

Anthem, Inc.

Moderator: Carolyn Cunningham, MD

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This is Conference # 3064158

Operator	<p>Good afternoon. My name is Felicia and I will be your conference operator today. At this time, I would like to welcome everyone to the NGS MAC Open Meeting. All lines have been placed on mute to prevent any background noise. After the speaker's remarks there will be a question and answer session. If you would like to ask a question during this time, simply press star then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key.</p> <p>Thank you. Ms. Carolyn Cunningham, you may begin your conference.</p>
Carolyn Cunningham	<p>Thank you. Welcome everyone.</p> <p>First of all, can the people in the room hear the operator, and hopefully, us?</p> <p>Okay. I think we're going to start off with Dr. McKinney talking some about how things are changing with the 21st century act. Doctor Awodele is our technical expert as well as Jeanne Roberts. And then we'll have a brief presentation about the policy, and then doctor Radcliffe will speak with us about his version of his thinking about Corneal Hysteresis.</p> <p>Greg?</p>
Greg McKinney	<p>Good afternoon. I'm going to talk really slow because this meeting will likely be very short if Boston is any indication of how things will last. Want to make it worth your efforts so I'll try to do at least fifteen minutes. I'm kidding. So you can claim at least an hour. We'll round up to an hour, how 'bout that.</p> <p>Hopefully everyone can hear me. I'm Greg McKinney. I'm chief medical officer for NGS, and want to welcome everybody to the meeting today. Some familiar faces - some who don't know me. Welcome. I do want to go over a few things about the process, what's new, what the new process entails, what that means for every MAC and every contractor, and sort of give you the lay of the land. An overview of the new LCD process.</p> <p>This process was the result of legislation called the 21st Century Cures Act in which part of that legislation outlined how LCD development in the process would be different. That legislation led to a remake of the LCD chapter in the Medicare Internet-Only Program Integrity Manual. It's chapter 13 - program</p>

integrity manual, of the CMS Internet-Only Manuals. So, if you can find it, and if your Ambien subscription I think has lapsed, and you want some reading, there are about thirty pages of redlined chapter - which means the entire chapter has sort of undergone a rewrite. In some respects, that's a good thing, because the chapter for the most part has not really been addressed for several years.

In this version, the process has really sort of turned around. Many of the components are the same, many of the processes are the same. The order and the workload on behalf of the contractor has changed, and that's kind of what I want to address. Just for reference, we did put out an article on our website about the first of the year - a reference for you to go back and look. It's a general, high level overview of how this process has changed for the LCD development process and how it has affected us, and what 2019 will bring.

First let me say we are learning. This year is sort of an experiment of what works best, what doesn't work best; because this whole dialogue about LCDs and the re-creation of the LCDs and the process by which we develop LCDs has been going on, that conversation has been going on for a while with CMS. They got input from contractors, from stakeholders, from legislatures from the act, and so they've been working on this manual revision for a long time before it became effective September the third.

It was effective October the third, so anything after October the third is affected by this new process. It's important to kind of keep in mind - even though it's effective October third, we were still having calls afterwards to kind of understand - really CMS, what do you mean, is what we do? How do we do it? To what level do we function?

Understand it's ongoing, it's a partnership with CMS, we are - I would say in my history of being a CMD - and we'll let others kind of comment - but having done this for eighteen years, this is the most intimate relationship we've had with CMS with this new change in quite a while. We're very involved with them, we want to make sure we get it right - they want to make sure they're communicating it right to us and that were understanding what the whole process is about

At a very high level - again we're going to a lot of boring details for you, a lot of that's in the chapter and some of that's in the article - but the LCD development process is undergoing a change that really promotes transparency, openness, and collaboration with the provider community, stake holders, other MAC's. So it's not just stake holders, not just providers, it's not just other MACs, it's a total overhaul of the collaborative effect of togetherness on LCDs.

Also, 21st Century through the transparency has now provided a means for us - every LCD, every source that we use - we have to comment on why we use of that source. I kind of liken it to -- some of you, most of you will not remember this because your age - but back in the day when we used to write a composition paper you got all your index cards and read everything. You started righting notes and on the back of index cards and you start for shuffle them all together and that's how you wrote your composition paper.

That's kind of what we do now for LCDs. We're going to get input from the provider community, stake holders, our CAC - and I'll address the CAC in a minute - and all that information comes together. We read through the articles. The ultimate decision, let me just say, is left to contractor discretion. We have the ultimate decision on the policy, but we have to be transparent about how they came to that decision.

Some of us feel we have always been transparent - but to some, if they can't get inside your brain and read every little thought that you have - then they don't think you're transparent. So we're going to give you every little thought that we have about every little article, the strength of that article, and why we chose it. That's going to magnify our policies volume wise quite substantially. Also, any stakeholder or experts that we talked to that comments about the policy, that we go to about the policy; their name will have to be listed in the policy. Every contact that we have will be listed on the policy for transparency and review by the community that's interested in LCD.

The process and the dates are similar. The forty-five days' notice comment - all that hasn't changed - but what has changed is that the CAC's role has evolved and changed. I think that's probably one of the biggest components of the LCD process. CAC's under the old method - we brought the draft like we're doing today, ready, and presented it to the CAC and let them comment on what we had sort of drafted up, and they could comment.

That process is no longer. We will come to the CAC saying we are going to write a policy on XYZ. Give us your thoughts - we don't have anything in writing, but let us know what you think. Give us your articles, tell us who we need to talk to, what is your expert opinion. We assimilate all that information and contribution of information from the CAC members without a draft.

So, typically - the fact that we have a CAC - the use of the CAC is optional. It depends in large on the nature of the LCD and that's up to our discretion. For example; don't take this is something that's coming down the road, but say if we had a genomic testing policy or a new technology or a new device and it's

more specialized - it's more oncologic hematology driven, we may have what we call a specialty CAC. What that would mean is that we would take our CAC representatives from our jurisdiction that were part of that specialized community, and they would be the focus of our conversations about the LCDs. Other CAC members can come, but our focus is to target those - what we call "specialty CAC" that have expertise and experience in the topic for which we're thinking about doing a draft.

That meeting, when we have it with the CAC/specialty CAC will be open to the public. You will be able to dial in - listen mode only - but you'll be able to dial in and listen to that conversation and that CAC meeting. All this information, the timeline, meetings, how you get in; will all be on our website. When we announce the CAC you will be able to call in and dial in on listen mode only and the CAC members will be involved. They are aware of this. They know that's the new rule.

Again, it was closed before. I think that's one of the more transparent things that CMS thought they needed to do. So the CAC was very closed. So now the CAC will be open for listen mode only. And all our CACs will be telephonic, so don't try to find out where we're meeting and come see us. It's all gonna be telephonic and so you can dial in. We won't be meeting in any basements or anything like that. All telephonic and you can dial in.

We will take the CAC, and then we'll take those comments, we will take all the information, churn it together, produce a draft; have this meeting. This meeting is open to anybody. We encourage our CAC members to listen / come if they choose. It's open to anybody and everyone.

If we have a CAC that involves speakers; I'll just let you know it is our right or authority or our privilege or however you like to limit your time. We have a big hook and will pull you off the stage if you go over your time. Due to timing constraints, the number speakers, what we have to cover...CMS does this, so we're not doing anything that CMS doesn't do. So we will limit your time based on the length of the meeting and what we have to cover. Generally, five to ten minutes. That's a loose figure of what we're gonna give our speakers. What we expect are little nuggets during our conversation.

That's kind of the mode that we're gonna go. Again - a learning year - we are one of the first MACs, I think the first MAC, to do this process. A lot of other MACs are waiting 'till further down the road, so we are kind of learning from this, and that's what the article on our web says. This is a learning process;

we're gonna be partners in this with our community, and learn to do it better. So, that at a high level is kind of the new process.

I do want to mention that the one additional thing to that that will probably be important to understand that wasn't part of the process before - We were always asked at these meetings or casually, "Are you going to do an LCD on XYZ?" And we probably said, "Well you know, probably not," or "It hadn't really touched our radar yet," or "Maybe not." Now there is a formal process to request an LCD. To request an LCD there's a process by which you have to go through to send it to us.

Having said that, you can imagine that the flood gates have opened. We have gotten numerous requests for LCDs. "Do one on this, do one on this, do one on this." You will get what seems to be an impersonal response that will say we have received your request and we have put it in queue. So, because we have to look at our work plan throughout the year - we only have so many bodies, we have so many time - this is the same thing that Medicare does with our national coverage determinations. We're going to be a little bit more attentive than they are. They don't do many NCD's; but it will be in queue.

We are working through a way to stratify those requests. An example would be if you say, "I want to do a request for an LCD on XYZ," and we get one claim a year, it's probably going to go low in the queue. If we get a million claims a day, it may go to the top of the queue. That's just an example of parameters that we're trying to work through. How we weigh all these LCDs and what we're going to do for those.

So, if you put in a request, just know it's got to get in the system, get in the pipeline, we're going to crank them out as much as possible - but unfortunately with the new method of detailed scientific review of every article - a detailed response and narrative about every article - the front load work is voluminous. The front load work to bring this to you today is a lot more laborious than it used to be. Cranking out LCDs will not be as smooth and as fluid and as fast as it used to be.

Hopefully, once we get running after this year, or as we kind of go through the process enough - it will speed up. But that's the way it's going to be at least for now, and it's not purposeful. Okay, so just understand. We understand that you want some kind of determination on your product XYZ, that's fine. It will also give us the opportunity to collaborate with other MACs if other MACs are having an issue with XYZ.

	<p>We may all do the same policy; we may have a national CAC if that makes sense. Have a call from representatives from every jurisdiction to have a MAC that will discuss that topic, so all MACs can hear. You will be able to dial into that. One MAC usually will take the lead on that policy to organize the call - all that kind of stuff. The group, the timing, the date, the sort of organization of that.</p> <p>So, having said that, that's pretty much it. These open meetings are for the LCDs only. It's not for "I want to talk about ABC even though we only have XYZ as a policy." This is not an open forum to discuss topics and issues. It's only to discuss the LCDs that we bring forward. Want to make sure that the open meeting really hasn't changed in that respect - that we're presenting a policy and that's what we're going to discuss. That's why it sometimes might be really short. I think I've talked about seventeen minutes, and so we'll round that up to an hour.</p> <p>I'll pause just for second. Can't take many questions, but if there's a burning question that you - yes? Go ahead.</p>
Dr. Awodele	<p>I just wanted to add a couple of things and maybe clarify a little bit. Obviously when someone comes to us and says "Write an LCD," they want a positive LCD. The fact that we say "We're putting it on the queue does not imply we are in agreement with you that it's going to be a positive LCD. In the same vein, the same thing with LCD reconsiderations. The change that we have now - once upon a time we were able to tell you; we're sorry, we don't agree, we're not going to do this.</p> <p>But now we just have to let you know - we interact with you once and we let you know that your request was valid. And valid just means you've checked all the boxes of everything that the manual now sees that you submit. So, by telling you that your request was valid it doesn't mean we are in agreement with your request and therefore "Stay tuned." I just wanted to say that.</p>
Greg McKinney	<p>Yeah, that's great. Thank you for clarifying that. It's like we usually say with CMS - be careful of what you ask for. If your claims are getting paid right now and we don't know about it - if you put in a request, then that might not be a happy moment for you. I'm not saying it will or won't, but just be cautious. Be careful of what you asked for in that.</p> <p>The other thing I want to mention is that back in the day when we had an LCD on... urinalysis, and a new diagnosis came out, and we said "Oh gosh." So, somebody'd say can you add these diagnoses, we used to be able to say "Yeah, add 'em on August first, start building it on September first," because it just</p>

	<p>takes us a month to get the edits in the system, the policy updated - boom you can bill it.</p> <p>That is no more. To liberalize a policy was very easy for us. Now to liberalize a policy we have to open the LCD back up in its entirety to go through this process. So, what once was a very streamlined, thirty-day max kind of process when you did a reconsideration - now they LCD has to be opened up in its entirety. So, what happens is those policies that have been in place for a few years are not under 21st Century Cures. They still are there. But if we ever take those policies and open them back up for whatever reason; new diagnoses new technology entire policy has to be opened up and it has to conform to 21st Century Cures. So, they have to be more detailed, more voluminous, and go through this entire process.</p> <p>So in some respects the process has been transparent it's more open. But, again, as you can see, the pipeline will get bogged down. We'll try to crank it out as much as possible. So, use that consideration for an LCD very carefully. We're not discouraging that, but think about that before you submit a request for an LCD coverage.</p> <p>Yes, ma'am?</p>
Female Questioner	<p>You mentioned that if several MACs come together and do a joint CAC or it could even be moved over into a national coverage. What are the determinations for that? Is it only, you know let's say two or three MACs get together the determination would only be for those? And at what point does it flip over even though a national coverage policy wasn't requested? When does it flip over into that?</p>
Greg McKinney	<p>Okay. A couple clarifications. A national coverage determination is done by CMS and CMS only. Contractors do not do that. When I say a national policy that's a "little n" right? Not NCD. But "Oh, well jurisdiction XYZ has that problem" - we all have to be in agreement - and in general it's all the MACs kind of collaborating as a joint national thing. But it's not an NCD - that's CMS.</p> <p>But each jurisdiction will have the policy. It should read roughly the same, the coverage should be the same, and it should be uniform across the country if we feel that it's an issue in every jurisdiction. A great example are labs. Some labs are housed in like three states. And that may only cover two jurisdictions. Well it wouldn't be beneficial for the jurisdictions where the lab isn't to do that LCD because we don't get any claims for that. To be involved with that policy is not worth it to us because we don't get claims on that item when the other two,</p>

	three, one jurisdiction gets all the claims because of where the policy or the lab that runs that test is housed.
Female Speaker	And what becomes national - sorry - is the fact that, remember, we said now CAC's are optional, but if we're going to have a CAC and everybody - and you can say national - anybody who is interested in working in that LCD can have that as one big CAC. That's what we meant by it'll be one big CAC. Mega-CAC. Then the open meetings will still go down to the jurisdictions like they need to.
Greg McKinney	Right. We'll have to have this meeting, still, but the CAC will be one universal CAC across all jurisdictions.
Carolyn Cunningham	I think it's important to say we still are required to have a CAC.
Greg McKinney	Correct. Not a CAC meeting, but a CAC. We still have our CAC. The people who are part of our CAC - we will still have that body. We maintain the body of the CAC, but the CAC meeting is evolving. That's a distinction. We still have the same CAC members; CMS is deliberating - we make can even go to a jurisdictional CAC whereas now we have three CACs, we could go to one CAC for J6. That is an option for us. We haven't exercised that yet. Not going to predict or say anything about whether that's on the horizon or not. Just a couple more questions. Yes, Sir?
Male Questioner	Yeah thanks. I just wanna make sure I'm clear. The ten-minute forum for the speakers is still an open meeting, not the CAC meeting.
Greg McKinney	Correct. Yes. The industry does not speak at the CAC.
Male Questioner	What about a provider? Is that still the open meeting, not the CAC?
Greg McKinney	Correct.
Female Questioner	When you mentioned adding codes to an LCD, even if it was to liberalize the LCD you would have to open it. Is that at a provider's request or a stakeholder's request, or does that mean even if you all knew that there were... like, when we went to ICD-10, you would have to open each policy up to add any code? Or just if it's requested?

Greg McKinney	If we change the policy at all, it has to open up. Whether we start it or anybody requests it.
Carolyn Cunningham	But Greg, I think when the ICD-10 changes come October first this year we can make those kinds of changes.
Greg McKinney	Right. The annual updates to codes, yes, but if we mid-year say we want to add XYZ code because now the literature says yes or whatever; that would open it back up to the whole process. But the annual updates are going to be just as annual updates have always been. [crosstalk]
Carolyn Cunningham	We can also change the policy of something if an ALJ makes some determination that would affect the policy. That doesn't happen very often - they make decisions that [are in concert] with the policy, but we don't have to change the policy, number one. Number two, if CMS comes out with something that contradicts what's in the policy we would need to change the policy. And third, if we had a policy for an eye device for glaucoma and the manufacture withdrew that device, we would do coverage for that.
Greg McKinney	Right. There's some subtle differences that probably don't happen too often - to Carolyn's point - if [NCD] comes out we can't contradict that; we have to support that. We made withdraw our policy and let NCD take over. The subtle things. But by and large those are kind of the rules of the game.
Carolyn Cunningham	And they're pretty much the same as they were before.
Greg McKinney	Except we can't just liberalize. Yes, Sir?
Male Questioner	[inaudible - off mike]
Greg McKinney	As I mentioned; as we get that stack of considerations for LCDs we have to kind of see claim volume, price we have to can take those all into consideration. We haven't perfected that formula yet so we just kind of [inaudible] queue, we discuss them all the time to see, you know, what is the level of evidence that's out? Are there no articles out there? What do we see? Are they manufacturer produced and there's no blind studies? So we kind of take a holistic approach to how we prioritize. We have enough on our plate that it's not gonna be a problem to -

Male Questioner	[inaudible - off mike]
Greg McKinney	<p>Sure. That still exists, and those rules have not changed. What I was trying to point out was what would affect you all as far as - you're approaching your perspective on how LCDs are done.</p> <p>One last question.</p>
Male Questioner	[inaudible] -transparent in queue. Will we know where we are at?
Greg McKinney	You will know that it is in queue, and you will not.
Female Speaker	Neither will you know what the decision or...because sometimes we don't even know. Again, like what we just said about the process.
Greg McKinney	<p>I think one last final comment before I turn it over back to Carolyn. If we decide to take a consideration for LCDs and we think, "Okay, we're going to take XYZ policy next June and it's from manufacture ABC," we can't call and say "Hey, just so let you know, we're gonna do this next June." That is privileged information. We can't give anybody the heads up. It has to be a transparent announcement on our website. It will go on our website - boom – "We're about to do an LCD on XYZ."</p> <p>Two days later as a courtesy we may call you and say "Hey, make sure you go to our website and see that." It has to be transparent first. We can't call you as a manufacturer and say "Hey, just want to let you know, no need to call us every other day, it's going to be June." We can't do that. But once we pop it out on the website - so if you're not on the Listserv we would advise you to be on the Listserv - you'll get a notification that come whatever date we're going to be posting LCD on XYZ.</p> <p>With that, I will - gosh, almost twenty-five minutes. A billable hour - okay, so I'll turn it back over to Carolyn.</p>
Carolyn Cunningham	<p>Thanks Greg. Well, we have the one policy to present today, and that's Corneal Hysteresis. This is a noncoverage policy, and it's for all Corneal Hysteresis assessments, whether it's for diagnosis or risk management or monitoring for prevention of Glaucoma or other eye disease. What it is, is a measured resistance to how elastic the cornea is. A puff of air is delivered at several times and it measures how fast it usually springs back. And not only is there a corrected intraocular pressure - that's a thing that also attracted intraocular pressure where the golden method is given.</p>

	<p>It's been proposed as a risk stratification tool for the treatment of glaucoma, glaucoma suspects and ocular hypertension. That's because a lower value is associated with people who have glaucoma or inter-ocular hypertension.</p> <p>There've been several studies in literature, and a number of them are summarized in the draft. But there's not any studies showing improved patient outcomes using corneal hysteresis.</p>
Female Participant	Sorry, I can't hear you back here so I don't think they can hear you.
Carolyn Cunningham	Sorry. This better?
Female Speaker	Doctor Cunningham, I'm not sure if you can hear me, but the sound has gone much lower for us on the phone. I'm having trouble hearing you.
Nathan Radcliffe	<p>Yes, this is doctor Radcliffe. I'm here. Is my voice okay? This is Nathan Radcliffe. Can you hear me now? [inaudible] I can certainly hear all and I'm off mute. [Inaudible]. Are you able to hear me? This is Nathan Radcliffe.</p>
Female Speaker	Okay. Try again, I think we can - Okay.
Nathan Radcliffe	I can certainly hear you better now, okay. All right. So, okay and so I'll begin, and I understand, definitely under ten and closer to five, ideally, right?
Carolyn Cunningham	Well, that's the usual guidelines but since you're the only speaker today for this we'll tolerate longer than that.
Nathan Radcliffe	<p>Okay. So I heard the initial comments. No one [respond and] focus on those, but I will quickly review just the data that we have. Glaucoma effects maybe two percent of Americans. Four million have it. Increase by age, increase in certain populations - African Americans/Hispanic populations have higher prevalence. Half the people in America you have glaucoma don't know it.</p> <p>Prognosis is a little bit tricky. Requires pretty thorough eye examine and good technology, and the treatment is to lower the pressure through laser and through surgery. One response to the first comment is that we're sure the only thing we have outcomes related evidence for in the entire field of glaucoma is that lowering pressure through laser, medication, or surgery can slow or stop the disease. All of the other technology that we use haven't had that type of evidence. That will include everything from OCT's, Corneal thickness, and a</p>

whole slew of testing including hysteresis because glaucoma is a slow disease and it takes a very long study.

I'm moving now to what is the second slide - how is glaucoma detected currently. We have basically a comprehensive eye exam, interact with other pressure, nerve evaluation, evaluation to retina in the fiber lair, visual field testing, and then central Corneal thickness. These things are all done in the office - many require trained technicians to be performed. They're all reimbursed, and they all also haven't necessarily been shown to affect outcomes, but are nonetheless considered indispensable parts of the diagnosis and management of glaucoma.

Importantly, in 2001 the ocular hypertension treatment study and NIH-funded longitudinal study did demonstrate that measuring the thickness of the cornea was very important to determine the prognosis of eyes with ocular hypertension. In fact, it was a strong predictor of who went on to ultimately develop glaucoma, and so we measure central corneal thickness in our glaucoma patients.

Since that time, and I'm now on the slide that says "Corneal Hysteresis - Independent Risk Factor for Primary Opening Glaucoma Progression." The ocular response analyzer came out not to measure the thickness of the cornea, which is a geometrical property, but to measure its biomechanics. This is done through basically an air puff machine that applies air. Cornea bends in. Infrared light measures the cornea's response, and from that it is able to determine the biomechanical properties of the cornea. So now this is the measurement not just of how thick the cornea is, but how stiff or strong it is.

Next, evidence of the utility of Corneal Hysteresis for primary opening of Glaucoma. I'm going past that slide to a slide that shows the timeline: Establishment of Corneal Hysteresis Evidence in Glaucoma. Seven hundred publications - and there is a lot of evidence, and what I would argue is I think it is true that we do not have outcomes evidence for hysteresis, but what we have is as good as evidence for the use of Corneal Hysteresis in the measurement of glaucoma or management of glaucoma as for anything else we're doing. In fact, hysteresis has been shown in prospective longitudinal studies to outperform the standard of care, which would include [contractual] pressure assessment, corneal thickness, and all of our standard tools. This may be a statement of how tough it is to measure change and progression in Glaucoma, but hysteresis is a strong "We're doing that."

The studies that have been showing this are part of the UCSD perspective diagnostic innovations in glaucoma study that has measured patients who were either glaucoma suspect or have glaucoma. Follow them for four to five years, and they prospectively measured hysteresis and indeed found that if your glaucoma suspect and your hysteresis was low - over time you're more likely to get the disease. If you already had the disease and your hysteresis with low, over time you're more likely to worsen.

The reason this is important here is because you can now use hysteresis to determine who should be examined more carefully, who should be treated more aggressively; and also who maybe doesn't require as many resources, who doesn't require as frequent follow ups, who doesn't require all the expensive medications and lasers. If used properly, hysteresis can save a lot of resources on the healthcare system. That's one of the reasons to use it. Not just to save money, but to save patients from unnecessary treatment and unnecessary examination and time requirements.

This slide says prospective longitudinal study establishes hysteresis as a risk factor for predicting the development of glaucoma, and this is higher than average eyes. What you see here is that eyes with a higher hysteresis tended not to progress over time. Eyes with a lower hysteresis did. And the difference between those two groups was quite dramatic. There were no eyes with a high hysteresis that we're rapidly getting worse.

What that means, is that if the patient has a high hysteresis - twelve, fourteen - highly unlikely to require surgery, highly unlikely to go blind in the next few years. They tended to be in a more safe space as opposed to those of the low hysteresis. Imagine being a patient who's very concerned about going blind from glaucoma, learning that your hysteresis is high, and that you're not in a high risk category. Hysteresis outperforms [interactive] pressure, age, and corneal thickness in this study for the development of glaucoma.

Moving along here to this last slide that says Prospective Longitudinal Study Hysteresis Associated with Risk of Glaucoma Progression. What you see here if you advance a little bit is a color coded slide that shows hysteresis and risk for developing a change in the visual field. And what this study found with that if you had both a low hysteresis and a high pressure, you were at a much higher risk for getting worse. Those two risk factors had a statistical interaction. These are the patients who were in trouble and deserve our attention.

The next slide is on normal tension glaucoma, and these are patients who are very hard to identify. The pressure is normal inside the eye, and in fact these

	<p>are the patients who might come back having had a normal pressure for months or years and they've gotten worse and they're going blind. They're much more likely to have a low hysteresis. So in the absence of a high pressure to tell you that there is a risk that needs to be treated; the hysteresis can provide evidence.</p> <p>Next slide is a study I published. Corneal Hysteresis is Predictive of Response to Glaucoma Therapy, and what we found in this study is that patients with a low hysteresis - this is the first quartile hysteresis - did much better when they were placed on drops. They had a good pressure reduction. Patients with high hysteresis tended not to respond as well. Now we see hysteresis not just as something that will tell us who might be developing glaucoma, but we see hysteresis also telling us how a patient might respond to a therapy. And again, it may indicate that we would consider using a different therapy, not using so many different therapies in those patients. That can be very helpful as well.</p> <p>The two cases that I'll show, and I'm not going to go into these patient details, but rather wrap up here. The important part of the cases is that. The patient - when you know the hysteresis - you will absolutely change the way you manage the patient. If they end up being higher risk than anticipated, you will either - at the very least - see them more frequently or order additional testing. What you may actually do is add additional medications.</p> <p>It isn't necessarily the case that you're going to do a surgery you wouldn't have done otherwise, but it helped you in the overall management much better. At the same time, if you have to patient with a high hysteresis, this is someone who you can often not worry about as much. You can reassure the patient that you can see them less frequency; you can use less resources. In many cases you can stop topical eye drop therapy that, in my cases is expensive and irritates the eye and causes the patients discomfort.</p> <p>I think I will let it rest there, and see if we have any questions.</p>
Carolyn Cunningham	<p>Questions or comments from those in the room?</p> <p>Operator, do we have anyone on the phone?</p>
Operator	<p>At this time, I would like to remind everyone - in order to ask a question, press star then the number one on your telephone keypad. We'll pause for just a moment to compile the Q&A roster. Again, that's star and the number one.</p>

Female Questioner	[inaudible - off mike]
Carolyn Cunningham	I'm not sure you heard that comment for those people on the phone, but it was basically that the request for coverage was just - Corneal Hysteresis used for primary open angle glaucoma. Operator any star ones?
Operator	There are no audio questions.
Carolyn Cunningham	Dr. Davis do you have anything else to add?
Operator	You did have one question to come into queue that was from Viktoria Davis.
Carolyn Cunningham	Very good. Dr. Davis?
Viktoria Davis	Hi, this is Viktoria Davis representing the Minnesota Optometric Association. I don't exactly have a question or anything, I guess. I'm just expressing the Optometric Association's agreement with what Dr. Radcliffe presented. I think he did a fantastic job presenting things. Certainly, Corneal Hysteresis is showing to be - in both the optometry and ophthalmology community something which - although the research may not be great at this point, there's a lot more but that's coming out as well - and really showing remarkable effects on treatment. And, hopefully, potentially, on patient outcomes. Time will show us that as well.
Carolyn Cunningham	We have a bibliography for Dr. Radcliffe's presentation. When the call is over, would you review it to see if there's other things that we need to review, please?
Viktoria Davis	Yes, I will
Carolyn Cunningham	And also if you could send the comment into us in writing, we would appreciate that. Thank you.
Carolyn Cunningham	Thank you again. Any other commenters, operator?

Operator	No, ma'am. Not at this time.
Carolyn Cunningham	Well thank you Dr. Radcliffe and thank you Dr. Davis. If there's no more questions or comments, we'll close the call and thank everyone again for attending either [inaudible].
Nathan Radcliffe	Appreciate the opportunity to speak. Thank you very much.
Carolyn Cunningham	You're welcome. Thank you.
Operator	This concludes today's conference call. You may now disconnect.