July 17, 2023 Jurisdiction M (JM) Open Meeting Transcript

Jason Stroud
I've just started the recording of this open meeting in compliance with CMS. For the record, prior to doing so announced that Palmetto GBA would make an audio recording of the open meeting and consented on behalf of Palmetto GBA.

Again, I'd like to welcome everyone this morning to our open meeting today. Palmetto GBA did receive several presentations. So, what we would like to do is get through all of the presentations first and then if there's any time at the end, we can have a few comments. Again, that is if any time is available.

Let me just remind everyone too that during this open meeting, Palmetto GBA cannot answer any specific questions regarding our proposed policies and also that if you would like to make a formal comment on any of our proposed policies, we encourage those to be done in writing. Those written comments can be submitted to either a.policy@palmettogba.com or b.policy@palmettogba.com. Again, we do encourage you to send those comments in writing. That is the preferred method. This is a very important part of the LCD process and if we're able to get those comments in writing, that will allow us to adequately address each of those comments in the response to comment articles that are associated with each proposed policy.

So, with that, we will get started with our first presenter, Dr. Okeke.

Constance Okeke
Thank you.

Jason Stroud
And let me just before we get started again, thank all of our presenters for taking time out of your day today to speak with us. Dr. Okeke is going to be speaking or addressing our Microinvasive Glaucoma Surgery policy. OK, go ahead and introduce yourself and I'll give you the floor.

Constance Okeke
OK. Am I going to be able to show my slides?

Jason Stroud
Uh, yes, Melissa. They should be able to do that, right?

Constance Okeke
I think I can.

Melissa J. Robinson
Yes, ma'am. You should be able to share the screen you have your presentation on and it will display to us here.

Constance Okeke
OK. Are you able to see any of my screen currently?

Melissa J. Robinson
Yes.

Constance Okeke
OK, great. Good morning, everyone. And yes, my name is Dr. Constance Okeke. I thank you so much for the opportunity to have the floor to be able to speak on this very important issue today happens to be my birthday and I'm also in the operating room today, but I wanted to take time off of my schedule in order to be able to share the comments that I have for you.

These are my financial disclosures. I happen to be a consultant speaker and do research for a number of different companies. I'm a Glaucoma Specialist; the lead Glaucoma Specialist at Virginia Eye Consultants in Norfolk, VA. A cataract surgeon as well, and also Assistant Professor of Ophthalmology at the Eastern Virginia Medical School teaching medical students and residents Ophthalmology.

I've been at Virginia since 2009. When I started the Glaucoma Division and now we're three Glaucoma specialists strong, but the practice is continuing to grow. It's a multi-specialty group practice with over 55 years of world class excellence in Ophthalmology. We have 15 Ophthalmologists, five Optometrists, three physician assistants, and also, we have a residency program for Optometry where we train two residents a year. Our practice has been ongoing and strong.

We have a goal to preserve vision and treat glaucoma effectively. We treat all the different stages of glaucoma from early diagnosis to advanced. We pride ourselves in innovation. We have been an organization that has done a number of firsts throughout our region, throughout the country, and I myself have participated that very much. So, in the area of MIGS we treat, I treat over 5000 Glaucoma patients a year due over 700 to 800 surgeries and Glaucoma and the majority of them are combined with Cataract Surgery.

I just want to give a little bit of my background. I was trained at Yale for college, and I did my medical school, also at Yale, and I remembered the day that I took the Hippocratic Oath. The two first you no harm for patients, which I take dearly, and everything I do.

I was in trained at Wilmer for Ophthalmology residents and Bascom Palmer for my Glaucoma fellowship training. I mentioned these things just to say that one could say that I had good surgical training and with beginning of Glaucoma Specialist and with the tools that that I was taught, I realized very quickly that it's a humbling experience because even with the best tools at the time that we had when I was in my training to do surgery, which has traditional surgery trabeculectomy is this being seen here and tube shunt surgery there despite you know, perfect technique, there were many times when there could be, you could have a perfect surgery going, but it could be route with things such as hypotony where the pressure is too low, blood leaks, choriodals which ensure that can cause vision to decrease and the risk for infection, not just in the perioperative period but even years or decades later. There could be movement and shifts of the blebs that can cause changes in alterations and vision swelling. Corneal decompensation. So, a number of complications. And so, despite, you know, these complications, it's what we had also tube shunt complications like corneal decompensation or tube erosion, or double vision.

Now when I finished my training in 2005 to 2008. These are my options, either medications, laser treatment, surgery for the trabeculectomy or tube shot, and I remember having situations where patients such as uh, let's say Mrs. Jones, who had early to moderate Glaucoma who could not tolerate medications, maybe could tolerate one and then needed still further treatment and did a laser such as SLT. The laser might have helped, maybe for a short period of time, or not effectively enough, and the

patient still continue to progress, not to the point where she had lost vision and wasn't functioning, but that we could see on our testing that she was progressing, and we know that with Glaucoma if we continued to leave it untreated it can lead to blindness and functional vision loss which we are trying to prevent. So, options being what I had of trabeculectomy mirror tube shunt, I did a trabeculectomy and the technique was fine.

The surgery went well, postoperatively she was healing well initially, but then she developed a blood leak, and the blood leak was difficult to treat or manage it which required further procedures in order to try to help and during that process she was worried. I was worried. I'd have sleepless nights because of patients such as these where you're concerned and worried for their best because you just you took that oath to do no harm and that was where we were, and I knew at that time between that years of 2005 to 2008 that we needed something different. And then that's when Microinvasive Glaucoma Surgery was born because of a problem.

So, my first Glaucoma Surgery was trabectome and I just want to go back to talking about in general, Glaucoma is a disease. It's multifactorial now. There's a lot of things that result in the end damage, which is progressive loss of the optic nerve tissue, which leads to vision loss. And we understand that there is an issue with have outflow. So fluid is always being made. The aqueous humor is supposed to get out of the natural outflow system, the drainage system. So, this is supposed to be a balance of fluid being made and fluid getting out now when there's an imbalance, there is a problem, pressures are raised and there's damage to the optic nerve. So, when we look at the outflow system, there's three major points. There's the trabecular meshwork which is like the filter like air condition has a filter. Fluid is supposed to be able to go through this easily, but we know that as an area of high resistance and the trabecular meshwork behind it is the Schlemm's canal. This is an open canal that's supposed to allow fluid to flow easily and well around the 360 degrees of the drainage system. And then behind it are the outflow collector channels and those channels are supposed to allow for that fluid to continue to flow into the episcleral venous system and the balance of fluid being made and fluid getting out. But if there's problems within these areas, there can be resistance, and that's where the heart of Minimally Invasive Glaucoma Surgery, Microinvasive Glaucoma Surgery began.

So, with the trabectome it removes some of that trabecular meshwork where that filter is. So there could be direct access goniotomy procedures do this trabeculectomy procedures do this and then with the Schlemm's Canal there can sometimes be adhesions there and they're what we do with Canaloplasty or VISCO dilation is to open this up so that there can be better flow and then you have the distal collector channels which also can be constricted or scarred or closed and so the flushing out do using viscoelastic fluid to within Canaloplasty or VISCO dilation to help to expand this to allow what naturally is supposed to be happening to happen better. This is essentially like using train out in cold, clearing out the clog within the drainage system. So, this is just a depiction of the drainage system. You see, it's 360 degrees and in the blue and below it is all of those outflows, channels that are being able to be expanded or that were treated by trying to treat with these procedures such as Ab-interno Canaloplasty which like the Omni device to help open up the natural drainage system, flush it out, both get your Trabecular Meshwork and the collector channels and the Schlemm's Canal and then make an opening with the Trabeculectomy to allow for that continued patency.

So, I mentioned my first procedure was the Trabectome. I started doing it in 2009 and after that continued to adopt all the additional MIGS procedures of the innovation that was happening because I

solved that. It was working. I felt like I had found a holy grail when I started because I was an early adopter and I was so passionate about it that I wrote a book about it because I wanted to share this information with the world because we now have in our tools things that we could use that could help to reduce the safety profile or improve the safety profile from what we were doing with our traditional Glaucoma Surgeries. So, is MIGS supposed to be safe? It's supposed to be an ab interno approach or an ab externo approach with minimal dissection of the scleral bed. It's supposed to allow for fast recovery, minimal trauma, favorable safety, and it's supposed to help to lower the eye pressure. Maybe not to the extent of some of the trabeculectomy or tube shunt procedures, but enough in those early to moderate patients who just need a certain amount of pressure lowering to get them stable. So, with these tools what I found is that now I have all these tools in my pocket in order to be able to treat Glaucoma.

Glaucoma is not a one size fits all disease. You need to tailor each patient individually with the tools that you have and also your skill sets with those tools, and so with this armamentarium that we've been using for the last decade, we've been able to use this as first line treatments for our patients and it's going to continue expand and it has expanded because we found we could use these Minimally Invasive Glaucoma Procedures with Cataract Surgery. Now the patient has an opportunity to see better, but they also have the ability to help to improve their vision at the same time, or improve their eye pressures at the same time, and also often have less medications, which is a big deal for patients. We know that medications work, but we also know that there are problems with medications.

I myself have done research in the area of compliance with medications and know that even once a day medication could be difficult for the patients, memory issues, tolerability issues, cost issues and so trying to find another way to help patients help themselves and keep seeing with Glaucoma. With more options coming out, there's more innovation. There's going to be more and why? Because the need for Glaucoma is expanding as we continue to have populations that age and more, Glaucoma will continue to ensue worldwide. And as we also understand that awareness is an issue with Glaucoma and we work on increasing awareness, there's going to be more patients who are found and more need for help with these procedures.

We need to consider more MIGS procedures. Why? Because I said before, we have to tailor our treatments to the patients. That's part of our training. That's part of what we learn. Patient selection, the title of my book was Building Blocks of Trabectome Surgery Patient Selection because there's an art in it and the more tools that you have in your pocket, some more that you can develop that art and treat patients. Also, there's various stages of Glaucoma, not just mild to moderate, but also severe. And the iStent MIGS procedures deal with all of those different types of stages of Glaucoma and also different types, not just open, also narrow with the use of *inaudible* and also the goniotomy to help to open up the angles and also stand-alone procedures being able to do it not just with Cataract Surgery, but also stand alone.

This is the current MIGS procedures that we have multiple options to be able to consider in order to choose the right tool for our patient and trabeculectomy surgeries went down. It makes sense because they were associated with more complications. So, we held off using these procedures for the patients who really needed them, who are typically the more advanced cases to help minimize damage or complications for our patients.

Now I myself I'm a MIGS trainer. I've trained on all different types of MIGS. I have taken upon myself being an early adopter to want to be able to continue to share these things with doctors and also

patients. And I've brought a lot of Glaucoma, big surgery to our Hampton Roads area. In fact, I was the first to bring it to our area and continue to expand.

When I see a patient, this is essentially the decision tree that goes through my head and I think about all these different things in order to figure out which one would be working best for my patient, where all the red lines are, are the ones that are on the table today that one could take away from my armamentarium of what I choose for my patient. Why are we here today? Because the LCD that has been listed is saying that there are numerous procedures that are being seen as investigational, these are procedures that have become standard of care that I've been using for over a decade and the procedures allow us to address those areas of resistance that I talked about, the Trabecular Meshwork the Schlemm's Canal, the distal collector channels and these procedures have been FDA approved. We've been using them, and the reality is that those procedures that within the LCD that you list like the istent procedures, they are very useful, but they're not useful in everybody for every single type of Glaucoma. And so that's why we still need to continue to have the procedures that we've been using today.

Now I don't have time to be able to go into the research for all of the different types of procedures. I will mention the Canaloplasty with trabeculectomy which has become one of the standards of care procedures and this is not investigational. There are a number of peer reviewed publications with this technology. With the OMNI surgical system, which has been FDA approved in order to be able to use Canaloplasty followed by Trabeculectomy. And this is a procedure that's seen it with the American Academy of Ophthalmology as one of the preferred practice practices. And I and along with thousands of surgeons, have been using this procedure for years and getting outcomes that are excellent in regard to some of the data for the OMNI.

You have the GEMINI study, which was a prospective study with 149 patients and with the findings were a significant reduction, 35 percent reduction in the mean unmedicated IOP. When we look at our practice patterns for lowering eye pressure, we're looking for 20 to 30 percent reduction in eye pressure upon to see as a good target for pressure reduction. The number of MIGS procedures that are non stents. They provide this type of 30 percent or more reduction in eye pressure, and they do it in a way where they're also allowing for the reduction of eye drops. Patients in this study had 80 percent of them were medication free and 80 percent of them had a reduction in their medications and we also have safety. So, when you look at the safety issues related to this OMNI study and you think about the ones that are related to trabeculectomy, the ones here are not they resolve without having vision threatening on issues and the long-standing issues, there's no bleb that's created that creates a long-standing issue of the potential for infection that could lead to endophthalmitis and losing the eye.

So, what are the real-world implications of this LCD? Well, the reality is that if we have less Minimally Invasive Glaucoma Surgeries, that means we have less tools in our pocket. That means that we have to go backwards. You will send me back to where it was when I started at my training of having more risky filtration surgeries to be used in order to help my patients to have more worry, to have more sleepless nights because of the fact that there are certain things that are not in my control when it comes to those procedures and we know that in regards to patient access, the idea about having these procedures not available for our patients. A lot of the patients that would be affected are those who are minorities and those who have less income because they may not be able to afford the medications or procedures. If these are not available to pay at cost and you have to understand also that medication is a burden, we

have been using medications, but we've been trying to get away from medications also and to the sense of that it's difficult for patients. Patients have trouble remembering to put in their drops. Or they have problems with the drops and how it irritates their eye, and it affects their quality of life. The reality is that less medications equal better compliance and less filters, equal less complications and also remember, yes, stents work, and I use stents. But what happens when stents are not a candidate for the patient? I personally had a really had a relative who had need for Cataract and Glaucoma Surgery and I was initially going to consider a stent. But when I realized that the patient who had a history, this relative history of aneurysms, I realized that she needed to have memorized regularly. My concern was the possibility of any type of artifact that could affect the quality of her scans. And so, I had to think about maybe a stent is not better and you know, not the best approach here. And let me do something that has to do with the non stent MIGS.

If you take those options away, what would I do at trabeculectomy? There is a need for these procedures and it's common sense and years and years of clinical evidence and clinical realities of what we've done are experience and our experience does matter. We went to school for training to be able to use these things. To use our experiences also to see what works for our patients in our hands and the patients and surgeons at the Hampton Roads area, those who are in my practice, they need access to these Glaucoma treatments which we've been using for over a decade. The patients need have options that are outside of just medications and also laser treatments that sometimes work but sometimes don't work. Glaucoma is an ongoing chronic disease, and we need all these different tools in our pocket to be able to treat the patients appropriately in the least and the safest and effective way.

So, in closing, I request that Palmetto [GBA] establishes coverage, does not deny coverage of these non stent procedures so that we can preserve access for our Medicare patients in Virginia.

In closing, I do want to read one statement from a patient because the patients I'm representing are not here, but I want to use their words in my book The Building Blocks of Trabectome Surgery. I highlight several patients of mine who have the procedure and this Miss Judy Graves said the first time I was diagnosed with Glaucoma; I was very concerned. I was relieved when Dr. Okeke told me that there was something she could do about it. Having Glaucoma is frightening because you cannot tell that you have any problems. Using any drops is very cumbersome and very confusing keeping up with them. I was using at least four to six different bottles a day that were very expensive. Sometimes the pharmacy would not have them available, and I would have to order them. Often the drops irritated my eyes. Now, looking back after my experience with surgery with Trabectome, I would say that the most beneficial aspect is that I'm not having to use so many drops. Now my life isn't centered around the management of eye drops, and it's a tremendous relief. I can focus on things that I want to do more of, such as time with family, friends, and travel. I absolutely worry less about my Glaucoma now after having Trabectome procedure. I don't even think about it. Now I remember my experience with having surgery being short and painless, and the fear that I had was completely outweighed by the success of the surgery. The recovery from the surgery was short and painless as well. Fortunately, I did not experience any problems after the surgery. I do not use any drops for glaucoma. Now my glaucoma is completely under control. I would not hesitate to recommend this Trabectome procedure to others. I would highly recommend it to others and try to help anyone to relieve them of fears of hesitation. The reason being that the surgery definitely improves the quality of your life.

Those are words of patients and thousands of patients that I have had who said the same thing. These procedures work. Please do not take them away from us as surgeons and please do not take them away from patients. Thank you.

Jason Stroud
Thank you very much for that presentation.

We'll go ahead and move on now to Mr. Badawi. Mr. Badawi is going to be addressing our Microinvasive Glaucoma surgery proposed policy. Go ahead and take it away.

Paul Badawi
Well, thank you all.

Thanks to all of you in the medical policy unit for taking the time out of your busy schedules to learn about Sight Sciences and our OMNI Surgical System Glaucoma Technology.

My name is Paul Badawi, and I'm the co-founder, President and CEO of Sight Sciences. I started Sight Sciences in 2006 with my brother, Dr. David Budowy, 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. 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've equipped Glaucoma surgeons across the country with a better, safer, more comprehensive and more effective surgical glaucoma technology. And in so doing, we've made a real impact on the treatment of Glaucoma. 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 diseased aqueous outflow pathway via an Ab interno approach. The technology allows surgeons to perform what has been referred to AS2 sequential.

OMNI does more. It allows surgeons to address all three sources of resistance and the aqueous outflow pathway. Sergeant can thereby reduce intraocular pressure and reliance on IOP lowering eye drops which are difficult to administer and have catastrophic 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's 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 overlooked several important peer reviewed studies demonstrating OMNI’s efficacy. I expect that when you do a full review of the clinical evidence, you're 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 eye drops on the left and more risky and invasive surgery on the right for some time makes involve stents and goniotomy, and these treatments

work for some of the some, but these surgeries target just one of the three sources of outflow resistance. The trabecular meshwork stenting goniotomy do not improve the aqueous outflow through some canal and the distal collector channels which are also implicated in Glaucoma.

OMNI is the 1st and the only technology that enables a procedure that comprehensively treats 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. 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 2021 based on its evaluation of clinical results from the ROMEO multicenter pivotal trial. The AAO identifies OMNI as a mixed treatment in 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 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 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 and almost 150 patients at 15 sites in the US 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. 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 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. 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 OMNI is broad effectiveness and broad indications for use. 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 before closing.

I do 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 A and B 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 MACs do not provide 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. 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. From my perspective, there is no greater joy than being in a clinic when a patient returns for his or her post op checkup. Patients are so relieved when the surgeon tells them that the post op IOP reductions and medication reductions are even better than expected. It is so rewarding to see the joy and relief on the patient's face. It is that feeling that keeps me and everyone at Sight Sciences motivated to continue to provide patients and surgeons with the best technology they need to keep this disease from progressing and to help them avoid blindness.

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, for example Canaloplasty followed by Trabeculectomy 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 all for your time, your interest, and your consideration of our mission and our purpose. I'm happy to address any questions. Thank you.

Jason Stroud
Thank you, Mr. Badawi, and again, if there's any comments, if we have time at the end, we can open the floor to those comments, but thank you for that presentation.

Our next presenter is Ms. DeVincenzo, and she will be speaking to our Scalp Cooling for the Prevention of Chemotherapy Induced Alopecia proposed LCD.

Julia DeVincenzo
Good morning. My name is Julia DeVincenzo. Thank you for allowing me the opportunity to present today on the proposed LCD DL39573 for Scalp Cooling for the Prevention of Chemotherapy Induced Alopecia. I am the Director of Patient Advocacy and Clinical Education at Cooler Heads. I am presenting today because Amma by Cooler Heads is an FDA cleared mechanical scout cooling device as of October 21, 2021.

I'm a registered nurse certified in breast cancer patient navigation and I'm advocating today for the proposed LCD as a healthcare provider. I have seen scalp cooling technology evolved over the years. Many years of my practice and it is no longer required that patients need to wheel into their own fusion center a large cooler full of frozen caps. Nor is it required that these patients must have a support person present with them for their entire duration of chemotherapy.

The proposed LCD recommends coverage be considered reasonable and necessary for FDA cleared scalp cooling devices as long as the patient does not have any of the listed contraindications. The applicable CPT codes for this LCD are 0662T and 0663T; the mechanical FDA cleared scalp cooling units. The process for both the patient and the Infusion Center and democratizes the option for scalp cooling. Why is this proposed LCD importance to a health care provider as a patient navigator? It is my mission to make sure every patient is given that every option available to their cancer care. This in turn has allowed my patients to make an informed decision and empowers them during a time of incredible uncertainty.

Why is this proposed LCD important to a patient simply knowing that there are FDA cleared scalp cooling devices that can reduce the likelihood of chemotherapy induced alopecia? It allows them to make that powerful decision and be part of their healthcare compared to the non-FDA cold capping systems, the FDA cleared mechanical systems are highly functional and well understood by the user.

Amma by Cooler Heads is a portable scalp cooling device, again, that has been FDA cleared since October 2021. It's comprised of three major components, the portable cooling unit you will see on the left-hand side of the screen, the inner cooling wrap portrayed in the middle, and the outer compression cap, which is on the right-hand side. Each patient completes a 60-minute training, led by a Cooler Heads customer care team, and additionally all Infusion Center staff are provided the same patient training as well as adaptive ways to accommodate AMA into their workflow.

Hair loss is said to be one of the most devastating side effects of chemotherapy. Hair loss can impact the quality of life. So significantly that 8 percent of patients refuse chemotherapy. Literature shows us that hair loss is associated with perceptions of aging, illness, loss of attractiveness, changing concept of self, loss of privacy, signs of societal failure, morning and entering, a religious order. Availability of scalp cooling changes this conversation and scalp cooling can provide that privacy, maintain their identity, and help promote that positive mental health.

Because Amma is also FDA cleared and demonstrates similar or better outcomes than those in peer reviewed journals, I'm proposing that Amma be added to the proposed changes in this LCD. Additionally, I'd like to propose the following:

- Remove requirement for materials used to make the cooling wrap and/or cap.
- Remove cap sizing specifications.
- Remove specificity about type of coolant solution used.
- Remove reference to payment tokens as each unique patient is billed for 0662T.

I've received countless feedback from patients who state that scalp cooling has enhanced the quality of life and allowed them to continue with their hobbies, employment, and family responsibilities. Thank you for allowing me to present today on behalf of Cooler Heads and oncology patients nationwide.

Jason Stroud
Thank you, Ms. DeVincenzo.

We'll go ahead and move to Ms. Bourestom and Richard Paxman. They will be addressing the same proposed LCD for scalp cooling.

Richard Paxman
Thank you. Well, it's a pleasure to be here today and we really appreciate your time and also consideration for the proposed LCD for Scalp Cooling for the Prevention of Chemotherapy Induced Alopecia. So today what we plan to do is present a brief overview of why this LCD is important, provide background on the FDA cleared devices and scalp cooling treatment, as well as address the patient impact and current adoption. And in addition to support for the LCD, we'll offer a couple of minor proposed changes to the draft for your consideration.

So, my name is Richard Paxman. I'm the CEO of Paxman Scalp Cooling.

Melissa Bourestom
And I am Melissa Bourestom. I'm the CEO of Dignitana. Both of our companies are passionate about the negative impact that scalp cooling chemotherapy induced alopecia and the need to improve quality of life for patients by increasing access to scalp cooling and for that reason, Dignitana and Paxman have worked in cooperation for several years to advance reimbursement and coverage for scalp cooling. And we appreciate the opportunity to jointly address the Palmetto [GBA] MAC today.

There are three primary reasons that support the approval of this LCD. First, it expands patient access to scalp cooling, providing broad and appropriate access for Medicare patients. So, it expands patient access, reduces financial disparities, inherit in access to scalp cooling and also addition to treatment, access and affordability. Hairless often can impact a patient's ability to work or continue with normal activities, and it also supports a large and robust data set, further demonstrating scalp cooling, efficacy and quality of life improvement.

Richard Paxman
Thanks Melissa.

So, scalp cooling has offered an FDA cleared solution for patients with chemotherapy induced alopecia since around 2015, and it reduces the likelihood of chemotherapy induced alopecia and is indicated for patients with solid tumors undergoing chemotherapy that causes hair loss. And I think it's important to note that NCCN lists scalp cooling as a category 2A recommendation for breast, ovarian, fallopian tube and primary peritoneal cancers, and more recently, the Oncology Nursing Society has actually included scalp cooling in their recently published guidelines, as well as well as a number of other global guidelines supporting cancer care.

So, the administration of scalp cooling via an FDA cleared device generally requires four components. Those four components include a computerized control unit so you can see the dignity and the Paxman device has shown here and single patient cooling cap that connect to the controlling unit. So, we pump a liquid coolant around those cooling caps and then two sort of characteristics is the cap fitting and patient education, which is generally characterized by the CPT code, 0662T and then that really represents about 30 to 60 minutes of clinician time prior to starting that treatment. So, a really decent education piece. Then what we've got is the actual treatment time, which is the time that the patient sits with the device. Each chemotherapy session, and that's known as the CPT code 0663T as well. So, it's about five minutes of initial therapy and then there's about 180 to 360 minutes of actual patient monitoring by clinical personnel during and after the chemotherapy infusion. Throughout this process, the patient provides direct supervision of scalp cooling before, during, and after the delivery of chemotherapy and is available by telephone to assist or direct as needed. Of course, the hands-on role of the chemotherapy nurse and nurse manager in the process are also really critical here. Interaction and proper communication between physicians, MTP and allied health professionals are needed to provide this supportive care service to patients at risk of chemotherapy.

Scalp cooling is a distinct professional service that should not be considered incident chemotherapy surface. You may wish to reference the workflow diagram that we and put together in our initial LCD request letter, which details the role of the physicians, the PAs, the MPs, and nurses as they work to dig it together to deliver this scalp cooling to appropriate patients. So, scalp cooling works reasonably simply so we know how chemotherapy works, damaging the mitotic and metabolic processing cancer

cells typically. So, what we're doing is we're cooling to really protect those hair cells from the chemotherapy.

Cooling to 64 degrees Fahrenheit initially induces vasoconstriction. So, we actually reduced the cutaneous drug perfusion to around 20 to 40 percent, therefore less drug actually gets to the hair cells or reaches the hair cells. What you'll also see is this reduction in hair follicle cell division. So, cell division is generally energy dependent process, so that slower rate of division makes ourselves less susceptible to the actual chemotherapy. So really important with that sort of taxation or microtubule types of chemo, we also know there are other mechanisms ongoing and and as we as we do more and more science, we start to learn a little bit more about the treatment and how we can advance it in terms of clinical data, both Paxman and Dignitana have a wealth of clinical data. So really large, randomized studies, real world evidence, prospective studies, and published in peer review, and the review journals and scientific journals. So very, very proud of the data that the companies have collated over the years. In fact, well over 8000 studies, subjects have been used with Paxman and Dignitana within our published data. I'm about 85 abstracts and publications, 65 clinical trials, and it's a really diverse and inclusive approach that we've taken. We've got clinical trials throughout the whole world, different ethnicities, men, women, different chemotypes and of course, different tumor types, which I think is really important to demonstrate our devices and success is often considered by looking at different scales, but we tend to say a patient is successful when they lose less than 50 percent of their hair, not require a wig or a head cover. If you look at the data across all of the data, we tend to see that around 50 to 60 percent of our patients are successful with scalp cooling, better with some regimens, less good with others. But again, what's really important to understand is that actually and again it's the data we have presented and published, is that even when a patient isn't successful, we see faster hairy growth, which is a real motivator for patients. And we also see a reduced risk in persistent chemotherapy induced alopecia as well. And we're seeing that talked about more and more in the clinic and I think we tend to see underreported levels of persistent chemotherapy induced alopecia in our patients.

So great data set, so back over to Melissa.

Melissa Bourestom
Thanks Rich.

So, scalp cooling, it really does come down to quality of life for patients with cancer. The published studies cited here have shown that hair loss I can cause up to 10 percent of patients to forgo chemotherapy or request a less efficacious treatment. So that is quite a startling statistic, and one that always is quite troubling of course to the Medical Oncologists and it is often the most traumatic side effect of the treatment leading to social isolation and often can affect self-image more than mastectomy. We hear this from plastic surgeons that we speak with that they say, you know, I can't do anything about their hair. And so those are some, it's really quite clear that CIA is the side effect that is rated by patients as most troublesome even over other very significant medical issues, nausea, fatigue, organ damage. So, it's very clear that CIA impacts quality of life and patient privacy as well.

The good news, though, is the availability of scalp cooling. Since the initial FDA clearance in 2015, it is quite broad, especially in the Palmetto [GBA] jurisdiction with FDA cleared technology available in all seven Palmetto [GBA] states. So, for Dignitana, Anna, and Paxman combined, this gives you 55 providers at 96 locations, so 96 infusion centers offer this technology. Nationally, we are combined in 762 cancer

Centers, 46 States and 43 of those are NCCN and NCI designated comprehensive cancer centers. So just really great coverage.

We thank the Palmetto [GBA] MAC for taking the important step of advocating for Medicare beneficiaries to have access to FDA clearance scalp cooling for solid tumors. And again, our request today is to encourage Palmetto [GBA] to finalize the draft LCD with four minor proposed changes and these adjustments to the LCD would more broadly represent scalp cooling devices that are FDA cleared now as well as those that may enter the market. So again, those changes would be to modify “silicone cap” to “closely fitting cap,” to remove the specific reference to manufacture cap sizes, to remove reference to a “glycol-based fluid,” and also to remove reference to pay for use tokens being scanned at the beginning of the cooling session.

Richard Paxman
Thanks, Melissa. So, in the seven years since scalp cooling first received FDA clearance, support has grown widely. And this technology is critically important to patients that you can see a couple of quotes here. One from Brooke and who did receive 100 percent insurance reimbursement. And Brooke explains how critical the coverage was in her decision to scalp cooling and the reality is without the coverage, she would not have scalp cooled and will have really been affected by the quality-of-life issues. And then in terms of the clinical support for scalp cooling, it is incredibly strong.

Melissa highlighted exactly where we are in the country, but Wake Forest was the first medical center in the country to offer scalp cooling following the clinical trial and FDA clearance from the Dignitana system and Dr. Susan Melin of Atrium Health. Wake Forest references the need for healthcare equity, which we know is a big problem. So that scalp cooling is available and affordable to all patients, not just those that can afford.

So, in summary, there are three primary reasons that the approval of this LCD, so expands patient access to scalp cooling, providing broad and appropriate access for Medicare patients, reduces the financial disparities inherent in access to scalp cooling and supports a large and robust data set, further demonstrating scalp cooling efforts efficacy and most importantly, quality of life improvement.

So, thank you again for your time. Really appreciate it. And of course, we were happy to answer any questions at the end of the session. Thank you.

Jason Stroud
Well, thank you both for that presentation.

The final two presentations are also addressing scalp cooling.

The first one is Ms. Amir.

Leah Amir
Thank you. I'm a scientist in health care economists, and I've been working with Cooler Heads and their technology relative to reimbursement and helping to advance the information through Medicare and that this particular product is FDA cleared in 2021 of with Paxman Medicates, so that all of the necessary criteria could be approved for sale in the US by the FDA and next slide please.

But we do know that there has been interest with place of service 11 and other settings where patients can receive their infusion therapy.

Next slide please.

And my comment relative to this proposed LCD with coding information focused more on reimbursement and how this might be properly coded on a claim warm, very technical questions. So, we know that the NCD that's quite old and not in any way contemplate these new technologies. We want to know that there [are] significant costs associated with these caps. These caps are very intricately designed in order to deliver the consistent appropriate cooling to enable the reduction in probability of CIA.

So, what our question entails relative to the LCD as it's written and then the accompanying coding document is, will there be coding available and reimbursement from Palmetto [GBA] relative to place of service 11 and as change might occur perhaps even face of service 19 or 24 and that is what we would seek some clarification on. Certainly, we want the AMA device to be added to this particular LCD as one of the relevant medically appropriate devices to prevent CIA. We welcome recognition of the extensive, high quality clinical evidence to demonstrate that this consistent cooling does reduce the CIA significantly in patients because it's a very important outcome criteria to help with the entire infusion therapy.

Next slide please.

So, we can address this and the questions for follow up, but now it's into the comments and I want to bring your attention to the in the DA5371 discussion that the information provided relative coding is relevant to all places of service. And I just want to make sure that as we go forward place of service 11 might be included and if you think there's any need to consider places where this 19 or 22 you know given that it was the surgery center, this might not be relevant. But I would like to hear your thoughts on that, and I thank you very much for your time and I apologize for the technical problems.

Thank you very much.

Jason Stroud
Well, thank you, Ms. Amir.

And we'll go on to our final scheduled presentation. Ms. Dilligan.

Kate Dilligan
Yes, good morning. So, thank you very much for your time this morning. I am Kate Dilligan, the CEO and founder of Cooler Heads and my presentation is in support of LCD L39573.

What got me on this journey is in 2016 I found a lump in my breast and throughout the rigorous care that I was provided by a truly outstanding medical team, no one brought up to me the fact that was I was facing four cycles of Adriamycin chemo and four of Taxol. Nobody talked to me about hair preservation. It was something that I found for myself and that I did for myself, using one of the over-the-counter solutions and it was really arduous process. So, I took my background as an MBA as a tech entrepreneur and decided that I wanted to make a product that would help expand access to this therapy for patients who are truly struggling as they go through treatment.

So, this is a picture of me halfway through chemo at Christmas in 2016 with two of my nieces and I don't look sick. And one of the things that was a real hallmark of my treatment, whether it was a Medical Oncologist, my surgeon, my Radiation Oncologist, people that did, my medical team would routinely

comment to me that I didn't look sick. I didn't fit into that to that idea of what they saw as a cancer patient, and it really allowed me to compartmentalize the fact that I was going through treatment for a very aggressive form of breast cancer, but I was also able to work. I was able to pursue, you know, the day-to-day tasks of life that the other people that have been speaking on this LCD have mentioned. I've really lived it. I was able to travel for work, be professional, be out in the world, even though I was living with a very difficult medical treatment.

So, what's scalp cooling is, is it decreases the delivery of chemotherapy to the skull. It's fundamentally medically induced hypothermia which causes vascular constriction in the hair follicles, which prevents them from absorbing the chemotherapy when it's at the strongest in the body. So, the patients are able to retain the majority of their hair.

There is a wealth of clinical data on the safety and efficacy of this treatment and peer reviewed studies show that two-thirds of patients are able to go about day-to-day life with keeping the majority of their hair, and the Dutch Scalp Cooling Registry as well as subsequent studies in the US have demonstrated that in terms of any concerns about scout metastasis or other long term health impacts, that there really isn't that as a concern for providers.

So, you know, as I said, when I was a patient, scalp cooling, you know, cold cap therapy wasn't presented to me. It was something that I had to find out on my own about, but it didn't occur to me that I would refuse chemotherapy because my goal is going through cancer treatment was to get through it and to go on to live, you know, a healthy long life.

But as has been noted earlier, 10 percent of patients refuse chemotherapy due to concerns about hair loss. We've seen that regularly in our own care for patients that patients have said, well, only because I have access to your product, am I going to move forward with treatment and for patients that do scalp cool, not only are they often they're more likely to keep the majority of their hair. They're also going to see rapid hair regrowth, which is getting back to normal. Getting back to that baseline, which is so important for patients and so you know what is what is efficacy, what does good look like because you know when we were talking about hair thinning, what does that mean?

How are we asking you to compartmentalize that? The CTCAE scale is whether or not patients keep more than half their hair and basically what more than half your hair looks like is your hair has thinned but you can still go about day-to-day activities without a wig without a head covering of some kind because while the patient knows that their hair is thinner really to the outside world. It basically looks the same and that that is what is so important and what allows people to go about their day-to-day life.

And so, our support for this LCD is about expanding access and decreasing the financial toxicity of cancer.

So almost half of cancer patients have described having financial distress during cancer treatment and almost 70 percent of physicians have stated that cost has been a huge barrier for scalp cooling. And so, what this LCD is going to allow is for patients to actually have that choice to be able to decide how they want to control the narrative on their disease. There's the capacity to have this reimbursed by Palmetto [GBA]. I really can't stress enough and there's just how much of a game changer that is for the patients that if they have a high deductible health care plan and they have a family, they get a cancer diagnosis,

they're immediately out of pocket over $15,000. So, you know the capacity to have this reimbursed by insurance is so, so, so important for those patients.

So, what we're asking for, you know, in terms of the coverage recommendation is you know 0662T, which is a one-time patient engagement which is the calibration of the cap and that patient training that the infusion centers do teaching patients about scalp cooling, teaching them about how to wear their caps system. And then 0663T, which is the monitoring of the patient as they're going through chemotherapy, making sure that they're using the system correctly so they can get the best outcome.

So Amma is an FDA cleared solution for scalp cooling. AMA received clearance by the FDA on October 21 of 2021. File K211526 we provide the same therapy as Dignitana and Paxman. we did use Paxman as our predicate device. Our indication for use is that we're indicated to reduce the likelihood of chemotherapy induced alopecia in patients with solid tumors and Amma was commercially available starting in Q3 of last year. And today, we've done over 350 infusions and more than 25 infusion centers, including several in the Palmetto [GBA] coverage area.

So, what is Amma? What are the components of it? So, we have a mechanized system that circulates cold fluid throughout the capping system that maintains a steady state temperature of with the goal of bringing the scout temperature down to 64 degrees, which connects to the cooling wrap. The cooling wrap is made of a Sentara Veltex blend. We designed it so it could be flexible so it can be velcroid around the patient's head and fit to their particular contours as well as then we have an outer compression cap. That's inflated with that error bulb like a blood pressure cuff, if you will, to make sure that there's a nice snug fit. And this is the device as was cleared by the FDA.

So, we do have a few requested changes to the LCD. We would like Anna to be included as one of the FDA cleared solutions for scalp cooling. We'd like to remove the specificity about any type of coolant solution used. We'd like to eliminate the requirements for materials used in the cooling wraps or caps. We'd also like to remove capsizing specifications, as well as eliminating reference to payment tokens, because with reimbursement that certainly makes it something that is no longer important.

So, you know, LCD L39573 really is critical. Medicare reimbursement is going to make access to scalp cooling much more broad for cancer patients across the country and scalp cooling is proven to help retain hair speed regrowth. And as I've told you, my story is direct pay benefit to patient quality of life.

So, I appreciate your time and attention this morning and I'm certainly available to answer any additional questions that you might have.

Jason Stroud
Well, thank you so much, Ms. Dilligan.

So that concludes the scheduled presentations for our open meeting. We do have a little bit of time left here for any potential comments. Let me just remind everyone again that Palmetto [GBA] cannot answer any specific questions about proposed policies today on this call. Also, as mentioned in the beginning of the meeting, the preferred method of formal comments is in writing submitted either to a.policy@palmettogba.com or to b.policy@palmettogba.com. With that said, I will open the floor for anyone that would like to make any comments today about the proposed policies. Anyone on the line that that might have a comment?

Leah Amir
Dr. Stroud, I have a question.

If we submit a formal question, when might we get a response back or when might we see finalization of this LCD and the associated coding information?

Jason Stroud
The end date of comment is July 22nd so comments can be submitted up to on July 22nd. After that the comments are reviewed and answered in a response to comments article that is published with the final LCD.

Melissa, correct me if I'm wrong. I don't think there's really any time frame from the time you would.

Melissa J. Robinson
We are just required to publish a final version or retire that draft version within 365 days of publication.

Judy Volkar
As the writer of the scalp cooling policy, it will not be 365 days.

And the concerns mentioned here are actually in the body of the evidence. But if you look at analysis of evidence, there's no mention of tokens and gel systems and and it says any FDA cleared device and that's the important part is the analysis of evidence, so all is good.

Leah Amir
Judy, thank you very much for that clarification. All pieces of information are helpful.

Jason Stroud
Thank you Dr. Volkar.

Any other comments? OK. Well, hearing none we will conclude this open meeting for Jurisdiction M. Again, I want to thank everyone for being on the call today. Thank you again to our presenters. It's so important that we have these meetings so that we can have these discussions and see these presentations.

Again, this is a very, very important part of the LCD process and we just want to thank everyone again for being a part of it today.

And as I said, that will conclude our meeting, and everyone have a great rest of your day. Thank you.