond Kong's phone line so he may speak?

Raymond Kong: Hello. Can you hear me?

Dr. Ella Noel: Yes, I can. Go ahead and start.

Raymond Kong: All right. Great. Let me start by just thanking the NGS medical directors, CAC members and staff for the opportunity to present today. I appreciate this opportunity not only to represent New World Medical, but also the ophthalmology community and ultimately the patients we serve who benefit the most from these procedures and technologies that we're commenting on today.

My name is Raymond Kong, and I serve as the Chief Commercial Officer for New World Medical. In the spirit of full disclosure, one of our flagship products is the Kahook Dual Blade. And so I am representing and am employed by one of those companies whose products are used in the procedures being discussed.

Dr. Emerick just spoke broadly on a number of procedures under consideration, and I know there will be others. So my talk will focus solely on goniotomy procedure and excisional goniotomy with the Kahook Dual Blade.

Next slide, please. Next slide. Next slide, please. In the interest of time, we'll go ahead and skip over this slide as well, as I'm sure we're all familiar now with the procedure and the anatomy of the eye.

Next slide, please. Before getting into the key points, it's important to share with you a quick overview of the product that will be referenced in most of the clinical data being represented, that is the Kahook Dual Blade.

We've seen significant advances in techniques and technologies in the space over the past 10 years, and KDB is certainly one of those. The KDB is designed to perform a complete excision of the disease trabecular meshwork, providing access from the anterior chamber to the canal of Schlemm and distal collective channels.

This is an important distinction because it is unlike goniotomies using an MVR blade or other unsophisticated instruments like bent needles, which were used in some of the studies referenced in the LCD.

The studies and results referenced in my presentation will all be consistent with true excisional goniotomy performed to remove the trabecular meshwork in adult patients.

Next slide, please. To begin my first point, the draft LCD cites incomplete evidence for goniotomy, which in our opinion is neither experimental nor investigational. Goniotomy has been performed to treat glaucoma patients for over 80 years. The procedure's safety and efficacy has been exhaustively documented as evidenced by over 94 peer-reviewed publications on excisional goniotomy alone, including a level one randomized clinical trial just shared by Dr. Emerick.

The draft LCD cites only a sliver of the clinical evidence related to goniotomy, and these citations include a listing of multiple studies with different goniotomy procedures and/or devices. This listing shows a commingling of different procedures and devices as well as the age of the references, which we believe certainly impacted the conclusions that were drawn.

The body of evidence continues to grow even as we speak. Having done this presentation three weeks ago to another MAC, at that time there were 88 peer-reviewed publications, and today we're sitting on over 94.

Next slide, please. This is a study that was just referenced by Dr. Emerick, and so in the interest of time, we won't go over this completely, but I would like to stop to share three key points.

Number one, I would like to emphasize at this point that the comparator in this study was the iStent device, which is being proposed by the current NGS LCD for coverage.

The second point is the results of this level one study were published in the most prestigious journal of ophthalmology, that is the Journal of Cataract and Refractive Surgery.

And the final point related to this is that while we are being challenged on the need for RCT data for an 80-year-old procedure, we are not aware of existing RCT data for the iStent Infinite, which is being proposed by the MAC for coverage. To be clear, we are not challenging that decision. We're only asking that the MAC be consistent in evaluating goniotomy using the same standards.

Next slide, please. Again, this data was just shared by Dr. Emerick and you can see at 12 months, 93.7 % of the eyes in the goniotomy with KDB arm met the success criteria versus 83% from the iStent arm, which again was a statistically significant outcome.

Next slide, please. The next four slides are a listing of all available data on excisional goniotomy as I previously noted to be over 94. We have shared this listing with NGS, and we will be uploading a copy, a PDF copy, of each of these to the site.

In the interest of time, let's skip over the next three slides and get to Slide 11, please. Moving on to my next point, goniotomy is a well-accepted procedure, as we've heard, among ophthalmic surgeons in treating adult patients.

What you're looking at here is an industry report conducted by (Mark)et Scope, a well-recognized market research group in ophthalmology. What you can see is 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 speaking or referring to ab interno trabeculotomy procedure, a term often interchanged with goniotomy, as was just pointed out by Dr. Emerick in his presentation.

In looking at this data, you can see in Q1 2023, total MIGS procedures were split almost evenly between stent-based implants or stent-based procedures and non-implant-based procedures, 55% to 45%, which shows a significant adoption by surgeons.

I would argue that an investigational procedure, as termed by the MAC, would not have this level of adoption from well-respected surgeons who have taken an oath to do what is in the best interest of their patients.

Next slide, please. In addition to the real world acceptance data shown on the previous slide as well as clinical data shown, at a society level, goniotomies have also receive broad-based acceptance and support, which is my fourth point.

You mentioned earlier the Multi-Jurisdictional CAC meeting, which was held by Palmetto in January. And you can see some of the comments by the CAC members on this slide, which showed tremendous support for the need for goniotomy as well as multiple procedure options to be able to treat this terrible disease.

Next slide, please. In summary, goniotomy is neither experimental nor investigational as demonstrated by broad acceptance in numerous publications. There are over 94 peer-reviewed publications, including level one randomized clinical trial data demonstrating the safety and efficacy of goniotomy.

Goniotomy is approved and accepted in accordance with standards of medical practice and supported by major ophthalmic societies, including the ACRS, AAO and AGS.

And the final point is related to financial considerations. While I realize it is not a primary focus, there are financial implications of a non-coverage decision by the MAC. 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, neither will the associated risks of implant-based MIGS. These substitute PM stent procedures have a markedly higher facility fee in an ambulatory surgical center setting where a vast majority of ophthalmic procedures are performed.

By forcing care in this direction, a non-coverage decision would increase Medicare costs and the financial burden borne by beneficiaries in the form of co-pay.

We urge the MAC to please consider the level of evidence that we have provided, and we propose that you include goniotomy in adult patients, given the procedure's thoroughly documented track record for to enhance the lives of glaucoma patients. Thank you again for this opportunity to present.

Dr. Ella Noel: Thank you. We appreciate the presentation. Can we queue up the next speaker's presentation, please? Please open up Paul's line. I know he's in attendance so that he may start his presentation.

Paul Badawi: Hello. Can you hear me?

Dr. Ella Noel: Yes, I can. Please proceed.

Paul Badawi: Okay. First slide, please. All right. Well thanks to all of you in the NGC Medical Policy Unit for taking the time out of your busy schedules to learn about site sciences and our OMNI Surgical System Glaucoma Technology. My name is Paul Badawi, and I am a cofounder, president and CEO of Sight Sciences. Therefore I'm an employee and a shareholder.

I started Sight Sciences in 2006 with my brother, Dr. David Badawi, who's an ophthalmologist. Our goal was to develop better treatments for glaucoma. We wanted to make sure that patients never go blind from this disease.

And 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.

Next slide, please. We've 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 disease aqueous outflow pathway via an ab interno approach.

The technology allows surgeons to perform what has been referred to as two sequential and comprehensive outflow 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 patient's IOP varying significantly over a 24-hour period, which can also affect disease progression.

OMNI is a more complex procedure. It's harder to master and requires training to practice, but it's worth it for the differentiated efficacy it provides.

Next slide, please. 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 OMNI's 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.

Next slide, please. This slide intends to illustrate where MIGS fits into 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 involves stents and goniotomy. And these treatments work for some, but these surgeries target just one of the three sources of outflow resistance, the trabecular meshwork. Stents and 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 all three sources of outflow resistance and does so without leaving an implant behind.

For these and other reasons that I will address, the MAC 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.

Next slide, please. 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 OMNI's indication in March of 2021 based on its evaluation of clinical results from our ROMEO multi-center pivotal trial.

The American Academy of Ophthalmology identifies OMNI as a MIGS treatment in its preferred practice patterns. The AO has never hinted that more evidence was needed to demonstrate the clinical value of OMNI.

Next slide, please. While I appreciate your effort 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 results from the GEMINI study. The key point regarding the GEMINI study is we modeled the study protocol, patient criteria and success endpoints after the three implantable MIGS stent studies that had been 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. Briefly here, you can see the compelling clinical outcomes from the landmark GEMINI trial in almost 150 patients at 15 sites in the U.S. 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 pre-specified endpoint and success criteria based on the consistency of the cataract historical control. The results from GEMINI showed that OMNI met its success endpoints 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.

Next slide, please. Next slide, please. 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.

Next slide, please. We provided brief summaries of some additional peer-reviewed studies involving over 630 patient eyes. Within these publications are a variety of clinical data to capture OMNI's broad effectiveness and broad indications for use.

Next slide, please. Here is 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 effects have been identified.

And before closing, I want to point out that many private insurers cover MIGS and OMNI procedures. For example, Cigna very recently updated its MIGs policy to cover canaloplasty, both ab interno and ab externo 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 canaloplasty.

I would expect beneficiaries will be outraged if the MAC denies coverage for procedures like OMNI when the majority of private insurers are paying for this procedure. It certainly seems to create a significant disparity in access for Medicare beneficiaries.

Next slide, please.

Dr. Ella Noel: You have 30 seconds left to summarize.

Paul Badawi: I'm honored to work with surgeons that are working to better treat glaucoma and improve the lives of patients who suffer from this blinding disease. There's no better joy to myself and to our team working every day to improve and elevate the standard of care.

Last slide, please. In closing, we believe the full scope of the OMNI 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, for example, 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 AEO and CMS involving coding for OMNI. Thank you all for your time, interest and consideration of our mission and purpose at Sight Sciences. Thank you.

Dr. Ella Noel: Thank you, sir. Can we queue up the next speaker? And I know that the good doctor is available so go ahead and start, (Mark), whenever you're ready.

(Mark): Okay. Can you hear me?

Dr. Ella Noel: Yes, I can hear you great.

Dr. Mark Latina: All right. Thank you. Thank you, Dr. Noel. Yes. I'll proceed very quickly. I have a lot of slides, but I'm basically going to reiterate, I think, all the comments that were made today. I think this is more or less a review as well.

Next slide. As I am the inventor -- next slide -- I am actually the inventor of selective laser trabeculoplasty so I actually understand the importance of time to adopt technology as well as the importance of coverage.

Next slide. Basically I think I want to reiterate that medication compliance really remains the weakest link in glaucoma management -- next slide -- which is one of the reasons why we are performing more and more MIGS procedures.

As we see here, my point in this slide is that we have a stepped approach and really we want to avoid going to the next step. SLT was now being used as first-line therapy. In the past, it was always medications. We get up to the MIGS procedure. But the red line is really incisional surgery. We'd

like to try to avoid proceeding to incisional surgery, which is why I think the MIGS has become such an important tool in our armamentarium.

Next slide. This slide is from the Canadian Ophthalmology Society. My point here is that we've had multiple large-scale clinical trials looking at medications versus no treatment, medications versus various surgical treatments.

And the results of these studies show that basically we can try to reach a target IOP based on the severity of the eye disease. So our goal is to try to reach these IOP levels, but how do we achieve that?

Next slide. And this slide basically shows the IOP lowering efficacy in the horizontal axis and risks of the procedure on the vertical axis, cyclodestructive procedures being higher risk. Trabeculectomies, of course, being higher risk.

But the point is actually that none of our procedures, unlike cataract surgery, which is a very effective procedure and almost 99% success, none of our procedures have the success rate. They have a success rate of about 90%. So we need all the tools in our toolbox to be able to treat these patients.

Next slide. This is the AGS MIGS statement. But the point is that the outflow pathway accounts for 70 to 75% of the outflow resistance, which is why these procedures are employed to and are targeting this area of the anatomy. And the IDRIS and iStent studies actually confirmed that lowering these pressures does reduce the resistance.

And we would expect therefore these newer procedures such as canaloplasty and goniotomy, which likewise access the trabecular meshwork should give you similar results.

Next slide. So we disagree again that the procedures, goniotomy, canaloplasty and cyclophotocoagulation are investigational. I also sort of agree with Dr. Geoffrey Emerick that why is cyclophotocoagulation actually in this group? I do not consider it a mixed procedure.

Next slide. We were very concerned - next slide. We were very concerned about these statements that these procedures are not as effective as lowering pressure as traditional trabeculectomy and that there were a lack of studies comparing these procedures to medical management, et cetera.

No, can you go back one slide? Go back.

Anyway, I think the point is that we have these studies - the MIGs are not really designed to be compared to trabeculectomy and also that we have these large-scale studies looking at medical management so we know what target pressures we should achieve.

Next slide. Again, the coverage regarding iStent and iStent Infinite was discussed. Again, these are devices which remain in the outflow track, and there are other procedures, of course, such as the canaloplasty and goniotomy, which do not leave any devices in the outflow track.

Next slide. So again, as stated, not all these patients are candidates for every procedure, and I think that the surgeon should have access to not only devices which do require an implant but also implant-free options.

Next slide. As discussed, I think, you know, there was an incomplete analysis of the data as was shown by Dr. Badawi and Mr. Kong. That there are adequate studies that actually are similar to those which were already - for the approved iStent Infinite and the approved iStent.

Next slide. Again, showing that this is the KDB study. I don't think we need to go over that. But these studies, again, provide significant evidence that they are effective procedures.

Next slide. I think we're - next slide. A word about cyclophotocoagulation. This is probably actually the most important procedure we have believe it or not. Because without this procedure, it's indispensable in the management of our glaucoma patients, especially refractory to glaucoma and it actually complements other treatments and without this treatment, actually the - without this treatment, really, the option is really blindness.

Next slide. So this is the only procedure, actually, that we have to reduce aqueous production. And again, those patients, if it's considered not medically necessary, really the only option in these cases would be blindness.

Next slide. So we feel that these procedures - that the newer clinical evidence should be included in the analysis. And these procedures are now accepted as standard medical practice.

Next slide. As was said, you know, these procedures are well adopted and performed by thousands of surgeons nationwide. And actually, a note about canaloplasty, it's actually the only procedure that preserves the overall integrity of the outflow pathway to allow for additional procedures to be performed.

Next slide. As has been stated, commercial insurers have also determined that they are necessary and medically necessary in patients 18 years or older.

Next slide. This is an example of the coverage, which I won't go into. But, you know, they're considered medically necessary -- next slide -- for the reduction of intraocular pressure for an individual with glaucoma when performed using an FDA -approved device.

Next slide. So in summary, we feel the LCD in its current form should be revised or retracted. I think these procedures are reasonable and necessary and not investigational.

Again, cyclophotocoagulation may actually be our most important procedure and is really the most effective and only technology that we have available to treat these glaucomas difficult to manage.

And the literature really supports that these procedures are able to reduce IOP and meet or exceed those target IOP standards set forth by those studies in the Canadian Ophthalmology Society slide.

Next slide. So, in conclusion, again, I think if Medicare beneficiaries, especially blacks or Hispanics, are denied access, this is going to force

these patients to undergo higher risk procedures with higher morbidity and risk of vision loss. I think it would be very disruptive to the standard of care.

And as was said, considering the commercial coverage, this is going to create a disparity of access for the Medicare beneficiaries who actually require them the most.

And finally, for just one practical issue, I'm a Medicare beneficiary. Next slide. You know, as a Medicare beneficiary, I would be very concerned and potentially irritated that a procedure that I had last year, which was successful and covered, will now be considered investigational and not covered should I need the procedure in the other eye.

And I think that's going to erode confidence in the physicians, but it actually could also have potential significant legal implications. Thank you very much for the opportunity to speak.

Dr. Ella Noel: Thank you for your presentation. Can we bring up the next presenter's slides? And Dr. Lagouros, I hope I'm pronouncing your name correctly, is next.

Dr. Evan Lagouros: Yes. Can you hear me okay?

Dr. Ella Noel: Yes I can.

Dr. Evan Lagouros: Okay. My name is Dr. Lagouros. I practice in Peoria, Illinois, and I'm representing our practice, Illinois Eye Center and Sight Sciences.

Next slide, please. And next slide, please. So I have not received any financial support. I am on the review board for AbbVie, the maker of the XEN Gel Stents and also a paid consultant for New World Medical, the maker of KDB and STREAMLINE.

Next slide, please. So our practice is a multi-ophthalmology and optometry sub-specialty practice. We have the only fellowship trained glaucoma specialist in all Central Illinois. This patient first practice, trying to offer our patients, which the vast majority of them are Medicare beneficiaries, the best option for their situation.

We treat a broad range of glaucoma severities and thus I'm familiar with many of the devices and procedures both being discussed today and on both ends of the spectrum.

One thing to also keep in mind is that glaucoma affects minority patients at a much higher rate than it does our Caucasian patients. In many patients, MIGS can prevent further loss of vision and decrease the cost to the system and to society.

Next slide, please. This is just a little graph of kind of the traditional treatment arc as far as glaucoma goes. And like Dr. Latina said, early on, you know, drops and laser therapy are kind of the standard of care at this point. And then as we go up the ladder, up the steps as he showed, that's where most of these MIGS come into play.

And as he pointed out, there's a big difference between the patient who could be adequately controlled with a much less risky MIGS procedure such as goniotomy or canaloplasty versus a patient who needs a trabeculectomy or a tube.

And so we have to remember that not all glaucoma needs to be controlled with the biggest options. And the reason we always are looking for less invasive options is because although effective, trabeculectomy carries significant lifetime risk for the patient.

Next slide, please. So the proposed LCD would prevent surgeons from performing necessary and effective MIGS procedures. As was stated before, and I won't belabor the fact, OMNI is considered investigational despite the study data, and I'll reference that as well to the contrary.

Our request is to ensure that patients have access to effective glaucoma treatment options that are necessary in treating the patients that we see and cover goniotomy, canaloplasty and other angle-based MIGS consistent with the FDA's indication and clinical evidence.

Next slide. So why are MIGs important? Well right now, as what's been said, the only standalone option in the proposed LCD for patients would be the Infinite. And right now, we have plenty of options for patients that

do not require cataract surgery, whereas currently the only option we have that is cataract-free is either goniotomy or canaloplasty for those MIGs procedures.

Medications have compliance issues. Any study that's ever been done on medications has shown roughly about a 50% compliance. In addition, medication costs continue to rise, and they're often not enough.

The safety of MIGs means that we can intervene earlier. And we know from many, many studies that the earlier we're able to intervene in glaucoma, the better chance the patient has of retaining good vision and the less burden they would become to society.

Glaucoma affects African Americans and Hispanics at a much higher rate, and thus we would be limiting vision-saving therapies to an already vulnerable population.

And I'm in no way saying that traditional glaucoma surgery does not have a place. However, very often the severity of glaucoma or the lack of the severity of glaucoma does not warrant the trip to a trabeculectomy.

Next slide, please. As was stated before, both of these published articles have been already discussed. I won't belabor them. There are also many other studies, as Raymond said, that shows that the technologies are at least as effective as the implant procedures that are proposed to be covered by the LCD.

Next slide, please. Next slide, please. So our recommendation is that providers in Illinois and throughout the region need continued coverage of approved standard of care treatments that we use to preserve our patient's vision and limit their morbidity.

Please reconsider the draft policy to preserve Medicare coverage and patient access to these MIGS procedures. And thank you for your time and consideration.

Dr. Ella Noel: Thank you very much. That brings us to the end of our scheduled presentation. We will now take comments from the general audience if there are any of those on the line that wish to make comments.

Coordinator: We have a comment from Anjali Tannan. Your line is open.

Dr. Anjali Tannan: Hi. I'm Dr. Anjali Tannan. I'm the CAC representing the State of Illinois and the Illinois Society for Eye Physicians and Surgeons. I want to echo multiple comments made by many of the speakers (unintelligible) today.

Dr. Ella Noel: Can everyone go on mute except for the speaker?

Dr. Anjali Tannan: I'd like to agree. Thank you. I'd like to agree with our first speaker's request to remove the word and in the proposed LCD and replace it with the word or to allow for progressive damage or an elevated mean ILP as an indication for insertion of the XEN glaucoma implant.

I would also like to echo Dr. Emerick's comment that multiple of the procedures listed as investigational in the LCD are actually standard of care and have been shown to decrease glaucoma drop burden, which I think is extremely important.

And so we need a variety of surgical procedures available to us to help treat the variety of disease levels and disease burdens that our patients have. Glaucoma is an irreversible progressive vision loss. And so if we are only allowing for treatments at more severe levels of glaucoma with a much higher risk profile, we are doing a disservice to our Medicare beneficiaries where we could prevent disease and vision loss.

CDC data from 2017 discusses that the economic burden of vision loss in the United States here is over $134 billion, including $98 billion of direct costs, including medical care and things like that. So I think anything that can prevent vision loss in this subset of patients with this disease is extremely important.

And having a wide variety of clinically proven procedures that will prevent patients from needing additional higher risk procedures is extremely important.

I had a couple other comments. I do agree with Dr. Latina that multiple of these MIGS procedures should not be compared to trabeculectomy as is noted in the LCD.

And I wanted to echo one more comment about medication burden and the cost of medication. In another study, it was demonstrated that the cost of medications has risen 59% from 2013 to 2019.

So if we get a non-coverage decision on multiple of these procedures as noted, it will significantly increase the cost to CMS and Medicare beneficiaries as noted in one of the previous speakers' talks as well just because they will remain on medications that they will be on lifelong because they will not be able to decrease the medication burden, which is one of the, I think, most important clinical successes from these MIGS procedures is the ability to do them and prevent and decrease medication burden for patients. So thank you.

Dr. Olatokunbo Awodele: Thank you. Operator, do we have any more commenters on the line?

Coordinator: I'm showing no further comments.

Dr. Olatokunbo Awodele: Okay. Thank you very much. We'll now consider the comments related to DL37244, Microinvasive Glaucoma Surgery, MIGS, we'll consider that closed.

So this brings us to the end of our open meeting today, and I'd like to thank all our speakers and observers for participating in the proposed LCD open meeting process.

I'd like to remind everybody who commented today, or even if you didn't comment but had comments, and all the speakers, to please send comments, the comments in writing, to NGS via the three ways that I had spoken about earlier.

The first way is via email to partblcdcomments@anthem.com. The second way is via snail mail or regular post, LCD Comments, PO Box 7108, Indianapolis, Indiana 46207-7108.

And the last way would be by clicking on the public comments block, which is located on the top left-hand corner of the proposed LCD on the Medicare coverage database. And so I'd like to thank everybody and have a nice rest of your day. Operator, we can disconnect.

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

END