Anthem, Inc.
Moderator: Bentz, Susan
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Operator: This is Conference # 449365

Operator: Good afternoon. My name is Latasha and I will be your conference operator today. At this time, I would like to welcome everyone to the NGS MAC Open Meeting Conference Call. 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 that time, simply press star then the number one on your telephone keypad. If you would like to withdraw your question, press the pound key. Anyone who speaks must disclose any conflict of interest on today's call. I would now like to turn the call over to your host, Ms. Carolyn Cunningham, you may begin the conference.

Carolyn Cunningham: Thank you Latasha. Can everyone hear? Okay, can you hear us on the phone?

Male Speaker: I can hear.

Female Speaker: Yes, very good.

Carolyn Cunningham: So welcome everyone. Thanks for your patience while we're getting set up. We're happy you're here and we'll proceed on with the meeting. We have four policies that we're going to discuss today, two of them have presentations connected with them, and otherwise the other two did not. So I think we'll get started with our first policy. Craig?

Craig Haug: Thanks Dr. Cunningham. As you mentioned, there are 4, we'll take them one by one. The first one is the percutaneous vertebral augmentation for osteoporotic vertebral compression fracture and the biomarker testing prior to initial biopsy for prostate cancer.

Carolyn Cunningham: Craig, hold on, they're having problems hearing in the room, so we need to think about.

Craig Haug: Okay.

Female Speaker: Latasha?

Operator: This is Latasha?

Female Speaker: Hi, this is Laketa. I just received a note from I guess someone on the other lines that they are not able to hear anything on the phone, not now but when we're speaking I guess.

Operator: All participants are in a listen-only mode and it is complete silent now.

Female Speaker: Okay, I'll verify if they may now.

Virginia Muir: Laketa, this is Virginia. I just sent a chat note say that I couldn't hear anything because there is no sound at the moment, but if that's what you're talking about.

Female Speaker: Okay, yeah, it's on, it's completely silent now.

Female Speaker: I guess they have us on mute at the moment.

Male Speaker: That's correct because no one's talking right now.

Female Speaker: Yeah, it's muted.

Female Speaker: Okay. Thanks.

Female Speaker: Okay, we have everybody?

Male Speaker: I'm still here.

Female Speaker: Good.

Male Speaker: Can you hear me?

Female Speaker: We can hear you Craig. How about the people who called in can you hear? You're not set up to speak all of you.

Male Speaker: [multiple speakers] operator.

Female Speaker: Okay.

Female Speaker: Can you guys hear doctor?

Male Speaker: I can hear through the microphone.

Female Speaker: Okay, we'll start over.

Male Speaker: Okay.

Female Speaker: But Craig, I think she wants you to check the different path as far as the order of presentation?

Female Speaker: Let's go ahead with the order that they are on the site.

Male Speaker: Okay. And can everybody hear me now so that problem is resolved?

Male Speaker: Is that yes?

Male Speaker: Yeah, everything is yes.

Male Speaker: Okay. Hi, so I was --- I think this slide currently up on the web access the four policies that are up for comment today. The Vertebroplasty policy, the Biomarker testing for prostate cancer diagnosis, the Microinvasive glaucoma surgery, AKA MIGS, and Water vapor thermal therapy for LUTS BPH. You can go to the next slide. So the first policy per comment is Percutaneous Vertebral Augmentation for osteoporotic vertebral compression fracture, DL33569.

This is a collaborative LCD among the MACs that resulted from the National CAC held on March 20th this year, which was instigated by a recent state of negative publications. This slide includes the draft LCDs positive coverage criteria encompassing fractured acuity, severity of symptoms, length, and nonsurgical management, and the need for multidisciplinary team consensus.

Next slide, okay. This slide just the contraindication for coverage, so the flipside basically on the other slide.

Next slide, in summary, we decided that the preponderance of the evidence made this consideration of early vertebroplasty in select patients. I don't think we received any request to present on this topic. Anyone in the room or on the call want to make a comment?

Male Speaker: Yes.

Female Speaker: We have one comment Craig.

Craig Haug: Okay.

Female Speaker: One person at this point.

Female Speaker: We're getting the person the mike so.

Male Speaker: Thank you all. Thank you very much. This is Dr. Asokumar Buvanendran from the Illinois Society of Anesthesiologists and pain physician.

Male Speaker: I'm having a hard time hearing, I don't know about anybody else.

Female Speaker: Maybe just like this.

Male Speaker: Can you hear me better?

Male Speaker: Yes just on the comment on the inclusion criteria?

Male Speaker: Yes, I can hear better.

Male Speaker: All right. Thank you.

Male Speaker: Under point C---

Male Speaker: And do we have a disclosure.

Male Speaker: Yeah, so let me repeat that again. My name is Buvanendran and I'm just from the Illinois Society of Anesthesiologists and I have no conflict of interest. So specifically talking about inclusion criteria, point C, where it says --- let me read that to you and then I'll send you my comment. The multi-disciplinary team consensus (it says referring physician, if there is treating physician) question is it is just a referring physician and the person performing the procedure or does it have to be a radiologist as to what the multidisciplinary team. The way it is written is not very clear. I would propose that if the referring physician and the person performing this procedure is sufficient for this multidisciplinary team. Thank you.

Male Speaker: Dr. Cunningham, please summarize it for me, I am not sure, I couldn't hear quite fair enough total together.

Female Speaker: He is concerned about item C, I think in the indications?

Male Speaker: Right, yeah I got that much and it was not clear --- we still don't have the clarity of it. Who is it going to be required?

Male Speaker: Okay.

Male Speaker: So it says, was there a question about the referring physician?

Male Speaker: The question Craig is where the brackets form or grammatical is a radiologist mandated or he is supporting that it just be the referring physician and the person performing the procedure be the only required personnel in the multidisciplinary team.

Female Speaker: And Alicia, could you go back to the slide before the one I had up please?

That's the one that has indications on it.

Male Speaker: The intent is that it requires a referring physician, it gives two examples. It is two examples of that. Examples were rheumatologist and endocrinologist. Treating physician in other words performing the procedure itself. And then, two more, potential team members will be radiologist and neurologist. So in that was that came from each of those has a citation, so it is going through some guidelines or something like that and that was linked in NCCN guidelines. So if the speaker could submit this comment writing, you know we'll take a look at it and we'll respond to it.

Female Speaker: Does that answer your question?

Male Speaker: Yes, just as a comment, as it said, again Dr. Buvanendran was stating like 10% of his procedures are done by pain physicians across the country. So they did not know performance by that category of physician group in this category C and so therefore I totally agree with a referring physician and the doctor performing it, but having a select physician group examine this patient again would prevent treatment for this acute condition and is under great decison for the surgical procedure. So with that, two groups that referring physician was performing the procedure, and ignoring the term anesthesiologist from our pain physician be included in this category of physicians. Thank you.

Male Speaker: Okay, do we have any other comments in the room or ---

Female Speaker: Do we have any other on the line?

Operator: Your first question comes from Douglas Beal.

Douglas Beal: Yes, I have a comment just something to point out. First, this change to the inclusion or exclusion criteria, they're logical, beneficial for the patients I think and reflect current literature, so well done. The only difficulty and I will submit these in writing is that because these are included changes on top of an old LCD, there are things that don't make sense.

For example, previous versions allow treatment of more than 3 vertebral compression fractures for people that have multiple myeloma or steroid induced osteoporosis with subsequent fracture. And this includes criteria there they ran UCLA methodology criteria that were only for osteoporotic vertebral compression fractures, that's an example.

The other example is one of the inclusion criteria includes the timeline of less than six weeks provided it meets certain criteria and that's reflective of current practice and current literature, that's good. But it doesn't mean that the previous criteria fractured greater than 6 weeks should be eliminated just added into that and that should be clarified.

Examples of the exclusion criteria that need to be modified that don't read as intended is, it says can have none of the following, other causes of back pain, well everybody that has vertebral compression fracture that's osteoporotic will have some other cause of degenerative disk disease or facet arthropathy, so that needs to be clarified a little bit.

Another example of that is greater than three fractures, another example is allergy to cement, you can have other film materials. So what it would include on the exclusion criteria is it the same criteria that were included on the inclusion criteria, just be included on the exclusion criteria to bring that up to date and that's using the same literature as was used for the inclusion criteria. I have all of these comments in writing and will submit those.

Female Speaker: Thank you very much.

Male Speaker: That's a real thank you for your comment and the support for the policy in general. This is a place in your policy, so I'm not sure if there was confusion about that, but the old policy would be retired once this becomes effective. This policy does not address anything but osteoporotic compression fracture, so what we do is in our expectations that the other indications for cancer, etcetera, that the expectations that they would be covered in this policy and its restrictions only applied to osteoporotic compression fracture, but will take a look at your other recommendations and respond.

Male Speaker: Will there be another policy that involves neoplastic fractures?

Male Speaker: I don't think so. I think that if the only was the most of the controversy in serving most of the activity is in the area of osteoporotic fracture that certainly most of the experimental data addresses and that's what we focused on.

Male Speaker: No that's very true. The neoplastic fractures represent a very significant category and a very significant in debilitated patient population, so if this was the case I would think that needs to be discussed. That wasn't brought up at all in our preliminary call earlier and I know a certain portion of people, I'm just speaking for the society of Interventional Radiology, there is a whole sub specialty that does interventional oncologic work and this is a substantial portion of that.

Male Speaker: Yeah, again, there's a lot of Medicare that isn't addressed by policy most in fact. We tried to focus on those things that we feel need a policy or need some type of restricted coverage. If you feel like that there need to be careful coverage or a more restricted coverage similar to this that should apply to the cancer patients we'd be happy to look at that.

Male Speaker: For now, I'll submit my comments on this and make a couple of editorial comments regarding the previous policy in the relationship to incorporating the new changes in the new policy, I think that's just the mechanics of facilitating that incorporation will be the main thing.

Male Speaker: Thank you.

Female Speaker: Thank you.

Male Speaker: Any other comments in the room or online?

Female Speaker: Go ahead operator.

Operator: Your next question comes from David Schultz.

David Schultz: Yeah, I just want to comment that the less than 6 weeks of duration after the fracture was identified - that seems quite short, I mean we often weight it to 12 weeks before we might consider vertebroplasty or kyphoplasty.

Well, I think most of the literature looks at or at least attempts to look at acute fractures as defined by time which is less than 6 weeks, so we're going -- - we're trying to stick to what the data shows. I know that there was some future I think Vertos 5 you could address more chronic fractures, but most of the literature address acute and in fact some people are focusing on hyperacute.

Male Speaker: Okay.

Male Speaker: Thank you.

Male Speaker: Operator, any other questions?

Operator: You have a follow up question from Douglas Beal.

Douglas Beal: Just a comment, the vapor trial done by Bill Clark focused on fractures less than 6 weeks and there's another randomized control and that was a placebo control or randomized control trial. But other randomized controlled trial by Yang also focused on this patient population, so there's quite a bit of recent evidence on the less than 6 weeks to be treated patient population as Dr. Hoag just stated.

Male Speaker: Thank you.

Operator: There are no further questions at this time.

Male Speaker: Any other questions in the room?

Female Speaker: No more questions here.

Male Speaker: Okay. So hearing nothing. No more further questions, will consider comments on this draft LCD closed. Thanks everyone for the comments. The next, if we could go to slide 8. Yeah, so this is already here. We've to cover the next three policies which are revisions for those policies. The official comments are limited to only the specific changes noted.

Next slide. This policy Biomarker testing prior to initial biopsy for prostate cancer diagnosis, DL37733. The change here was addition of coverage of the EPI test comparable to several other tests that were previously covered. And this addition was made on the basis of recently published literature and they're listed there, those two. The first is a revision for the NCCN prostate cancer early detection guidelines and also a second validation study in references listed there.

Currently, we have one registrar presenter on this topic Mr. McLain, a representative of the test manufacture. Mr. McLain, if you're there, please proceed. And also if we could get, okay you already put in presentation now. Thank you.

Mr. McLain: All right. Thank you very much for the opportunity to speak to you today. Next slide, our test is exosome prostrate intelliScore. This is a test that is run by exosome diagnostics, a wholly owned subsidiary of biotechnic corporation in support of the proposed changes. This test is used in a population of men who have a grey zone PSA results where it's indeterminate as to whether you should proceed with prostate biopsy. The clinical reality is 80% of these biopsies proved to be unnecessary because the disease is benign or a low grade prostate cancer that does not benefit from treatment.

We've created a novel test in the space urine base looking at RNA from the patient and calculating our risk score for high grade or the prostate cancers that needs to be treated. And it addresses our test the clinical concerns that have been raised by the US Preventive Services Task Force about unnecessary biopsies and the overtreatment of low grade prostate cancer. This is the most extensively validated test in the space and Dr. Haug cited the recent publication in European Urology and the inclusion in NCCN guidelines as of January of this year and I'm speaking today to support finalizing these changes to the local coverage determination to include EPI.

Next slide please. The EPI test is a urine-based test, it's very simple for the sample to be collected. Again, it looks at RNA markers of high-grade prostate cancer. It evaluates the levels of those markers using QPCR and then an algorithm looking at those levels of expression create a very simple risk score. Unlike the other tests that are on the market, this test is standalone. It does not include any standard of care risk factors already being considered by the urologist in determining that risk score, so it is completely independent.

It adds new value to the assessment of the patient and the need for biopsy. So physicians utilize this single risk score along with the standard of care factors that they already consider to work with the patients to determine whether it's necessary to proceed with biopsy. Adding this test to that discussion can help avoid up to 50% of unnecessary prostate biopsies.

The next slide please. EPI is the most clinically validated test in the space. It is supported by 14 peer reviewed publications and presentations. The clinical study supporting this number more than 5000 patients across 11 different patient populations in the United States. One study that we've done it provides level 1 clinical evidence or two validation studies provide level 2A clinical evidence meeting the standards for evidence here.

The validation studies are publishing reading journals in the Urology space and we are conducting --- we are publishing data from a large thousand patient utility trial that is showing the actual value of the test in practice that will be published this year. That study shows not only that we avoid 30% of unnecessary biopsies, Urologist compliance with the EPI result is 93%, and when the EPI test is available the population where it's available versus a population where it isn't, the test also helped out of 500 patients identifying 30 more men with high grade prostate cancer. So the clinical benefit of the test is significant.

Next slide please. At the beginning of 2019, EPI was added to the NCCN guidelines for early detection of prostate cancer. It is put into the guidelines at the same level as the other tests that had been under this coverage determination. As a further a brief update sent submitting these slides, I just want to inform you that the EPI test has been cleared by New York State Department of Health.

The lab and the tests are now certified. That has significant implications because New York State Department of Health is a designated reviewer for FDA, so it's substantiating that we've met FDA evidence standards. Also we were just informed a week ago that we have been given a designation by FDA that this is a breakthrough. What that means is FDA has assessed that our technology platform looking at exosomes is a breakthrough technology that there are no FDA cleared or approved tests that meet this clinical need, that EPI is going to have a significant benefit for clinicians and patients and that EPIs approval by FDA will be in the best interest of the US population. Thank you.

Next slide please. So in conclusion, we strongly support these proposed changes to the LCD to include coverage for EPI consistent with the other biomarker tests and we recommend that NGS should finalize the L37733 as proposed. Thank you very much for the time today.

Female Speaker: You're welcome.

Male Speaker: Thank you.

Male Speaker: Thank you Mr. McLain for the presentation and support of the draft. One question I had for you, you mentioned in level 1 study, is that the one that's not published yet, is it?

Male Speaker: That's correct Dr. Haug. It's a level 1 study. There were a thousand patients who were being biopsied. We collected a sample and ran an EPI test for all 1000. As part of the study, these patients were blinded and randomized and EPI test result went back to the same urologist for 500 of the patients. It wasn't available for the other 500, so with the same urologist at the same centers we were able to observe how they made the biopsy decision with and without the EPI report. That is in draft now, the one year follow up period has been completed. We're drafting that publication. It will be submitted over the summer and will be published this year.

Male Speaker: Yeah and the reason I ask is that was one of the reasons we have somewhat constrained coverage of all these tests is that there was no level one data and I just want to make sure that as of now this included the EPI test, but as of now there's no level one data that's been published. So please get that information to me when it is published.

Male Speaker: We absolutely will, thank you very much.

Male Speaker: Anyone in the room or on the call want to make any additional comments?

Female Speaker: I don't see anyone in the room Craig, how about operator?

Male Speaker: Operator?

Operator: There are no questions here on the phone line.

Male Speaker: Okay. All right. Then, will consider comments on this draft LCD closed.

Female Speaker: And Craig, you talked closed in the meeting today but not during the comment period.

Male Speaker: Right, closed in the meeting today.

Female Speaker: Yeah.

Male Speaker: Yeah, so let's go on to the next I think slide 10 in the original slide deck, that's the Dr. Katz presentation, present back to the slide deck.

Male Speaker: I think Dr. Katz is ready to present.

Female Speaker: Yeah, but she wants to go back.

Male Speaker: Well, okay, let me just---

Female Speaker: You need to --- sorry ---

Male Speaker: I just want to introduce the topic here. So the next policy and the consideration is Microinvasive glaucoma surgery (MIGS) DL37244. There were two changes to this policy. The first one a new device called iStent inject. Coverage for this device was added identical to the original iStent device based on pivotal study data the same one referenced down below in the slide.

And also we deleted coverage for CyPass which was another completely different device because of the FDA recall due to safety concerns last September. Two people registered to speak on the topic of iStent inject. The first is Dr. Katz who is the chief medical officer for Glaukos and also a professor of Ophthalmology at Thomas Jefferson University. Okay, we can switch to his presentation. Dr. Katz, please proceed.

Male Speaker: Thank you. Good afternoon. I appreciate the opportunity of speaking to you today about iStent inject, which is used for the treatment of glaucoma.

Female Speaker: Craig, can you hear him well enough?

Female Speaker: I can hear him fine.

Male Speaker: Okay great.

Male Speaker: Thank you. My financial disclosure is you heard as I'm the chief medical officer for Glaukos, the maker of the iStent. Glaucoma as some of you may not know is a disease of the eye where the pressure is too high that leads to damage of the optic nerve and blindness if left untreated. Currently, there are two ways to treat glaucoma by lowering intraocular pressure that's easier to help the fluid exit the eye or decreasing the fluid production inside the eye.

Next slide please. Glaucoma is a very common disease. Unfortunately, it's the second leading cause of blindness in the world, the number one cause of irreversible blindness which could be prevented by lowering intraocular pressure the only treatment we have currently for this disease. The worldwide prevalence of Glaucoma is estimated to be approaching 80 million by the year 2020. Unfortunately, 6 million of those patients are expected to be blind bilaterally because of inadequate treatment or access to treatment. This glaucoma problems goes up with age and our population's aging in the United States, there is going to be a definite increase in prevalence of the disease within our country. And unfortunately, many of the patients remain undiagnosed, up to 75% remain undiagnosed in our country.

Next slide please. We'll hear a little bit later, but the treatment for glaucoma can be very challenging especially early in the course of the disease where many of the patients remain asymptomatic initially. And the treatment with medication can fraught with a lot of problems with compliance with chronic therapy on a daily basis.

Next slide please. This slide is just showing the kind of the current treatment paradigm that we have for the treatment of glaucoma starting early in the course of disease with medical therapy, drop therapy on the eye, laser treatment as well in the office leading typically in the past towards incisional surgeries like trabeculectomy and tube shunts, which are high risk procedures that we resort to when there are no other effective therapies for the disease and the alternative would be blindness if left untreated. All of these again I must emphasize are to lower intraocular pressure, the only treatment for glaucoma.

Next slide. The iStent is a bypass device that help fluid flow out of the eye and thereby lower intraocular pressure. The original iStent was approved by the FDA in 2012 with the CPT code 0191T and you can see this is an L-shaped stent device, it's about one millimeter long. More recently, the next generation of iStent inject was approved by the FDA in 2018 and these two stents work in the same fashion as the original iStent in terms of improving outflow of fluid outside of the eye with CPT code also 0191T initially used, but we're asking that 0376T also be used for this device.

Next slide please. This slide summarizes many multicenter trials, longitudinal studies funded by the National Institute of Health. All of the common theme of lowering intraocular pressure making a difference in the outcome of the disease. In other words, lowering intraocular pressure definitely stop the progression towards loss of vision and blindness if pressure was lowered

effectively. This translated into one millimeter reduction equaling a 10% reduction in the rate of progression of the disease within a year.

Next slide please. In review, some of the evidence specific to the use of the iStent and how it works on lowering intraocular pressure.

Next slide. There have been perfusion studies done on cultured human anterior segment samples as well as whole eye profusion models in essence which this shows is that the placement of a single iStent does improve flow of fluid out of the eye, which should lower intraocular pressure. But if you place it an additional stent, it improves the outflow that much more and lowers the intraocular pressure yet further in these experimental lab studies.

Next slide. This is actually a human trial, so this is now in the operating room and I'm just going to highlight for you two different patients here in this picture. The first two rows are one patient, patient A and the second row patient B showing that when you inject a dye looking at flow before an iStent is placed, you can see a certain flow pattern that once you place a stent which is the second row, there's a marked enhancement of flow in two regions. So the placement of two stents improves flow of fluid out of the eye in two regions that really are enhanced tremendously by the placement of two stents in two different locations.

Next slide. This is now looking as the clinical setting of how it actually does lower intraocular pressure and this meta-analysis really combines data from 28 different studies, almost 2000 patients eyes were looked at the analysis here. And there are two things I want to point out. Number one is that the intraocular pressure reduction looking at 1, 2, or 3 stents, there is an incremental benefit in lowering intraocular pressure. To lower the pressure obviously the better for our patients and increasing the safety of preserving the vision.

And going from 1 to 3 stents, there is an incremental improvement in lowering intraocular pressure. Also on the other graph there, I want to point out there is an additional benefit of reducing the need for glaucoma medications. Again, the compliance issues, the side effects of medications were always trying to keep the medication use down to minimum, and you're much more likely to get down to a lower medication schedule with multiple stent use.

Next slide. As far as the duration of effect of multiple stents, this one study site show that yes you could lower intraocular pressure going out to 5 years effectively and also reduce the amount of medication needed at 5 years of follow up using 2 stents for the reduction of intraocular pressure.

Next slide. This last slide, kind of summarizes a little bit of what we're trying to point out today with the use of multiple stents and the benefit of multiple stents in glaucoma surgery. I was involved in this trial as one of the investigators and this was looking at the use of iStent 1, 2, or 3 for the reduction of intraocular pressure. Now in the United States, the iStent is approved for use in conjunction with cataract surgery, so cataract surgery is done and a stent is placed.

In this study, there is no cataract surgery and we're not suggesting to have an indication here, but the reason for this study being done is to show the cure effect of an iStent as opposed to combining with cataract surgery because cataract surgery does also lower intraocular pressure to modest degree that can be transient. So this is looking at iStent alone, no cataract surgery 1, 2, or 3 and what this shows is that there's a definite reduction of pressure with 1 stent, but it's certainly better with 2 or 3 stents. There is a further reduction of pressure going up from 30% to 37% and 43% comparing 1, 2 and 3.

And if you look at the target pressure, we have target levels of pressure. We tried to attain with surgery for glaucoma and if you have a target level, let's say 15 in the eye, the ability to reach that target with multiple stents is 85% to 90%. With a single stent, we can only approach that target with about 65% of the time. If you look at the survival of ability to keep patients off medication, multiple stents are much more likely to keep people off glaucoma medication and reach the target level of intraocular pressure.

The last comment I'll have for you is that when you look at these results and the multiple surgeons involved including myself, this was the first time we had an opportunity to do the surgery. So this was before it was released in the United States, this was an experimental closed system here that we were involved with. And the results after this study meaning after the learning curve are certainly in my experience even better than what I'm showing here, but nevertheless the theme here is that multiple stents are more effective than a single stent in lowering intraocular pressure and keeping patients off glaucoma medication. Thank you.

Male Speaker: Thank you Dr. Katz.

Male Speaker: Yeah I had a couple questions for Dr. Katz especially since he is the chief medical officer at Glaukos. Do you or the company advocate a selective approach when planning one or both the iStent inject stents?

Male Speaker: I think at this point is at the discretion of the surgeon on a case by case basis. There's certainly some patients that one stent may suffice, but in the majority of patients I think 2 stents often desirable, but that's really at the discretion of the surgeon at the present time.

Male Speaker: Okay because the device is the two-stent system and that's what was FDA approved and that's what we're covering. So to my knowledge they really haven't done a study with it just on one of the iStent inject stents, which was different than original iStent, yeah iStents too many stents. So my point is that what we're covering is the two-stent system. We don't know what the results would be just using one of the two.

Male Speaker: Well as I've pointed out I think in this last trial that is clearly when you're talking about multiple stents, there's an incremental benefit which is supported by basic science research as well. And this is reflected in clinical practice. Also, we certainly have had experience with a single stent in the past and now we're having experience with 2 stents as well, but there hasn't been a direct comparative studies we mentioned in that sense. We do have ---

Male Speaker: Originally, my point is that we don't know what the iStent, inject stent by itself, one just by itself with the pivotal study and pretty much all the studies I've seen have involved putting in both of the iStent inject stents, that's what was FDA approved. That's a device defined by the FDA that was approved and that's what we're covering, we're not covering just one of the two.

Male Speaker: Right. Again, the experience has been and it's identical in terms of mode of action to the original iStent that have pivotal studies published and then we have now the iStent inject which are two stents as you mentioned, but I think the evidence suggests that multiple stenting does have a different outcome in single stenting. There are studies looking at for example 2 versus 3 stents as well combined with cataract surgery where there seems to be a benefit to 2 or 3 versus 2 stents and that is in the literature as well. So we do have some information with multiple stents being more effective in lowering intraocular pressure than a single stent.

Male Speaker: Right, but you don't have data of what one iStent inject stent does?

Male Speaker: No but again I don't want to be repetitive and I apologize, but I think that the original iStent really accomplishes the same purpose and is identical in mechanism of action to.

Male Speaker: It's a different design though, it's a different design.

Male Speaker: Well, the design is only in the sense of one is mushroom shaped and one is L-shaped, but really there are going to the same pathway and the pathway enhancement is the same between the two. There's no difference really there in terms of mechanism.

Male Speaker: I guess my point is that we're covering this for two-stent system, not one stent of the two-stent system, so we'll probably make that clear in the final policy. But hopefully you can communicate that to your users. The other question I had --- let's say where you're still on that slide.

The last slide that you talked about comparing the 1, 2, and 3 that you were on it's really hard to find any either on the slide or the paper that the notes whether any of this is statistically significant. Am I missing something or why wasn't there much mention of statistical significance in this paper?

Male Speaker: You know, I apologize. There are P values for this and when you're comparing for example the ability to control intraocular pressure with 2 or 3 versus a single stent, it is statistically significant. And I've left off also the need for medication use. The need for medication use is dramatically different between one stent versus multiple stents and that in the one stent group 18, ended up needing medication control pressure as only three or four cases in the multiple stents required medication follow ups, so those were statistically significant differences.

Male Speaker: But again, they are not mentioned in the paper itself, right? These statistical evidences?

Male Speaker: In the most recent paper it is, so I think we can kind of look that up for you.

Male Speaker: Okay the 2018 paper, I did not find any. There was one mention of a nonstatistical difference in visual acuity or otherwise, if you do a find on the word significant or statistical nothing really comes up, but yeah if I'm wrong in that please send me a paper and I can be corrected.

Male Speaker: We'll check, I will explain it also.

Male Speaker: Okay, I appreciate it, thank you Dr. Katz. We have a second speaker on the topic, Dr. Chaku, Director of the Glaucoma Service at Loyola University. Dr. Chaku, please proceed. Dr. Chaku, are you on?

Female Speaker: Yeah, I'm here. Can you hear me?

Male Speaker: Yes.

Female Speaker: All right, so I'm Dr. Chaku, I'm the Director of the Glaucoma Service at Loyola University Medical Center and I have the opportunity to speak today. Thank you for including me today. So Dr. Katz just actually about what we're talking about here today as far as glaucoma treatment and care, glaucoma is a very challenging disease. Actually, can treat from glaucoma specialists. Patients with glaucoma don't know that they have the disease and wants to detect it clinically by an exam and very difficult to discover that you have glaucoma and so you have actual an examination by an ophthalmologist or optometrist someone who can identify this disease in most patients.

When patients actually know that they have glaucoma or actually have peripheral visual field loss, they are really advanced, very advanced in their stage of disease and that's really more critical getting their pressures down. So it's really important to identify the patient. Many patients go undetected as Dr. Katz said and treatment challenges really occur because of this. The standard treatment for glaucoma treatment is usually medication, laser, as well as surgical options.

Medication does offers unique set of challenges as Dr. Katz actually touched upon. Patients do not want to take glaucoma medications every day. It's very difficult, adherence issues are very high in a glaucoma patient population. Patients that take glaucoma medications can tell you that it is not an easy drop to take, really irritates the eye quite a bit after the service. Many of these drops remain preservative as well as additionally becomes an intolerance issue for many, many medications that are available in the market for these patients.

There's also a cost issue here that comes with a plan many patients can't afford all the treatment that they need and many medications, patient may start on one medication initially but often need 2, 3, 4 medications as time goes on that you can imagine how difficult it is to really take many medications everyday like this. It can be very difficult for patients in controlling their disease. That's why we need to look at other options. Laser is an option as well; however, this is limited in duration and surgical options have always been reserved more for invasive procedures until now.

Next slide. So this is where our microinvasive glaucoma surgery really comes into play here is the very safe procedure. As Dr. Katz mentioned, the indication here is actually to be done in conjunction with cataract surgery. We actually do the actual procedure of iStent inject through the same insertion as the cataract procedure, so it doesn't offer any additional incisions to the patient and it's very safe, very minimally traumatic. This is a really great option for patients. We can intervene early in the disease process, mild to moderate disease, we would usually reserve for the more invasive procedures. And patients really tolerate the procedure quite well.

Glaucoma is a disease of the aging population. We have many patients that are getting older overtime. Many of them cannot sit for a long procedure and offering them a quicker procedure that can be done in conjunction with cataract surgery really is a benefit here. Next slide. So this is a little bit about the preoperative planning that we started think about when see patients in the clinic. I'm actually also as the Glaucoma Service director, as I mentioned I teach our residents this procedure as well. And it's really important to kind of talk about what will involve in surgical planning when we discuss these options of patients as well.

So we see a patient in the clinic. They have cataracts and glaucoma. We identify the severity of the disease, look at the number of medications they are on. We look to see if there are easy patients to examine if we can actually do this stenting procedure here. We actually do gonioscopy, which we have to look at the angle or drain of the eye and that's what we're kind of deal of the inflow, outflow pathway that Dr. Katz as mentioned earlier. And we want to make sure that pain is normal in order to do this procedure, so these are really things that we think about and we're doing this. This is really a higher level and that's like so much training is really involved in learning these surgical procedures.

Next slide. So when I teach my residents, you know the really important thing is to make sure that they practice, practice, practice. This involves straight level practice, one way practice, just kind of give me an idea of what's involved in the surgical standpoint and learning a new procedure like this. Practicing in the OR really enhancing our muscle memory.

Next slide. So when we do these procedures in the operating room in conjunction with cataract surgery, we do them under the microscope. We actually have to place a special lens on the cornea, the top part of the eye. The front part of the eye, the anterior chamber muscle maintain and it's actually very sensitive to pressure, so when you do this procedure, you actually place a lens with one hand on the surface of the eye, maintain very little pressure if you have to maintain enough time in order to get a clear view to the drain of the eye in order to implant the stent. The other hand actually is used then to go through the incision with the injector and implant those stent.

Next slide. This is the old design that we have prepared earlier.

Next slide. And this is the new design for the iStent inject. So this is what the view looks like and we're doing the procedure. As you can see, we have the trocar that's kind of coming out there. That actually has two stents actually placed on it, what do you do is you go ahead and approach the trocar, you go ahead and implant one stent. And then, you actually have to shift to a different location with your hands and implant the second stent, now that may not seem challenging at all, but it's actually technically very difficult.

This whole time you're maintaining the view with your other hand making sure you're not placing any pressure, you have to move your other hand to another space in the canal implant the stent. The patient may move at this time. There's always some blood reflux with the person that also in your view and the space maintained in the anterior chamber during this time also is technically more challenging. So implanting two stents actually is more technically difficult procedure than implanting one and I just wanted to make sure that we understood that.

Next slide. So let's look at some of the studies that have been offered. Dr. Katz reviewed some of the randomized controlled studies. There has been some data out there. So this is a 3-year study that showed continuous reduction in IOP and medication use with iStent inject for cataract surgery. This is a single surgical study any one eye that you can look here. The mean IOP of these patients are intraocular pressure with 22.6. This is a 37% reduction at 3 years down to 14.3 of mean IOP.

As a glaucoma specialist, I can tell you this is a very important thing we do look at basically measuring the intraocular pressure and looking at reduction and that's how we treat our patients, every single patient with glaucoma with decrease in intraocular pressure. Also important factor that really to know here is that the mean number of glaucoma medications that receive preoperatively in this patient group was 2.5 medications.

At 3 years, 0.8 medication were found to be used by the patient population of 3 years, so at 68% reduction. I can't stress enough how much that's really answers the glaucoma patient. This is not only a numbers thing but this is also a quality of life issue for our patients and really important to stress at this point.

Next slide. This is another retrospective study that was actually done in Australia, this is a five-surgeon study group here that look at their patient population from one year retrospectively doing cataract surgery with iStent inject. If you look at the mean IOP, it was around 18 and it dropped significantly by 23% to 14% at 12 months. The main number of medications here preoperatively were 1.7 and postoperatively was 0.5, so 72% reduction. If you actually look at the patients or medications free preoperatively only 18%, but postoperatively specifically significant 76% again stressing the importance of reducing medication burden on our patients.

Next slide. And the last study, we're gonna discuss here the retrospective study results that favored iStent inject over iStent in terms of IOP resisting potential. We are targeting collector channel for every stent. More stents will be placed and more collector channels we can target, and then the various decrease intraocular pressure and you can actually see that, that was shown here in the studies.

If you look at iStent inject, the mean IOP definitely reduced compared to the iStent actually more so and this specifically significant and if you look at the patients that were under 18 mmHg, a 100% of those patients who are actually under 18 mmHg further pressure at 6 months compared to only 86% of the iStent patient. So there was a significant difference there.

Next slide and this is really the most important part to really look at the medication. I know we're looking at pressure, we always measure pressure, but I can't stress enough the importance of quality of life and improvement. This patients are living longer and they will have glaucoma for the rest of their lives and we can reduce their medications. This is really an improvement in their quality of life.

So if you look at these patients, their medication burden is a huge reduction of iStent inject went from 2.3 medications preoperatively to postoperatively 0.4, this was 80% or so reduction here in their medication burden. iStent itself went from 1.8 to 0.4 or so about a 77% reduction in their medication burden. If you look at the patients that were medication free, iStent inject 71.1% and iStent itself 74.3% for about medication free of 6 months again stressing 10 points further.

Next slide. So in conclusion, just wanted to stress a couple points. I have seen a lot of these similar results in my own practice. I can test the difficulty of the procedure actually teaching the new surgeries that are coming out into practice the next generation of surgeons and I just wanted to stress the importance of this procedure, really offering patients surgical advantages early in their disease process. As far as reducing their medication burden, it's really important aspect that we can give them care for care as patient.

iStent inject is medically necessary for FDA labeled indication, the data from the randomized control trial, real world evidence, as well as studies that address the NGS objective that benefit and multiple stenting has not been demonstrated. But more sense, the intraocular pressure is really what we're stressing here.

Work, effort, time, and something justify the payments of the insertion of the additional stents as described by the CPT code 0376T and we request that this code 0376T be removed from group 2 to group 1 and the related article A56588 billing and coding for microinvasive glaucoma surgery. Thank you.

Male Speaker: Thank you Dr. Chaku. Anyone else in the room or on the call have additional comments?

Female Speaker: We have one person Craig.

Male Speaker: If they could identify themselves in at any time of interest?

Male Speaker: May be in the building. It was not a question Craig, we're done, I think in the audience.

Male Speaker: Okay.

Operator: Operator, are there any questions on the line?

Operator: There are no questions via the phone.

Male Speaker: Okay. So hearing no further questions. I will consider the comment from this track closed for the purpose of this meeting at this point.

Male Speaker: Okay. Next slide. Water vapor mixed draft for consideration for comment. Water vapor thermal therapy for lower urinary tract symptoms, LUTS BPH PL37808. In this case, the change that was made was the policy criteria was liberalized and that the requirement that the patient had a significant obstructing median lobe component was removed. This restriction was put in there because the 3-year data showed some worrisome trajectory in some of the data.

But yet, the device has particular potential, particular benefit for patients with an obstructive medial lobe over some of the alternatives. So we covered it, but required that it particularly have that component where this procedure seemed to potentially shine and there were additional alternatives.

In the interim, this 4-year data that comes out that is reassuring in terms of those worrisome trajectories and so we decided to liberalize the criteria and not require that the obstruction involve the medial lobe requirement, but that it could just have general lateral or median or both type of obstructions. I don't think we received any request to present and this was as I mentioned as a result of the new data, the four year results that came out which is listed now. I don't think we received any request to present on this topic. Anyone in the room or on the call wanted to make a comment?

Female Speaker: We've nobody in the room.

Male Speaker: Operator, anybody online?

Operator: There are no questions via the phone.

Male Speaker: Okay. In that case, we close comments on this draft as well and which is a final draft.

Next slide. And as you mentioned, the comments extend beyond today to July 20th.

And the next slide. This is the address to send any comments. I want to remind people that comments must be accompanied by disclosure of any conflict of interest. So with that Dr. Cunningham, I will hand the things back to you.

Female Speaker: Thank you Craig. I'll turn my phone back on. Thank you Craig very much. We might also want to turn the lights on. Anything we need to entertain as far as open discussions? Thank you all very much for those who are on the phone and also those who are here physically. We really appreciate your interest and your participation. Thank you.

Male Speaker: Thank you.

Female Speaker: This concludes today's conference call. You may now disconnect.