WPS GHA Open Meeting – June 18, 2019

Moderator: Noel, Dr. Ella

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OPERATOR: This is Conference # 9388564

Dr. Ryan Holzmacher: First. DL382111 corneal hysteresis is draft LCD replacing the current WPS article A54957 corneal hysteresis, which is a non-coverage article. This new LCD embraces the requirements of the Twenty-First century (inaudible) Act. This draft LCD is a non-coverage policy for all corneal hysteresis assessments as immunitive risk assessment or monitoring for progression of ophthalmology disease activity.

Hysteresis is a measure of resistance to the formation to applied force. Corneal hysteresis is a measure of the viscoelastic dampening property of the cornea and is postulated to be a surrogate for the viscoelastic dampening properties of the posterior sclera and lamina cribrosa through the retinal ganglia cell axon as it passed through an exited the eye.

Multiple articles were referenced in the draft policy, most for observational studies. Practice guidelines do not recommend corneal hysteresis in the management or risk assessment of glaucoma, glaucoma suspect, or ocular hypertension.

A two thousand eighteen Hayes review of sixteen qualifying studies found that corneal hysteresis testing has some capacity to detect the presence of glaucoma, to predict the risk for glaucoma progression, and to predict the response of glaucoma to certain types of treatments.

However quote, "The evidence is mainly comprised of very poor quality correlation studies, which lack the rigor to determine diagnostic or prognostic accuracy. Most of these studies did not use reliable methods to determine the accuracy of diagnosis or prognosis. No studies were identified that directly assess the clinical utility of corneal hysteresis measurements for selecting treatment for glaucoma or for impacting long-term health outcomes."

	In summary, corneal hysteresis is promising as a risk assessment tool in the diagnosis and management of glaucoma or corneal pathology. While the body of evidence is large, the overall quality of the evidence is poor. The studies are relatively small observations, often compounded by lack of treatment control, uniformly citing simple correlations precluding cause and effect conclusions. It is still unclear whether corneal hysteresis provides useful additional information, much less it's optimal role in any diagnostic, prognostic and treatment algorithms. The lack of level one evidence, absence of proven clinical utility, known clinical practice guidelines endorsements, as well as no Medicare nor commercial coverage argue strongly against current corneal hysteresis coverage, as reasonable and necessary for the treatment of Medicare patients. We do have one provider who would like to make some comments and also provided us with a power point presentation. Operator, if you could open it up for Dr. Jay Pepose.
Operator	Excuse me, Sir, all of the lines of the speakers are already open.
Dr. Ryan Holzmacher	Dr. Pepose, are you with us? I'll ask it one more time, Dr. Jay Pepose, are you able to speak, are you with us?
Female Speaker	(low volume)
Tameika Lewis	She says she has all of the lines open.
Dr. Ryan Holzmacher	Operator, we are sure that Dr. Pepose is able to speak with us, he doesn't have to do anything else?
Operator	All right. I was able to locate Dr. Jay. I will just open the line of Dr. Jay, one moment.
Dr. Jay Pepose	Hello.
Dr. Ryan Holzmacher	Dr. Pepose, hi, Dr. Holzmacher with WPS, how are you today?

Dr. Jay Pepose Good, how are you?

Dr. Ryan Holzmacher I'm good, thank you. Sorry about the little technical delay there, but we are ready for your presentation. I do have your power point open for those who are in person here with us today.

Dr. Jay Pepose Okay, thank you.

Dr. Ryan Holzmacher Sure. If you want to let me know when you want me to change the slide, I'm happy to do that for you.

Dr. Jay Pepose Okay, great. And you have the first slide up, just the title slide. Great.

Dr. Ryan Holzmacher Exactly. So, if you want to introduce yourself, we can go from there whenever you're ready.

Dr. Jay Pepose Okay, thank you. So, I appreciate the opportunity to comment on the proposed coverage policy for corneal hysteresis. And I do urge you to consider the evidence that's available today and decide to cover and pay for the service and let me explain.

Next slide please. So, corneal hysteresis is an important test, in my opinion, for primary open angle glaucoma, which is the predominant type of glaucoma that we see today. Fifty percent of patients with glaucoma don't know they have it, it's painless and results in blindness if untreated.

And I believe that the evidence of clinical utility using corneal hysteresis in identifying patients at risk for poor progressive open angle glaucoma is robust, especially given the goals that we have for treating glaucoma, which is to reduce the intraocular pressure because we know that elevated intraocular pressure results in advancing disease, which, in turn, results and irreversible vision loss.

Next slide please. So, how is glaucoma detected currently? There really is no single test that's strongly predictive of disease progression and no test cited in the LCD letter has gone through randomized studies, so, I would emphasize that. We have many tools to measure changes in anatomy and the functionality of the eye that gives us information to what has already happened in the eye.

So, for example, optic nerve OCTs, intraocular pressure, retinal nerve fiber layer, visual fields, but that's telling us the damage that's already occurred. We need tools to help us predict how the condition will progress.

Now, in the past the OAT study showed that corneal pachymetry provided some potential indication. But, as we found out, corneal thickness or pachymetry is just a small element of corneal biomechanics and that led us to defining colonial hysteresis.

Next slide. So, corneal hysteresis is an independent risk factor, independent of IOP, independent of corneal thickness for patients at risk for progressive open angle glaucoma progression, as well as a response to treatment. It measures the degree to which the cornea can absorb and dissipate energy. And this translates to an indication of the likelihood of the cornea to manage the increasing pressure indicative of open angle glaucoma and, in turn, the expected rate of glaucoma progression.

And this is a significantly different and, I would say, clinically important that bit of information that we gather from the other tests, such as visual field exams, for example, that are only documenting the amount of damage that's already happened.

Next slide please. So, what is the evidence of clinical utility for corneal hysteresis for primary open angle glaucoma? Next slide please. Now in PubMed there are over seven hundred publications to date on corneal hysteresis and glaucoma dating back from is really is two thousand and five. And these have shown that corneal hysteresis is associated with progressive visual field loss, is predicted the magnitude of intraocular pressure reduction following treatment with various therapies, and the most common is topical prostaglandins, as well as laser trabeculoplasty.

It shows that lower corneal hysteresis is associated with more rapid visual progression in patients with normal pressure glaucoma, which is the most difficult group to identify and they are at risk. And it shows that low hysteresis has shown prospectively to predict the development of glaucoma in patients who don't yet have any visual field changes. And it's shown to be predictive of the rate of nerve fiber loss over time.

And if you do look at the Academy of Ophthalmology preferred practice guidelines, it does state in several places it says, "Corneal biomechanical properties, such as hysteresis, may also have an impact on IOP. Management in glaucoma risk." It says, "Low corneal hysteresis

is associated with glaucoma progression."

It says, "Under risk factors for glaucoma progression corneal hysteresis is a measure of the viscoelastic dampening of the cornea and has been shown to be associated with the risk of glaucoma progression." So, I think it's well-documented and accepted within the academy's preferred practice guidelines.
Next slide please. I think some of the strongest studies have been prospective longitudinal studies that have shown that corneal hysteresis is a risk factor for predicting the development of glaucoma. And this is independent even when adjusted for age, intraocular pressure, and central corneal thickness.

So, every millimeter lower of corneal hysteresis is associated with an increase of twenty-one percent in the risk of developing glaucoma during follow up. So, this allows us to identify patients who are going to need more careful monitoring, who are going to require treatment, and, also, means that patients who don't have these risk factors don't need to be followed as frequently.

Next slide. Another perspective longitudinal study showed that corneal hysteresis, again, confirming this, was associated the risk of glaucoma progression more than other factors. It shows that, in terms of outcomes, corneal hysteresis explained the impact of intraocular pressure rates on progression and the combination of corneal hysteresis and intraocular pressure we're both critically important in the assessment of or progression.

Next slide please. And, again, the group that's the hardest to diagnose is those that come in with normal pressures, particularly early on when we don't see optic nerve changes or visual field changes. And this study, if we look at these other metrics; retinal nerve fiber layer thickness on OCT, corneal thickness, we see here the only corneal hysteresis is statistically significant in terms of the P value in a logistic regression correlating with visual field progression in the step wise study. So, I think these findings suggest that corneal hysteresis can be used as a prognostic factor for progression independent of corneal thickness or IOP.

Next slide please. I think, also, in terms of clinical utility, we need to know which patients are going to respond to which types of treatment. And it shows here that, again, corneal hysteresis is predictive of the response to glaucoma therapy, and in this study it was the topical prostaglandin therapy, the baseline calling hysteresis was

	independently associated with the magnitude of IOP reduction from prostaglandin therapy. And, again, lowering the pressure is the only thing that we're able to do to lower the risk in these patients. Next slide please. So, to summarize, we can rely on the corneal hysteresis measure of the eye to titrate up the intensity and urgency of follow up care, to eliminate unnecessary interventions and costs by its results. We can rely on corneal hysteresis to give us new information about patients' disease progression and their risk and, in turn, greater confidence in our treatment decisions. And the final slide, so, my colleagues I ask you to modify this policy to cover corneal hysteresis for primary open angle glaucoma, specifically for patients at risk of glaucoma. And those patients at risk are already defined by Medicare; patients with diabetes, with a family history of glaucoma, African Americans age fifty or older, Hispanics age sixty-five or older. And this is in alignment with our current primary open angle glaucoma management strategies. Thank you for your attention.
Dr. Ryan Holzmacher	Thank you, Dr. Pepose, thank you for taking the time to join us and add some comments to this draft LCD today. Operator, can you see if there's anyone else on the line that would like to make a comment on the corneal hysteresis draft article?
Operator	At this time, I would like to remind everyone in order for you to ask the question, please press star followed by the number one on your telephone keypad. Again, that's star one on your telephone keypad. We'll pause for just a moment to compile the Q&A roster.
Robert Kettler	Ryan?
Dr. Ryan Holzmacher	Yes?
Robert Kettler	Hi, this is Bob, when there's chance I have a question that I'd like to ask Dr. Pepose.
Dr. Ryan Holzmacher	Why don't we, while we're waiting to see if there's any other callers, go ahead, Dr. Kettler?

Robert Kettler Okay. My question is, and I apologize I don't have the slides here, this might have been obvious if I had the slides. Has this test actually been tied to an improvement in the outcome relative to other means of following glaucoma? And then I have a second question after that.

Dr. Jay Pepose Well, this has been, again, studied prospectively longitudinally and shown to be the most productive risk factor for glaucoma. Up till now we've had basically just intraocular pressure but then we realized that the measurement, itself, of intraocular pressure, was modified through the biomechanics of the cornea because that's how we're taking the pressure.

Then we realized that corneal thickness was a part of the biomechanics, so, the OAT study that was conducted, the ocular hypertension study showed that there was some significance to corneal thickness, but nowhere near the magnitude of corneal hysteresis. And the reason that we think that this is so important is that the biomechanical structures of the cornea turn out to correlate with the biomechanical structures of the lamina cribrosa, which is the structure holding and supporting the optic nerve as it goes through the framing.

So, there's two aspects of corneal hysteresis the turn out to be important. One is it affects the pressure measurement, it gives a greater fidelity. And that's how we're titrating treatment and efficacy, in addition to the to field loss.

And secondly, it reflects the actual structure around the nerve. So, this is the first metric we have the correlates with that. So, I think to answer your question, this is being used right now, clinically, in patients.

And there are no randomized studies of any tests right now in glaucoma. I would say that of all the tests that we have right now, all the ways we have of defining glaucoma, there's probably more support for corneal hysteresis than there is for any other single metric.

Robert Kettler Would you say, then, this is a screening test, a diagnostic test, or a way to follow therapy?

Dr. Jay Pepose Well, for example, I don't think a patient needs to have corneal hysteresis tested many times a during the year as you would measure their pressure. I think basically we would like to identify those patients who are at the highest risk, just like measuring the corneal thickness, particularly those patients who are at the highest risk, as defined by

Medicare, the diabetic patients, the patients the family history, the African Americans and Hispanics over a certain age, because those are the patients at high risk.

So, if we could look at those subsets and say, "Okay, within those subsets, this patient has low corneal hysteresis, the most risk to developing glaucoma, they need to be followed the most frequently. And here's another group that has high corneal hysteresis, they're at much lower risk, maybe seeing them twice a year is going to be adequate.

I think that's very useful information. So, I think it helps us to identify the patients at risk. It helps us to identify those patients who are going to have the greatest progression, if we're seeing a patient who already has some signs of glaucoma, some evidence of visual field loss. And, also, most importantly, I think it identifies the patients who are going to respond the most to different types of therapy.

Robert Kettler Okay. And then just one last question. Would this be a test administered by optometrist, by ophthalmologist, or any other practitioner, or can anybody do this?

Dr. Jay Pepose Well, I think most commonly this test will be performed by ophthalmologists and optometrists. I think that it's an objective test, it could be performed by technician. But I think the interpretation is more likely going to be conducted by either an optometrist or an ophthalmologist.

Robert Kettler Okay, thank you.

Dr. Jay Pepose And those are the doctors who are going to be managing those patients with glaucoma. Thank you for letting me answer.

Dr. Ryan Holzmacher Thank you, Dr. Kettler. Is there anyone else on the line that would like to comment regarding this draft LCD? Okay, well, we'll move on then to our second draft LCD, that's DL34228; Percutaneous Vertebral Augmentation or PVA for osteoporotic vertebral compression fractures. This draft LCD will be replacing WPS LCD 34592, which is a limited coverage policy for the treatment of osteoporotic compression fractures. And this is an updated document embracing the requirements of the Twenty-First century (inaudible) Act.

This draft LCD is a restricted coverage policy for the treatment of acute vertebral osteoporotic induced compression fracture PVA or otherwise known as two different procedures; percutaneous vertebroplasty and percutaneous kyphoplasty is covered in patients meeting conditions outlined in detail in the article, including acute symptomatic vertebral compression fractures without the presence of an excluded condition.

Some background on this LCD osteoporosis and low bone mass affect fifty percent of people over fifty years of age or over fifty million people in the United States. The primary impact, fractures, also called fragility or low trauma fractures, occur secondary to normal activities such as bending, coughing, lifting fall, from standing height, and eventually occurs in fifty percent of women and twenty percent of men.

Vertebral compression fractures constitute one quarter of osteoporotic fractures, often at the md-thoracic T7, T8 and thoracolumbar C12 through L1 junction. They may cost significant acute and chronic pain leading to complications of impaired mobility comparable to a hip fracture. Other complications, including pneumonia, loss of bone or muscle mass, incident of falls, deepening of thrombosis, depression, and isolation.

Medicare claim status shows eighty-five percent ten-year mortality following a vertebral compression fracture diagnosis. Under diagnosis and under treatment may exacerbate morbidity and mortality. Treatment options of symptomatic osteoporotic vertebral compression fracture range from nonsurgical management, including anti-osteoporosis therapy, analgesics, limited activity and bed rest, back brace, physical therapy to percutaneous vertebral augmentation, again, two forms; vertebroplasty or kyphoplasty.

Percutaneous vertebroplasty involves the percutaneous injection of bone cement under image guidance into the vertebral compression fracture. Percutaneous kyphoplasty adds a balloon tamponade within the fracture vertebral body to create a low pressure cavity prior to cement injection. Both treatments aim to immobilize the fracture, reduce pain, and improve alignment.

Summary of evidence, numerous articles were referenced in the draft policy. The review of evidence generally supports the premise of weight bearing fracture immobilization to limit pain and deformity. Super impose is the recent trend towards the immediate focused surgical immobilization and away from prolonged general immobilizations, such as casting, bracing, bed rest, and prolonged systemic pain

management, such as opiate analgesics, particularly in the elderly.

The preponderance of evidence, studies, national and society guidelines, systemic review, and multi-specialty panels, clinical care pathways, and Medicare claims data favor consideration of early percutaneous vertebral augmentation in select patients, those with moderate to severe disabling pain due to acute osteoporotic vertebral compression fractures confirmed by physical examination and advanced imaging findings. There's nobody in the room with any comments. Operator, is there anybody on the phone that would like to make a comment regarding this draft LCD?

Operator — Yes. We do have a question from the line of Janet from Nebraska. You may now ask your question.

Janet Fett — I'm so sorry, my question had to do with the corneal hysteresis. I just wanted the name of the presenter, I came in late.

Dr. Ryan Holzmacher — Sure. I can do that. And then, Dr. Pepose, if you're still able to speak, you can also provide any additional information. It's Dr. Jay Pepose, he's the professor of clinical ophthalmology at Washington University.

Janet Fett — Thank you.

Dr. Ryan Holzmacher — You're welcome. Any other comments regarding vertebral augmentation or the hysteresis draft LCDs?

Operator — Yes. We also have the line of Douglas Beall from Oklahoma; your line is open.

Douglas Beall — Thank you. So, the question is under the coverage indications, the inclusion exclusion criteria, as was mentioned part of the summary of the evidence for the inclusion criteria included the rand use of the leg, expert recommendations using the appropriate methodology. And that's been adequately reflected by the inclusion criteria, specifically under B part symptomatic. That takes the portions of the recommendation directly out of that rand use of leg methodology from the expert recommendations.

But it's a little bit deconjugate because the exclusion criteria do not where it says, can have none of the following in the exclusion criteria, it lists all of the exclusion criteria. But the expert recommendations from

	the rand use of leg recommendations did not reflect that. It stratified these into absolute contraindications and relative contraindications. And as it reads there in the exclusion criteria all these, A through J, would be absolute contraindications. And this kind of doesn't make sense. For example, an allergy to contrast or cement as impasication agents are alternatives if people have allergies. So, that would negate treatment in somebody that has a good viable option, as an example.
Dr. Ryan Holzmacher	Thank you. Can I have your name just for the record and for those listening?
Douglas Beall	Yeah. Douglas Beall.
Dr. Ryan Holzmacher	Okay, thank you. Any other comments regarding this LCD?
Operator	And, again, if you would like to comment, please press star one on your telephone keypad. That star one on your telephone keypad.
Dr. Ryan Holzmacher	And, Dr. Beall, thank you for your comments. If you could also send your comments into the LCD comments, as well, so, we can have those on record. Anyone else have any comments regarding either of the LCDs today?
Operator	Yes. We do have the line of Renee Taylor; your line is open.
Renee Taylor	Yes, hi. We have an ambulatory surgical center, I'm not sure if this is even where to ask this question. But my doctor wanted me to get on this call and find out if this is something we can get answered. When we're doing these in our ambulatory surgical center a reimbursement is less than when we're doing them if we were to do them in an office setting. And I was wondering if there was a reason for that?
Dr. Ryan Holzmacher	Yeah. This is just comment period regarding this LCD, not reimbursement questions, so, we can direct you to the website they'll help you go through that.
Janet Fett	Okay.

Dr. Ryan Holzmacher	And you'll be able to get some help from WPS regarding that question, okay?
Renee Taylor	Okay.
Dr. Ryan Holzmacher	Thank you, though.
Renee Taylor	Thank you.
Dr. Ryan Holzmacher	Any other comments or questions>
Operator	Again, please press star one on your telephone keypad. Presenters, we don't have any questions or comments at this time, you may proceed.
Dr. Ryan Holzmacher	Well, again, thank you everybody for taking the time to join us today to discuss these two draft articles. Again, these are on our website and published for further review and for the comment period it'll follow this open meeting today. Thank you, everybody, have a good afternoon.
Operator	This concludes today's conference call. You may now disconnect.