Jurisdiction M Open Meeting Transcript November 2, 2020

Dr. Shane Mull:

Good afternoon. My name is Dr. Shane Mull from Palmetto GBA. I have just started the recording of this Open Meeting, in compliance with CMS, for the record. Prior to doing so, I announced that Palmetto GBA would make an audio recording of this Open Meeting and consented on behalf of Palmetto GBA. So good afternoon everyone. I want to welcome you to this Jurisdiction M Open Meeting. We have a pretty full agenda.

My goal is going to be to stay on time here. I really appreciate everyone submitting their comments and their presentations ahead of time. This is important part of the LCD process, because this is one method where stakeholders get to provide us with their feedback and any comments or concerns that they have. We have several presentations here. First one is from Dr. Fiscella. I hope I said that right. Sir, are you on line?

Dr. Fiscella:

Yes, I am sir. Thank you.

Dr. Shane Mull:

Excellent. So, I'll let you go ahead and get started again. You'll have 15 minutes. I'll turn it over to you.

Dr. Fiscella:

Great. Thank you very much. My name is Rick Fiscella and I'm with Allergan. I'm addressing the Glaucoma Surgical Interventions (Drainage Implants, Non-Penetrating Drainage Surgery, Cyclodisruptive Procedures, ab interno trabeculectomy), specifically it's DL38759 and DA58334. So again, on behalf of Allergan and AbbVie Company, the manufacturer of the XEN Glaucoma Treatment System, I appreciate you allowing me some time to discuss a few comments regarding the above captioned graph, local coverage or LCD and coding article respectively.

XEN is an FDA approved device for the management of refractory glaucoma's and that's including cases for instance, previous surgical treatments have failed, cases of Primary Open Angle Glaucoma, Pseudo Exfoliative and Pigmentary Glaucoma and these are with open angles that are unresponsive basically to maximum tolerated medical therapy. Now, the XEN directions for use, they currently require an administration from inside the eye to the outside and when it's administered external the XEN procedures appropriately reported with the CPT code that is 0449T.

That's specifically stated in an insertion of an Aqueous Drainage Device without an extra ocular reserve, our reservoir and internal approach into the subconjunctival space for the initial device. Palmetto GBA appropriately identifies the XEN as a covered service. Now that procedure approaches under 0449T, has a covered code. It is a Micro-invasive Glaucoma Surgery LCD and the coding article A56866, respectively. But currently XEN is not FDA approved for external administration, meaning from the outside of the eye and the safety and effectiveness of XEN for this use, they have not yet been established. However, in order to expand XEN's label to include the AB external surgical approach, Allergan submitted a traditional pre-market 510K in October, 2020 of this year to the FDA. We expect a substantive decision in early 2021 from the FDA pending a favorable review.

The reason for this is currently Ophthalmologists are administrating XEN, the AB external approach. And when administered AB externally, the American Academy of Ophthalmology recommends that providers report their XEN procedure with a CPT code of 66183, which is insertion of an anterior segment aqueous drainage device without extra ocular reservoir, external approach. While the proposed LCD and the coding article do not address XEN by name, the documents do propose restrictions and coverage for glaucoma surgical procedures reported with CPT code 66183 more broadly.

So, anticipation of the FDA's decision, an elegant special 510K. Elegance provided clinical data to the FDA to support the traditional 510K. Just to summarize the response for the AB external approach has offered favorable clinical benefits to surgeons. These include similar IOP reduction to the AB internal approach, a similar reduction in the number of glaucoma medication required to control the intraocular pressure and a similar safety profile.

However, there are some advantages and in particular, there's better blood management and often reduced number of blood revisions, or kneeling's required a lower requirement per second surgery and, or even reduced treatment failures. Surgeons are often trained on the AB external approach for other seat procedures like trabeculectomies may allow for additional ocular landscape in particular, the super temporal location. And that's where additional surgical procedures, if needed down the road just less for days with intravenous enhancement.

Therefore, there's less resistance with aqueous humor outflow, and there's even less for corneal endothelial. So, I'm going to end there and ask if there's any questions? We appreciate your time and written comments and body of evidence will be forthcoming soon.

Dr. Shane Mull:

All right. Thanks, Dr. Fiscella. You ended a little bit early, so we'll just see if there's any questions or comments concerning this presentation. Does anyone have any questions or comments for Dr. Fiscella?

Dr. Lisa Banker:

Shane, this is Lisa. There was so much background noise on the very last, just that last minute of what Dr. Fiscella said, if he could repeat the advantages of the AB external approach.

Dr. Fiscella:

Oh, sure. I'd be glad to. I was mentioning that when we look at the AB external approach, they're similar interaction with pressure reduction as we see with the AB internal. A similar reduction in the number of glaucoma medications that are required to control the interocular pressure and basically a similar safety profile. But some of the advantages in particular are better blood management and there's reduced number of blood revisions or needling's required. That's a very critical and important aspect of the AB external approach. There's a low requirement for a second surgery and sometimes even, and/or reduced treatment failures. It's a preferred approach in some regards by surgeons because that's how they're often trained. They're trained in the AB external approach for traditional surgeries, like trabeculectomies as an example, it also allows sometimes additional ocular landscape. So that means an additional area in the eye the super temporal location in particular. And that allows for surgical procedure, additional surgical procedure down the road if needed.

There's also less concern and for what they described as entanglement, meaning there's less resistance to aqueous outflow and better blood morphology. So, it's easier to visualize on the contact type of tissue based on the location and should an adjustment be required. And there's even a lesser risk or corneal endothelial cell loss.

Dr. Lisa Banker:

Thank you.

Dr. Fiscella:

Sure. Thank you.

Dr. Shane Mull:

Okay. Excellent. Thanks. And that was a Dr. Banker, but I believe she is the one that did the majority of the work on this policy. Are there any other questions? I'm sorry, was there a question? Again, we got just a couple minutes. I just want to make sure if anyone else had any questions or comments concerning this presentation. So okay. Hearing none. Thank you, Dr. Fiscella. We will move on to our next presentation, which is Owen Bishop from Ocular Therapeutix. Are you on the line sir?

Owen Bishop:

I am, Dr. mull. Thank you.

Dr. Shane Mull:

Excellent. Thanks. So, this will be concerning the Dextenza®, which is the brand name for the Dexamethasone Intracanalicular Ophthalmic Insert (Dextenza®) DL38792. And you may go ahead sir, and I'll give you 15 minutes if you need it.

Owen Bishop:

Okay. Well, and I was going to say, I will probably do good in keeping you well ahead of schedule because my comments are going to be extremely brief. But as was stated before my name's Owen Bishop. I'm the Senior Director of Market Access at Ocular Therapeutix and certainly appreciate the opportunity to address you all. Really specifically, we just wanted to convey that we really appreciate and compliment the comprehensive and complete analysis of the available literature for Dextenza®. We're certainly in agreement with all that was reported or proposed within the LCD and the recommendation to consider Dextenza® medically necessary to its indication of inflammation and pain, following ocular surgery. That said, I don't really have anything else to add.

I'll certainly yield back my time, but I do want to make at least a closing comment to simply say that I certainly look forward to the day where we can all safely meet in person again and have wishes for good health and safety of everyone on this call and I'll entertain any questions.

Dr. Shane Mull:

Yes. Please go ahead. Any questions on anyone concerning Dextenza®? All right. Well, sir, I appreciate that. And I certainly echo your comments about meeting in person again. These meetings certainly have their limitations. There is nothing like a face-to-face communication. I look forward to those times as well. I'm just not quite sure when that's going to be.

Owen Bishop:

Yep. We're all hoping for sooner than later, but it will get there. Right.

Dr. Shane Mull:

All right. We will go ahead and move forward. The next one is Colon Capsule Endoscopy, and this would be Dr. Rancati, hope I said that correct as well. Are you on the line?

Dr. Francesca Rancati:

I'm on the line. Yes. You pronounced it correctly.

Dr. Shane Mull:

Yes. Excellent. Thank you. Right. Ma'am, you may go ahead, and I'll give you 15 minutes.

Dr. Francesca Rancati:

Thank you. Good afternoon everyone. Thank you for this kind invitation to the meeting. My name is Dr. Francesca Rancati. I've been working with Medtronic since 2015 as Medical Affairs Director and today on behalf of Medtronic, I want to highlight that we appreciate the effort that went into the development of the proposed LCD Colon Capsule Endoscopy. We appreciate in the recognitions of Palmetto, that PSM column to qualify for medical college as a diagnostic test, a test that is safe and effective and also reasonable and necessary for a defined patient population.

And for the audience that doesn't know about the patient population that is approved, I found the FDA indication. Basically, these capsules might be used for the detection of colon polyps in patients after incomplete colonoscopy to evaluate the colon that was not possible with optical colonoscopy, despite an adequate prep. But it can be used also as a first line for the detection of colon polyps in patients who have a high risk for colonoscopy or major sedation.

For example, patients that have a lower GI bleeding and those patients who could not tolerate colonoscopy in case an abnormality is seen with a capsule endoscopy, they will have to undergo a colonoscopy anyway. So, the proposed LCD indicates that a colon capsule does not qualify the Medicare benefit for colorectal cancer screening despite, risk factors that patients might carry, including family history and Medtronic support these limitations since the FDA did not approve the colorectal cancer screening indication.

To conclude, Medtronic respectfully requests Palmetto to move forward with the coverage for Colon Capsule Endoscopy based upon the FDA approved indication. Thank you.

Dr. Shane Mull:

All right. Thank you. And with that I'll open it for any questions concerning Colon Capsule Endoscopy. Well hearing none, we will move forward. Thank you, Dr. Rancati.

The next presentation is for Facet Joint Interventions for Pain Management DL38765 with Dr. Barnhill. Are you on the line, sir? All right. Keith Barnhill, are you on the line? Okay, well, we are quite a bit ahead of time, so maybe he hasn't called in yet.

Dr. Shane Mull:

With that we will try and move forward to the next presentation. And then we will circle back if Melissa or anyone has a contact for Dr. Barnhill could reach out and see if we could get him on the line earlier. Because we'll probably finished up early, but we'll see if Bilal Khan from New World Medical, are you on the line?

Bilal Khan:

Yes, I am.

Dr. Shane Mull:

Okay, excellent. Do you mind going ahead with your presentation?

Bilal Khan:

Of course. So firstly, I would like to thank Dr. Mull and the Palmetto staff for the opportunity to participate today. I appreciate how much effort goes into coordinating these forums, particularly given the current circumstances, so thank you. My name as stated is Bilal Khan and I have the privilege of serving as CEO of New World Medical. New World Medical is a Glaucoma Surgical Device company based in Southern California.

Today, I would like to share our perspective on the proposed Glaucoma Surgical Interventions DL38759 LCD. We support continued coverage of the Ahmed implants under the LCDs drainage implant language and urge the MAC to finalize this portion of the LCD, after reflecting the American Glaucoma Society's recommended edits. Additionally, we request that Palmetto GBA not finalize a non-coverage decision for goniotomy.

I will focus my remarks on systematically walking Palmetto GBA representatives through the evidence substantiating this latter point. I intend to focus on four points. First, the draft LCD included incomplete evidence for Goniotomy, which is neither experimental nor investigational. Second, there is vast clinical data substantiating the safety and efficacy of Goniotomy with the Kahook Dual Blade®, also known as the KDB, including a level one randomized control trial. Third, Goniotomy with the KDB is performed in accordance with accepted standards for medical practice of Specialty Societies. Fourth and finally, while I realize it may not be the MAC's focus, I will briefly touch upon the unintended financial consequences of such a key non-coverage decision that as I believe it is worth noting. Please feel free to reference our submitted comment letter that includes more detailed information and references related to all the points that I will discuss.

To begin with my first point the draft LCD cited, incomplete evidence for Goniotomy, which is neither experimental nor investigational. Goniotomy has been performed to treat glaucoma patients for over 80 years. The procedures, safety and efficacy have been exhaustively documented. Goniotomy involves making an opening in disease trabecular meshwork tissue to lower interocular pressure by allowing aqueous to flow from the anterior chamber to the distal outflow channel. Notably, the LCD specifically sites, KDB in its non-coverage language.

The KDB is simply a tool used to perform Goniotomy. Goniotomy is the actual procedure performed and associated with a CPT code in question 65820. The KDB is a device that enhances this procedure by empowering surgeons to cleanly excise disease trabecular meshwork reducing failure from tissue

leaflets scarring back together. The LCD being discussed cites only a sliver of the clinical evidence related to Goniotomy. For example, the LCD's clinical evidence summary related to Goniotomy with the KDB is taken from the American Academy of Ophthalmology I-Wiki page discussing the procedure.

This I-Wiki article includes 18 citations of which the LCD only includes four. Further of the four citations included only one is peer reviewed. This dovetails to my second point. There is extensive clinical data demonstrating safety and efficacy of Goniotomy with the KDB, which is a subset of the broader Goniotomy literature. There are 31 peer reviewed publications related to Goniotomy with the KDB including 28, describing the clinical safety and efficacy of the procedure in over 1,450 eyes with up to two years of follow-up. A complete listing of these publications and a summary of their findings aren't included in our comment letter.

This clinical data spans indication, including procedures combined with Cataract Surgery and performed standalone studies related to patients with mild, moderate and severe Refsum Disease and angle closure data. Importantly, Goniotomy with the KDB is the only Microinvasive Glaucoma Surgical procedure that has clinical evidence demonstrating safety and efficacy in treating Angle Closure Glaucoma patients through two years of follow-up. Additionally, this vast clinical data includes level one evidence in the form of a perspective, multi-center, randomized control trial, comparing Goniotomy with the KDB and implantation at the time of cataract surgery in mild to moderate glaucoma.

I would like to pause at this point to emphasize that the comparator in the study Trabecular Meshwork Stent Implantation is covered by Palmetto GPA under its November 8th, 2018 LCD L37531. Results of this level one study were published in this past August edition of the Journal of Cataract Refractive Surgery, one of the most prestigious journals in Ophthalmology. The study included 82 Open Angle Glaucoma Eyes in each arm for 164 in total.

Procedures were performed across nine clinical practices. The study success definition was Interocular Pressure Reduction greater than or equal to 20% or medication reduction greater than or equal to one. The investigators found that at 12 months, 93.7% of the eyes and the Goniotomy with KDVRB are met the success criteria versus only 83.3% in the eye center. This difference in outcome was specifically significant. There are also multiple peer-reviewed retrospective publication confirming this conclusion in real world settings.

I'm moving to my third point. Goniotomy with the KDB is performed in accordance with accepted standards for medical practice. The AAO I-Wiki article that the LCD leveraged concludes, "When compared against other MIGS devices, such as the eye stent KDB produced equal, if not improved IOP lowering." This was corroborated in the World Glaucoma Associations, 11th consensus report on glaucoma surgery that was published late last year, which stated KDB can be used, "Standalone or combined with cataract surgery in early moderate or severe, open or closed angle glaucoma to reduce IOP hypotensive medication burden or both."

Forth and finally, while I realize it is not a primary focus, there are financial implications of a non-coverage for CMS and Medicare beneficiaries. The non-coverage decision for Goniotomy and Canaloplasty would force surgeons to substitute Trabecular Meshwork Stent Implantations for these procedures, which requires leaving a foreign body in the eye. These procedures also have a markedly higher facility fee, an ambulatory surgical center setting where a vast majority of procedures are performed as they are designated as device intensive by CMS.

In Jurisdiction M, this difference translates to an average additional facility fee of over $800 for every Goniotomy and Canaloplasty procedure that is replaced. Just to revisit the last point in Jurisdiction M, this difference translates to an average additional facility fee of over $800 for every Goniotomy and Canaloplasty procedure that is replaced, and this amount is actually under the proposed rule to CMS for 2021. The gap is projected to be more than $900 per procedure. By forcing care in this direction, a non-coverage decision would increase Medicare costs and the financial burden born by beneficiaries in the form of copays.

To summarize, One: Goniotomy is neither experimental nor investigational as demonstrated by numerous peer reviewed publications. Two: there is extensive evidence, including a favorable level one randomized control trial versus a procedure covered by the MACs demonstrating the safety and efficacy of Goniotomy with a KDB in particular. Three: Goniotomy with KDB is performed in accordance with accepted standards for medical practice and supported by major uptown societies, including the American Academy of Ophthalmology, the American Society of Cataract Refractive Surgery, the American Glaucoma Society, and The World Glaucoma Association. Fourth and finally: A non-coverage decision would increase CMS expenditures and the financial burden on Medicare beneficiaries.

In conclusion, I strongly urge the MAC not to implement a non-coverage decision for Goniotomy, given the procedures thoroughly documented track record for enhancing lives of glaucoma patients. Thank you again for this opportunity. I welcome any questions you may have.

Dr. Shane Mull:

And with that I'll open up for any questions concerning the presentation that was just given. Any questions for the current presentation? Alright. Sir, I appreciate your time. I also appreciate that you sent in written comment. I didn't mention it earlier, but that's an important aspect of how we gain feedback on these coverage decisions because all of the comments will be compiled and we will publish a response to comments article, which will address any comments that are brought up. That comment period is still open. We encourage everyone to continue to supply us with any comments, good or bad on these proposed policies.

Dr. Shane Mull:

Well, did Keith Barnhill join us yet? Okay, well, we're still running a little bit ahead of time, so we'll give him some time. I'll go ahead and open it up again for any comments or questions about any of these presentations that we've gone through so far. Anyone on the line have any questions?

Melissa Robinson:

Dr. Mull, this is Melissa. I did reach out to his office to see if he could join a little early, but I haven't heard back from him yet.

Dr. Shane Mull:

Okay, thank you. Okay. How about from any of the Medical Directors? Do you have any questions or comments for the presenters today?

Joel Almanzor:
This is Joel Almanzor from the Medical University of South Carolina. Sorry, I signed on a little bit late because I was doing a case. I'm just wondering if the LCD for Peroral Endoscopic Myotomy has been

discussed yet?

Dr. Feliciano

Hey, good afternoon Dr. Almanzor, this is Dr. Feliciano from Palmetto. There was no one registered to present on that particular policy so the way that we hold these meetings is that individuals wishing to present comments during the open meeting register ahead of time and submit their comments. Now that notwithstanding, there's always the ability to receive comments even if not presented at this meeting.

I just want to communicate that, that this is just one vehicle for receiving comments and the comment period for the POEM policy is open until November 7, so if you wanted to submit written comments, by all means; I'm sure that you've seen or maybe you haven't seen instructions for getting those comments to us. But if you would need the instructions on how to get comments to us, I'd be glad to send you those.

Joel Almanzor:

Sorry, for my confusion on this, Dr. Feliciano. I actually have no comments beyond what the information provided in the synopsis we recently reviewed. So sorry about that. I didn't realize it was a process, I apologize.

Dr. Feliciano:

No, not at all. Thank you. Just out of curiosity, has Dr. Barnhill joined us yet?

Dr. Barnhill:

Yes. This is Dr. Barnhill. The American Association of Nurse Anesthetists appreciates the work of the Medicare Administrative Contractors and for inviting the ANA to participate as a subject matter expert on the development of this draft LCD. We appreciate that Certified Registered Nurse Anesthetists or CRNAs are being recognized for the vital role in providing patient focused, comprehensive pain care in communities throughout the United States.

Today, I'm responding as a CRNA who practices in a predominantly rural setting and has experienced firsthand or really, onus regulations that increased costs and lower access to rural Medicare recipients. I'd like to comment on behalf of myself, rural CRNA practitioners and the ANA. My goal is to help Palmetto GBA and CMS improve health care for all our seniors, improve their access to rural pain care and hopefully, reduce costs nationally.

This brings me to my first point, according to the Institute of Medicine in 2011, report is widely accepted that chronic pain in America is at epidemic proportions. During the same timeframe it was estimated that over $635 billion was spent treating chronic pain related to problems or related problems. In 2014, an article by Foreman estimated that $300 billion was the cost of addressing lost wages and the opioid epidemic. He further suggested that the major contributors to the opioid epidemic were a lack of specially trained, rural pain management providers and primary care practitioners lacking the education to treat chronic pain disorders leaving them to rely on opioids as the main treatment option. Today, rural communities across the US are still facing multiple barriers to access quality pain care. One reason is that physicians with fellowship and specialty training are still less likely to settle in rural communities. This was an article by Peterson in 2013, such as those served by the Palmetto GBA.

This leaves additional strain on primary care providers who are at the forefront of rural health care and often lack training in chronic pain management. Additional barriers include workforce shortages, the inability to afford health insurance and the need to travel long distance to access healthcare. These three barriers are contributing to opioid over prescribing in rural over urban communities.

Across the US, CRNAs are currently filling some of these gaps in rural health by providing chronic pain care and contributing to a decrease in rural opioid crisis and these communities and based on their state Advanced Nurse Practice Acts, they worked collaboratively with primary care providers, Orthopedic and Neurosurgical Spine Specialists and Physical Medicine and Rehab Physicians to address these chronic pain needs. As members of the ANA, these CRNAs adhere to their state advanced practice, nursing acts, the ANA pain management practice guidelines and the non-surgical pain management fellowship training.

My next point, the proposed LCD does a good job of identifying coverage, indications, limitations, and the medical necessity criteria for Facet Intraarticular Medial Branch Block. I also appreciate the treatment of Fast Synovial Cyst, which is now being addressed. My concerns with the LCD derived from two issues. Number one, why is the second diagnostic medial branch nerve block prolonged to a minimum of two weeks? Number two, the dual medial branch nerve block is considered a prognostic block to determine the predictive value for radio frequency ablation procedure.

So, I'd like to talk about my first point. Why is the second diagnostic medial branch nerve block prolonged to a minimum of two weeks? I understand that 80% pain relief and increase in functional activity is as confirmatory as a facet joint, most likely being the pain generator. I understand that recommendations of the North American Spine Society, colon, and other pain medicine groups. However, waiting for two weeks only prolongs the patient's pain experience.

The patient may receive transient relief for the duration of the local anesthetic, but now I have to wait another two weeks for the second block. And another one to four weeks were Radiofrequency Ablation based on their secondary insurance. In reality, two to three days is enough time to calculate level of pain relief and performing the initial diagnostic procedure.

From a practical point of view, I would recommend decreasing the timeframe from two weeks to one week. This would result in the patient receiving pain relief on a shorter timeframe. The dual medial branch nerve block is considered a prognostic block to determine the predictive value for radio frequency ablation procedure. In the Palmetto group region, Medicare insured patients can be referred to as CRNA for evaluation of mechanical axle spine pain. I also understand that these referred patients already have an ICD-10 code at diagnosis from their primary care or specialist referring for the evaluation.

This will use me in the diagnosis or symptom of low back pain based on the patient's account, radiographic findings of pulses or similar diagnosis and a recommendation to treat this pain. I believe at this point it is important that a distinction be made between a diagnostic block and a diagnosis. Cohen in 2020 in answering the question, can history and physical examination be used to identify a painful facet joint or to select people for prognostic blocks?

I'm still talking about Cohen and his article on Prognostic Blocks. So, Cohen confirmed that the diagnosis

for lumbar facet generated pain relies on a combination of symptomology. Physical exam and confirmation by diagnostic block, a notion supported by multiple pain practitioners. Cohen also went on to differentiate the diagnosis as the process of identifying a disease, condition or injury from its signs and symptoms. So that was diagnosis. The term prognosis was defined as forecasting or likely course of a disease and it meant sort of determined the predictive value of a therapeutic intervention.

Diagnostic blocks when applied to subset medial branch nerve blocks are considered a prognostic procedure for potential radiofrequency ablation. The pre-existing diagnosis made from the physical examination and radiological review remains. So in conclusion, I'd like to see CRNAs in the Palmetto GBA region be allowed to practice to the full extent of their license, reimbursed for their services related to this LCD and adhered to patient centered healthcare that adheres to the key principles of affordability, accessibility and the reduction of opioid use in the Medicare population.

I appreciate the opportunity to comment. I believe CRNA is vital to resolving the short supply of rural providers and our important step in reduction of opioid crisis. I also appreciate you allowing me in the ANA to partner with Palmetto GBA to achieve reform, reduce healthcare costs and improve the healthcare of the patients that we serve. Those are my two main points. Thank you for listening.

Dr. Shane Mull:
All right. Thank you, sir. I appreciate you taking time out of your day to present those comments to us. With that I'll open it up. Are there any questions for Dr. Barnhill?

Okay. Well, as we mentioned earlier, we've gone through all of our presentations. I'll just open it up one more time for any questions or comments from anyone on the line. Okay. Well hearing none, again, I appreciate everybody calling in today. We are going to take a break here and then reconvene at 2:30 for the JJ Open Meeting. We have a full plate there as well. With that, I will sign off.