WPS GHA Open Meeting

Moderator: Dr. Ella Noel
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OPERATOR: This is Conference #: 3596601

Operator: Ladies and gentlemen, thank you for standing by and welcome to the LCD Open Meeting.

At this time all participants are in a listen-only mode. After the speakers' presentation there will be a question and answer session. To ask a question during the session, you will need to press star one on your telephone.

Please be advised that today's conference is being recorded. If you require any further assistance, please press star zero.

I would now like to hand the conference over to speaker today, Dr. Ella Noel, thank you. Please go ahead.

Dr. Ella Noel: Thank you. So I want to welcome everyone to the WPS open meeting today for J5 and J8. This will be a teleconference only due to requirements of social distancing.

I'd like to start by introducing the WPS staff. I'd like to announce that Dr. Barry Whites has joined the staff at WPS. Dr. Kettler from J5 is on the call, as well as the policy nurses, Beth Scanlon, Ann Everson, Kathy Fisher, Melissa Jacobs, and Melissa Lietz.

So, now that the introductions are done, I would like to go over some rules for today's meeting. Any presentations will be stopped after 10 minutes. Please do not repeat comments that have already been made to allow everybody an opportunity to speak.

Written comments are due by July 11th, 2020. And please send those written comments to medicarepolicycomments@wpsic.com.

We're going to start with, oh, and then I forgot to include in the introduction, Rich Staley, our administrative assistant who takes care of so many things for us. Thanks, Rich.

All right. Now I'm going to turn the meeting over to Dr. Kettler. He has a topic to discuss with the group today. Dr. Kettler?

Dr. Kettler: Thank you Dr. Noel. The purpose of the open meeting is for stakeholders and the general public to comment on the draft LCDs that are up for consideration. And it's become apparent in a few of the recent open meetings that we may have drifted away from the overall purpose of the meeting.

And so what we've done is we have come up with a set of guidelines to help bring us back to this. These guidelines are going to facilitate the main purpose of the meeting, which is to provide a time and place for discussion of the draft LCDs.

They do establish some guidelines for conduct on the part of all participants, expectations of all participants. And there is also in there a set of steps that will be taken if there is a deviation from these guidelines.

This – I'm not going to go through the code in any detail right now. It will be published on our website and it will be available for 45 days for stakeholders to comment on it. Depending on the comments that we receive, we may modify it somewhat. And then a final version will be posted to take effect for the October open meeting.

Just by way of some background as to the process that we've gone through to get here. This was developed after internal discussion among the policy departments. We also did get some input from various stakeholders.

We had this reviewed by our corporate counsel and it has also been reviewed and approved by CMS. So hopefully it's all set to go. But again, we are giving stakeholders the opportunity to comment on it, and it will be available for your

comment for 45-day period beginning shortly. Are there any questions on this?

Operator: As a reminder, if you would like to ask a question please press star one on your telephone, to withdraw your question press the pound or hush key. Please stand by while we compile the Q&A roster. Again, if you would like to ask a question, press star one on your telephone. There are no questions at this time.

Dr. Kettler: OK. Thank you. Dr. Noel. I'll turn it back to you.

Dr. Noel: Thank you, Bob. So we have eight draft LCDs to speak on and six presentations. So I'm going to take things out of order and do the MolDX first, because there are no formal presentations with these today.

The first one that we will look at is the MolDX Policy Breast Cancer IndexTM Gene Expression Tests. I am the lead on this with Beth Scanlon. It has a DL number of 37913. This LCD is being presented for comment due to the receipt of a reconsideration request. Coverage over patients with N1 status as opposed to N0 status has been added.

There was an update in the bibliography and analysis of evidence as well as coverage indication, limitations, and or medical necessity. This LCD provides limited coverage for this test, which is a gene expression tests for the management of postmenopausal women diagnosed with early stage T1 to 3 pN0 to N1, MO nodes negative or positive non-relapse ER and or PR positive HER2-negative breast cancer who are being or will be treated with primary adjuvant therapy.

This test is used to provide a genomic based (estimates) of distant recurrence risk when considering the addition of chemotherapy and or late distant recurrence risk and endocrine responsiveness when considering extension of endocrine therapy depending where the in-care testing is completed.

Evidence shows that this test predicts disease reoccurrence and for some patients also predicts response to adjunct therapy. NCCN guidelines explicitly

recommend the use of not only clinical characteristic, tumor stage and pathology, but also consideration of the inclusion of gene expression classifier.

Do we have any comments from the telephone line?

Operator: Again, if you would like to ask a question, press star one on your telephone. Again, if you would like to ask a question, please press star one on your telephone keypad. There are no questions at this time.

Dr. Noel: OK. Thank you. We'll go on to the next one. This is a MolDX Policy. Again, I am the lead with Beth Scanlon. DL38684 is the LCD draft number. It's a prognostic and predictive molecular classifiers for bladder cancer.

This is a new policy. This contractor will cover molecular diagnosis tests for the use in bladder cancer with the following conditions. The beneficiary is being actively managed for bladder cancer. The beneficiary is within the population that has the indication for which the test was developed and discovered.

The beneficiary has not had a cystectomy. They must meet at least one of the next two criteria. They must be a candidate for multiple potential treatments, which could be considered to have an ordered intensity based on a consensus guideline. And the physician and the patient must decide among these treatments, or the patient needs to be a candidate for multiple therapies. And the test has shown that it predicts response to a specific therapy along acceptor therapy options based on a consensus guideline.

Testing must demonstrate analytical validity. If an algorithm is used, it must be validated. Clinical valid validity has been demonstrated and the test completes the technical assessments. Do we have any questions about this particular MolDX extract LCD?

Operator: Again, if you would like to ask a question, press star one on your telephone keypad. Again, if you would like to ask a question, press star one on your telephone keypad. There are no questions at this time.

Dr. Noel: Thank you will go to the next MolDX policy. It is draft DL38678. Again, I am the lead with Beth Scanlon. This is for phenotypic biomarker detection in circulating tumor cells. This is a limited coverage policy for assays that detects circulating HER2-positive cell. These essays are covered when the following conditions are met.

The patient has been diagnosed with breast cancer. One of the following two criteria must be met: the cancer has not previously been tested for HER2 or there's newly metastatic cancer that has not been tested for HER2. Clinical validation includes a comparison to tissue HER2 testing. And the tissue based HER2 testing is not feasible.

Do we have any comments about this particular draft?

Operator: Again, if you would like to ask a question, press star one on your telephone. Again, if you would like to ask a question, press star one on your telephone. There are no questions at this time.

Dr. Noel: Thank you. Next we have liquid biopsies for solid organ transplantation, DL38680. Again, I am the lead with Beth Scanlon. This policy provides limited coverage for liquid biopsies to assess transplanted allografts for rejection status when the following criteria are met.

It demonstrates analytical validity. It demonstrates clinical validity by providing information about at least one of the two following clinical status determination. Those two determinations are rejection status, and T cell mediated versus B cell mediated. It is used in a patient population in which the test was analytically validated and has demonstrated clinical validity.

It is being used in place of tissue biopsy to make a management decision in a patient. It should not be used in place of protocol biopsy and transplant centers that do not have a management algorithm for using that kind of testing. Benefit to risk profile of the liquid biopsy is more favorable than the benefit to risk profile of a tissue biopsy or it is not possible to get a tissue biopsy and completes the technical assessments.

We will now take any questions on or comments on this policy.

Operator: Again, if you would like to ask a question, press star one on your telephone keypad. We do have a question from Mr. Raj Stewart, your line is open.

Dr. Raj Stewart: Thank you very much to the medical directors and contractors. This is Dr. Raj Stewart on behalf of Guidehouse. No financial disclosures to note rather than our involvement in the space and oversight and work with various product (assay) manufacturers.

I just wanted to say on behalf of various interested parties that we appreciate the depth of the proposed draft LCD, as well as the concurrent publication by this contractor of a billing and coding guide. Thank you very much.

Dr. Noel: Thank you. Do we have any other comments?

Operator: Again, if you would like to ask a question or have a comment, please press star one on your telephone keypad. There are no further questions or comments at this time. There are no questions at this time.

Dr. Noel: Great. We'll move on to the last MolDX policy. This is EndoPredict breast cancer gene expression test, DL3763. This is being presented due to a reconsideration request. The LCD was updated to reflect additional published data in the management of breast cancer patients who have received the EndoPredict test and for whom extended endocrine therapy is being considered.

This resulted in changes to the bibliography and coverage indications, limitations, and or medical necessity. This policy allows limited coverage for this test for the management of postmenopausal women, diagnosed with early stage ER positive HER2-negative breast cancer who are either lymph node negative or have 1 to 3 positive nodes and for whom which treatment was adjuvant and a good therapy is being considered.

Molecular testing has been shown to improve prognostic accuracy compared to standard clinical features, and had become increasingly important for patients with ER positive HER2-negative breast cancers. This test should not be answered if the physician is not going to act on the results.

Do we have any comments or questions from the phone lines on this last MolDX draft?

Operator: Again, if you would like to ask a question, press star one on your telephone keypad. Again, if you would like to ask a question, press star one on your telephone keypad. There are no questions at this time.

Dr. Noel: All right, I would ask that you send any written comments by July 11th to the Medicare policy comments mailbox as noted before. Please note that these comments for these drafts will be compiled and answered in a group for all the members of the JOA for MolDX.

Now we're going to go ahead and move on to the non- MolDX policies. We'll start with the fluid jet system treatments for lower urinary tract symptoms and BPH. This is a national work group policy and the draft number is DL38682. This LCD addressed the use of fluid jet system treatment of the lower urinary tract symptoms attributed to BPH.

Treatment by this method will be allowed once per lifetime and patients with the following indications age less than or equal to 80, prostate volume of 30 to 80 cc's by transrectal ultrasound, persistent moderate to severe symptoms despite maximum medical management including all of the following.

International prostate symptom score of greater than or equal to 12, maximum urinary flow rates of less than or equal to 15 milliliters per second, failure contraindications or intolerance to at least three months of conventional medical therapy, they should neither have known or suspected prostate cancer or a PSA greater than 10 or other pivotal study exclusion criteria.

Literature reviewed included the WATER and WATER II studies and a look at several guidelines. We have presentations for this LCD. I believe there is one, two, three, four presentations. And then we'll fill the questions from the telephone lines after the floor presentation.

In no particular order, the first one up is Matt Salkeld, VP from Healthcare Economics and Reimbursement PROCEPT BioRobotics. Mr. Salkeld, please take it away.

Operator: Matt, your line is open.

Matt Salkeld: Great, thank you. Can I be heard?

Dr. Noel: I can hear you.

Matt Salkeld: Great. OK, thank you. Thank you Dr. Noel.

My name is Matt Salkeld. I'm the Vice President of Healthcare Economics and Reimbursement for PROCEPT BioRobotics. I would like to thank WPS for the opportunity to speak as part of the open meeting process.

For the next 10 minutes, I'd like to review some of the evidence that was highlighted in the LCD, as well as review some recently published evidence that is not reflected in the LCD but relevant to the proposed coverage policy. And I'll just note which slide I'm on as we go through it.

Slide two is my conflict of interest. I'm employee of PROCEPT BioRobotics. In terms of on slide three, what we'd like to cover in the next 10 minutes is, first of all, support coverage of the fluid jet system as medically reasonable and necessary, based on the body of clinical evidence that we'll touch on here, the (what) and there's really, although there's more studies, the three studies that we'll touch on are WATER, which is the randomized study comparing aquablation to TURP which is the gold standard.

WATER II, assessing aquablation in large prostates, and then OPEN WATER, which is a multicenter post market registry evaluating aquablation in a real world setting. Second of all, society support, aquablation was added to the – in 2019 to the American Urologic Association. BPH surgical guidelines based on the one year published data at the time. And have also been referenced in the European and Canadian Urology Guidelines.

And then lastly, recognizing that payment methodology is not coverage methodology, however, as part of the transitional pass through a new

technology add on payment, CMS did a rigorous review of the clinical evidence in order to designate aquablation and looking at the one year outcomes of WATER and WATER II as a substantial clinical improvement over existing surgical therapies.

So, again, supporting coverage of the fluid jet system is medically reasonable and necessary. Slide four, we'd ask WPS to expand coverage criteria beyond the inclusion exclusion criteria that was noted in the WATER study. And really two areas, one is providing coverage for prostates and increasing the upper limit of the prostate to 150 milliliters and that's consistent with the FDA labeling which has no size limitation.

But more importantly, additional clinical evidence that's not reflected in the LCD, the WATER II study, the two year outcomes, recently published looking at aquablation and large prostates as well as the OPEN WATER looking at the one year outcomes, again recently published literature, looking at the real world registry in 20 to 150 grams. And we'll touch on those a little more detail.

And then second is providing coverage for patients with no restrictions on catheter dependency or PVR. That was an exclusion criteria in the WATER study. That was the first pivotal study, the technology, and more conservative in terms of inclusion. Subsequent to the WATER study, there have been several studies where catheter dependency was not a exclusion criteria, enrolling nearly 400 patients and showing a very good outcomes. And so we'd like to discuss expanding the coverage on that.

Moving to slide five, just touching on the two landmark studies for aquablation. And there's two of them. And it's based on prostate size. The WATER study was the only FDA pivotal study randomized to TURP which is considered the gold standard for prostate less than 80 grams. And the outcomes of the study demonstrated a superior profile of aquablation compared to TURP. Similar efficacy in the entire patient cohort and the three year results were recently published demonstrating durable outcomes out to three years, symptom improvements, flow rates, as well as retreatment rates.

The WATER II studies the only FDA prospective study looking at large prostates. And it's worth noting is the inclusion criteria was 80 to 150 gram

prostates. These are primarily candidates, patients who are candidates for open prostatectomy, which is a more invasive with higher complications.

The outcomes of this study showed safety and efficacy, very similar to the WATER study in smaller prostate. Aquablation is used in smaller prostates demonstrating reproducible outcomes. And now with two year results, durability again, symptom improvements, flow rates, and retreatment rates.

On slide six, looking at the three year outcomes of the WATER, again, this was recently published. On the left is efficacy which is symptom improvements. The chart on the right is objective measure flow rates. And what you'll see here are up to three years statistically significant improvement in baseline stability out to three years in terms of the outcomes and consistent outcomes between TURP and aquablation. And as WPS noted, in the LCD, the three year results were essentially unchanged from two years.

Slide seven looks at a pre specified subgroup of the WATER study. These were prostates, 50 to 80 grams. The average prostate was about 54 grams. So this is about half the patient set in. And as prostates get larger and larger, they get more surgically complex. And what this demonstrated was superiority both in safety and efficacy of aquablation compared to TURP starting to speak to the reproducibility of the outcomes based on the technology, so again, superior safety and efficacy in this subgroup.

I'm going to skip through slide eight just to summary the retreatment rates compared to other receptive techniques. Slide nine summarizes the AUA BPH surgical guidelines from 2019, which aquablation was added.

And slide 10, again, in the spirit of time, just summarizes the FDA labeling where there's no restrictions. But getting on slide 11, which is the WATER II study, the large prostate study, this just shows a comparison of the patient demographics in the WATER study, which was randomized to TURP with smaller prostates and in the WATER II and you'll see that the main difference to highlight here is on the fourth line, the prostate volume and WATER II was 107 grams, which is essentially double the size of the prostate and WATER.

So nearly double the volume, again, as prostates get bigger and more surgically complex. But as we look at the outcomes on slide 12, and comparing the outcomes of WATER versus WATER II, the two year outcomes, what you'll see here is first of all, in WATER II, sustain results out to two years in terms of symptom improvements, but interestingly is that consistent with the WATER study at all time points in terms of the improvement and symptoms scores at each time point along the study, again, despite the fact that the prostates were double in volume.

Slide 13, just looks at the symptom improvements in another graph, looking at storage and voiding specifically but again, nearly identical. And so the conclusions on slide 14 show that, again, aquablation, clinically normalizes the outcome among patients regardless of the prostate size and shape. And again, the benefits that we saw in the WATER study were reproduced in the WATER II.

On slide 15, rather than comparing it just to WATER, we look at other surgical options for large prostates. And as I mentioned earlier, open prostatectomy is the most common procedure performed on these large prostates and bring to your attention the first two lines and the two columns on the right. And you'll see that in a meta-analysis of 35,000 open prostatectomies looking at Medicare data. The average hospital stay was 5.4 days and the perioperative transfusion rate was 24 percent.

If you look at what was published in the two year data, aquablation had a min length of stay of 1.6 days and perioperative transfusion rate is 6 percent or 5.9. And this was really the literature that supported, help CMS get comfortable with aquablation as a substantial clinical improvement.

Slide 16 demonstrates the results from OPEN WATER which is a all-comers study 178 patients in five centers, broad range of prostate size from 20 to 148. Very similar safety profile is what was published in the WATER study. And as we look at the outcomes in the two graphs, symptom improvements on the left and flow rates on the right, and we've plotted OPEN WATER compared to WATER, WATER II, OPEN WATER, falls right in line. So

demonstrating that the reproducibility even in a commercial setting in terms of the primary endpoints of efficacy on symptom improvements and flow rates.

Moving to slide 17, and we'll probably comment, add this to our – more detail on our comment letter. This just shows why there's limited surgical options for large prostates. There's a number of complications and risks that are associated with different op, surgical options. And so today, open prostatectomy is still the most common procedure performed in large prostates. And this kind of summarizes that.

On slide 18, the second point in terms of the modification to the LCD, we asked that exclusion catheter dependent patients. And subsequent to the WATER study as I referenced earlier, there were three studies. WATER II, OPEN WATER, and BOC at all a single center experience where nearly 400 patients were enrolled, about 80 patients who were catheter dependent, very good outcomes. Patients were catheter free following the procedure. So aquablation is a alternative, minimally invasive alternative for patients that are catheter dependent.

So finally on slide 19, in conclusion, we support the proposed LCD that considers aquablation to be medically reasonable necessary. We request the modification to the coverage beyond the WATER study inclusion, exclusion, primarily increasing the upper limit of the prostate size, as well as excluding patients that are dependent on a catheter.

And based on the WATER study, which again, first study randomized to TURP, three year data recently published. In addition, the two year data that was just published from the WATER II study that's now available, as well as society guidelines and transitional pass through an NTAP from Medicare designating aquablation as a substantial clinical improvement.

Thank you for your time. And I'll pass it on. I think we have a couple surgeons. I know that we're going to speak. And I know they were breaking away from the operating room. So I'll turn it over to you. Thank you.

Dr. Noel: All right. Next, we'll hear from Dr. Hal Rosenbaum from First Urology. Dr. Rosenbaum?

Operator: Dr. Hal Rosenbaum, if you're on the call, please press star one so we can open your line.

Hal Rosenbaum: Hello?

Operator: Dr. Rosenbaum, your line is open.

Dr. Noel: Hello.

Hal Rosenbaum: Can anyone hear me?

Dr. Noel: Yes. We can hear you Dr. Rosenbaum.

Hal Rosenbaum: Oh, there we go. Sorry, I'm on the road. I'm driving to taking my kids someplace. So thank you for letting me speak and thank you for letting us come on.

You know, I'm a general urologist in Louisville, Kentucky, in Southern Indiana. So, you know, I guess I could speak to the – I can speak to the effectiveness of it and how it our general urologist, how this technology benefits us.

I mean, it's – I thought he did a really good job of talking about, you know, the problems that can be associated with treating large prostate, you know, from a general urology standpoint, if you get a gland that's, you know, 60, 80, 100 grams, a lot of the times the general urologist will try to do a standard T or prostate or a TURP on that.

And the problem with that is that if you do really good resection, you run into a lot of problems or you can get hyponatremic because you're using sorbitol solution. And aquablation doesn't do that. We're just using a saline solution.

So and there are multiple other issues, if you're having big glands, they're asleep a lot longer to do a full resection. You're looking at, you know, 60 minutes, 90 minutes, plus per section time, throughout the lithotomy, just the complication rate just starts to go up.

And unfortunately what happens, a lot of times is that general urologist won't sit there and they will don't want to stay there for an hour and a half or two hours. So they really just do a limited resection. And the problem is, is that they end up coming back two years later. And if it's a big prostate, you know, that's where you run into problems with bleeding because people were adequately resected. Or they just, you know, they don't do a very good resection, then they have reoccurrence to their symptoms, two years, three years, four years down the road.

An open prostatectomy is an incredibly morbid procedure. I mean, I think he gave stats of a median hospital stay at five days and the transfusion rate. I mean, I think those are probably mild a minute, you know, they have an incision, they have a catheter for upwards of a week. It is an incredibly morbid procedure that they did in the 70s.

One of the good thing is, it's 2020 now. I mean, it's – technology has come a long way and there's really no reason to subject someone to such a morbid operation. And one of the other options that people have for that is a holmium laser enucleation of the prostate or a HoLEP. And that's a great procedure but the problem with that is that, there is such a high learning curve because I can do those procedures.

You have to do well over probably 100 to really be able to be – to do those with any sort of precision. So it's an incredibly high learning curve. Aquablation is very unique and that it will allow a general urologist like myself to be able to treat these large glands, 80, 100, 120, 150 gram gland with a much, much shorter learning curve.

And the other advantage is that, it's a much more precise procedure because we're using ultrasound, we're using real time where you can actually plot out exactly where you're treating. You just don't have one view where you're looking through a scope. So you can treat these larger glands with a much, much smaller learning curve. And you're not having to run into the same problems as a TURP.

So that – I mean those are just some of the highlights that I think that this technology is really going to be a game changer. For the, you know, tens of

thousands of general urologist that you have, that are taking care of your Medicare patients, because unfortunately, you know, I think sometimes open prostatectomies are being done. And you're paying a heck of a lot more for these people to stay in the hospital, or they're end up getting referred to an academic center. And there's a long wait with that.

So I really think this is going to be a game changer on multiple levels for that. And I can't see the video. I know I've got a couple slides, you know, my experiences, we've just got started. I've only done four or five patients. We got started two, three months ago, and then the coronavirus debacle hit. So that really kind of put the brakes on everything.

But I can tell you from the experience that we've had so far, the patients have done very well. It's been really seamless in the operating room. Again, it's a technology that's very, very adaptable. It's very, I think, for a general urologist, it's going to be very easy and for them to pick it up.

So I think without going on and talking for a while. That's all I really have. If anyone has any questions for me, from my standpoint, I'm happy to take them. If not, I'll probably pass it on to the next person.

Dr. Noel: Thank you. Next up is Dr. Ahmed from Comprehensive Urology in Michigan.

Operator: Dr. Ahmed, if you're on the call, please press star one so we can open it. Dr. Ahmed, your line is open.

Muzammil Ahmed: Great. Can someone hear me?

Dr. Noel: Yes. We can hear you.

Muzammil Ahmed: Great. I just wanted to be sure. Well, good afternoon to all of you. I'm Dr. Ahmed. I practice in a large single specialty group in Michigan. And I'm also (inaudible).

Dr. Noel: Dr. Ahmed, your connection is not good.

(Inaudible)

Dr. Noel: That's better.

Muzammil Ahmed: OK. I was saying, I'm a general urologist practicing in Michigan with a large single specialty group. I've been in practice for about 20 years and we've seen a lot of technologies come and go.

And currently for larger prostate use lasers and robotic prostatectomy, prostates that are large are challenging to take care of. They do require extensive time to put patients at increased morbidity due to the length of the procedure and the recovery involved. This procedure was very attracted to us initially because it allowed us to decrease the amount of time it takes to treat patients and increases their – and decreases their recovery time so they don't have to spend more than a day or so in the hospital.

We've been – we've had great outcomes with the five or six patients that we have treated in the past year and a half or so ago when we took care of them. One of the concerns I had regarding this procedure and some of the requests we had for modifying some of the indications for the procedure, I do agree that it should be available for larger prostate.

I discourage the Committee from giving an upper limit though, because the prostate size and the configuration varies, the anatomy can change. And I think as long as the prostate is greater than a certain size, I think they had thought 50, 60 grams or so in size. I think that should be sufficient. I don't think there needs to be an upper limit, because as the prostate get larger, different anatomical considerations take – can occur.

And the aquablation technology may be suitable for prostate even as large as 200 grams. But again, I think that's something that should be left up to the discretion of the doctor after they've examined the anatomy and the configuration of the prostate. Secondly, one of the most common presentations for patients with urinary, with enlarged prostate is urinary retention. And these patients are catheter dependent.

So I think moving that language about catheter dependency, excluding people from being a candidate, so that this technology would be appropriate. We don't want to – we do want to be able to treat people who do have

catheters so that we can relieve them of the need for having these external devices, drained the bladder.

And besides that, again, we've been very pleased with the outcomes and I hope the Committee is very supportive of the proposed changes.

Dr. Noel: Thank you. Our last presentation on aquablation is from Dr. Trainer and Dr. Arther, are one of you or both of you on the call?

Hal Rosenbaum: They're just getting out of surgery right now. Sorry. They're just getting out of surgery. I think they're trying to dial in right now.

Dr. Noel: All right, well, then we're going to go to the next LCD and come back to them while they're trying to get on the call.

Hal Rosenbaum: Thank you.

Dr. Noel: The next draft is the percutaneous vertebral augmentation for osteoporotic vertebral compression fractures. Dr. Barry Whites is the lead on this for WPS. This is also a national workgroup policy. The number is DL38213. This LCD is a product of the national workgroup. It's been modified from the original that was finalized in the past.

The coverage indications, limitations, and or medical necessity and sources of information and basis for decision have been updated. This LCD addresses vertebral augmentation for osteoporotic vertebral compression fractures. Coverage remains available for medically necessary procedures for other conditions that are not included in the LCD.

Do we have any comments from the telephone lines on this draft?

Operator: Again, if you'd like to ask a question or make a comment, please the star one on your telephone keypad. And first question comes from (Scott Cue), your line is open. (Scott), your line is open.

Scott Cue: You mentioned that there were other diagnosis codes that were going to be included in these codes. Do those include the cancer diagnoses that are not just limited to osteoporosis?

Dr. Noel: Normally we don't answer questions during this meeting. It is my understanding that there is coverage available. I do not know that the codes that will be necessarily added to the LCD because they are not part of the LCD. And I'm getting confirmation of that from one of the policy nurses. So only the osteoporotic codes will be in the LCD. And they will be in the coding and billing article.

Any other comments?

Operator: Again, if you would like to ask a question and make a comment, please press star one on your telephone keypad. There are no other questions at this time.

Male: OK.

Dr. Noel: OK. And I understand the Dr. Trainer is now available to give the last presentation on aquablation before we go to the last two presentations in the last LCD. Dr. Trainer?

Trainer: Yes, hi. Can everybody hear me? Hello?

(Inaudible)

Trainer: Hello?

Dr. Noel: Hello.

Matt Salkeld: Yes. We can hear you Dr. Trainer.

Trainer: OK, great. Hi. Thanks for giving me the opportunity to speak today. I was the principal investigator for the WATER I and WATER II trial, at which time we did a number of cases and had really good outcomes and results. And I wanted to go over those with you today. Are you guys able to see the slides?

Dr. Noel: No, this is not a webinar. It's just the teleconference.

Trainer: OK. All right. So, so basically with the WATER I and WATER II trial, the average size prostate volume that we did was 80 and 105 grams respectively. To put that in perspective, a normal sized prostate is about 25 to 30 grams.

So, on average, these prostates were probably three to four times larger than a normal sized prostate would be. What we found in the study is a significant improvement in their overall bother score. And when I talk about bother score, we have what's called the IPS symptom score, which is a standardized set of questions that has been validated that looks at obstructive and irritative urinary symptoms. So to be like, weak stream, going out at night, urgency, frequency straining to pee, things like that.

And in both arms of the study and carrying out over a period of over two years, there was a significant improvement in the symptom score, meaning that they went from a very high bother score up into the 20s to down below 10 which is something that is extremely good. And it's shown to be durable throughout the two plus years. And I'm speaking from my experience with my patients who have come back all doing very well from that standpoint.

The other thing that we look at is how the patient's empty their bladder, and how fast they're able to go. BPH or Benign Prostatic Hypertrophy basically is a condition where the prostate grows in and pinches on the channel. I describe it as like squeezing the neck of an hourglass, the tighter the neck, the more difficult is to get the sand out.

And for these gentlemen over time, their prostates have squeezed significantly and they're not able to pee very well. But the flow rates from the data that we presented, again, shows a significant improvement in which was born out statistically that was improved. So there's the results that we saw here in Omaha were comparable to the results that we saw across the study in general.

I guess kind of the reason that I'm involved is I think it's a wonderful technology. It allows the provider to operate on significantly larger prostates. Kind of larger prostates now are treated in an open fashion.

And when I talk about open, they usually receive an incision from the belly button down to the pubic bone. The bladder is opened and the prostate is actually kind of enucleated or scooped out, which generally results in a hospital stay of four to five days with significant work by the nursing staff and

a large amount of kind of expense in time running fluids and things like that, as these men tend to bleed for prolonged periods.

So this really allows us to operate in a more, I think, safe, efficient fashion. The amount or degree of pain that the patients experienced was really quite minimal. And they overall did very well. I certainly think the upper limit of the prostate size is currently capped at 80 grams from my understanding. But certainly I think that this could be increased.

The reason I say that is, when we do the procedure, we actually have a combination of visualization from ultrasound which is a great advantage because you're able to see landmarks that one normally doesn't see at the time of surgery. And then also we have direct utilization through the system scope.

The ability to treat with ultrasound and with this device allows us to treat larger prostates in a safer fashion, so that's why I think the actual prostate size should be increased. And the majority of patients who come in with prostates of this size are generally in retention or having problems emptying their bladder so they have varying degrees of an ability to urinate.

So one of the things that I think we were hoping to do as well is to remove the exclusion criteria for patients on retention. Again, this is the majority of patients who come in not being able to pee. They have catheters in place. So, which is which basically means that diseases or the pathologic growing of the prostate has gotten to such an extent that it's just basically closed off the urine channel.

That's kind of really all I have. I'm happy to address any questions or concerns from anybody if necessary.

Dr. Noel: Thank you very much, Dr. Trainer. Do we have any comments from the telephone lines on the aquablation LCD before we move on?

Operator: Again, if you would like to ask a question or make a comment, please press star one on your telephone keypad.

Trainer: I guess the only other thing that I'd like to say is that the amount of technology being used in this case is quite a bit more than kind of a standard transurethral resection of the prostate. You have a transrectal ultrasound that is needed. You also have to have a generating device that can deliver the pressurized saline to open up the prostate, as well as disposables and things like that.

And if you were to compare the open suprapubic prostatectomy, or a lot of cases around the country, a lot of places are doing robotic suprapubic prostatectomies, the costs incurred are significantly higher than what's currently being reimbursed for this case. So I think it stands to reason that the hope is, is that there would be better coverage for this case.

Because as I mentioned, the other two options, open cases are laparoscopic. You have a longer operating time. You have more disposables that are used. And the inpatient length of stay is significantly increased. So I think that's something that hopefully won't be overlooked. And you're always making this decision. So is there anything else?

Operator: Again, if you'd like to ask a question, press star one on your telephone keypad. There are no questions at this time.

Dr. Noel: All right, we're going to move to the last LCD draft. It's draft DL38686. Dr. Kettler is the lead on this policy. It is implantable continuous glucose monitors. This is part of a national work group policy. These devices are considered reasonable and necessary by Medicare when all of the following coverage criteria are met.

The beneficiary has diabetes and has been using a glucose monitor and performing frequent testing. Beneficiaries is insulin treated with multiple daily injections of insulin or on admitted care covers continuous subq insulin infusions. Insulin treatment regimen requires frequent adjustments on the basis of testing results.

Within six months of ordering the device, the treating practitioner has had an in person visit to evaluate diabetes control. And there is an in-person visit with a treating practitioner every six months. We have two presentations. The

first one will be Jesse Bushman, senior director from Health Policy JDRF. Go ahead, Jesse.

Jesse Bushman: Thank you. Can you hear me?

Dr. Noel: Sure, can.

Jesse Bushman: Great. So my name is Jesse Bushman. I am the Senior Director of Health Policy with JDRF International, which is the leading charitable organization funding type 1 diabetes or T1D research. And our mission is to accelerate life changing breakthroughs and offer better treatments along the way to curing and eventually preventing type one.

I have no financial relationship to the organization that manufactures the device that is the subject of this proposed LCD. JDRF strongly supports the conclusion of the proposed LCD that coverage of this device will be in line with current CGM criteria. There are more than 300,000 Medicare beneficiaries with type 1 diabetes. The mainstay of their treatment is use of insulin.

And while it's been around for over 100 years, there's still significant unmet need in terms of disease management burden. Today, people with type 1 and their caregivers are responsible for 24 hours a day often minute by minute disease management needed to survive. And subcutaneous exogenous insulin replacement does not work the same as endogenous insulin and those without diabetes, leading to significant challenges with glucose control and subsequent increased risk for complication.

Data published earlier this year from the T1D exchange, which is a clinical registry of endocrinology practices tells us that less than one-third of adults and only a fifth of children in the U.S. are meeting the recommended glycemic targets as measured by HbA1c. The average patient spends seven hours a day hyperglycemic and over 90 minutes hypoglycemic.

In addition, real world studies have estimated that most individuals with type 1 diabetes experienced approximately two episodes of hyperglycemia each week and one severe event per patient per year. Because of the state of

diabetes care, there is a need for technologies that can improve outcomes and meet the unmet needs for the type 1 population.

Continuous glucose monitors their CGM's have been proven repeatedly to improve outcomes in people with diabetes. This specifically lowering their A1c. A study of older adults using CGM funded by JDRF was just released yesterday actually published in JAMA. And it demonstrated that the use of CGM in this population reduces incidence of hyperglycemia, increases time in the optimal glucose range, and lowers A1c.

Anything that we can do to encourage the use of CGM will help improve outcomes and decrease costly consequences of diabetes treatments like hyperglycemia. JDRF knows from unpublished internal surveys that people with diabetes are very sensitive to the variation in features of CGM's. Some will not use a CGM if its specific features are problematic for them.

Making another CGM option available to Medicare beneficiaries like this proposed LCD will do, will increase the number of people who use a CGM, and this will have beneficial results. JDRF strongly supports the conclusion of the proposed LCD that implantable CGM should be covered by Medicare.

We also support the designation of implantable CGM in the physician service and as payment under the physician fee schedule. We would request three changes in the eligibility criteria. First, the proposal requires the beneficiaries be conducting at least four finger sticks per day in order to qualify for CGM coverage.

We would ask that that be eliminated or reduced to no more than three finger sticks per day. People who are diabetic and using insulin three or more times a day will necessarily be testing their blood glucose levels every day. It's unnecessary to impose that as a requirement, there will already be conducting such testing.

Further, Medicare standard coverage for test strips only provides for three test strips per day. And because of the complexity of the documentation requirements associated with getting more than three test strips per day, some major suppliers including the chain pharmacy CVS, have refused to

provide more than three test strips per day because of the challenges with that documentation requirement and the associated potential audit risk.

Finally, subgroup analyses in two important studies have looked at the use of CGM. And they have concluded that there was no difference in the outcomes of CGM use between those patients who had previously tested with four or more finger sticks and those who had tested with fewer than four.

An article reporting on these subgroup analyses concluded that quote, there is no evidence that frequent self monitoring blood glucose, that's the standard blood glucose meter, or type of diabetes is predictive of successful outcomes with CGM use.

The proposed LCD requires that the patient be treated with quote, injections of insulin, in order to receive coverage for a CGM. There is at least one form of inhaled insulin on the market. To accommodate that reality, we suggested this wording within the LCD must be modified to require administrations of insulin because some suppliers take the word injection very literally and will not provide a CGM to somebody who is using the inhaled form of insulin.

The proposed LCD requires a visit with a prescribing professional at least every six months. The only implantable CGM on the market, the subject to this proposed LCD must be replaced every 90 days. Therefore, patients will by default be seen the professional who manages this service at least that frequently.

The manufacturer of the device is working to get approval for a 180-day version of the device which would still necessitate the visit with the prescribing professional every six months. In the case of this CGM, it would seem that a requirement that the patient visit with the prescriber at least every six months would be unnecessary, since the nature of the device already requires that.

Consequently, the inclusion of this is an eligibility requirement simply create the paperwork burden for patients, providers, and suppliers that could be eliminated. If CMS chooses to retain a requirement for periodic visits, we believe that this requirement should be modified to require visits at least once

per year, and only more frequently if the provider and the patient determined it necessary to do so.

Some beneficiaries are well stabilizing the treatment regimens and requiring very frequent visits simply entails extra costs and paperwork burden for them, the providers and suppliers and CMS claims processing contractors.

Thank you for the opportunity to comment today and we look forward to the finalization of this proposal LCD.

Dr. Noel: Thank you. Now we have a presentation from Dr. Francine Kaufman, chief medical officer from Senseonics. Dr. Kaufman?

Francine Kaufman: Yes. Thank you Dr. Noel. And I'd like to thank WPS very much for this opportunity to present on the ever since continuous glucose monitoring system. The first long term implantable CGM system available. My name is Fran Kaufman. I'm the chief medical officer at Senseonics. And I'm also a practicing pediatric endocrinologist at the University of Southern California School of Medicine and Children's Hospital of Los Angeles.

I do want to add that a number of Senseonics colleagues are on the call today including our president, Tim Goodnow. And my (conflicts) are obvious and that I am an employee of Senseonics.

Slide number two, this describes that continuous glucose monitoring or CGM is considered the standard of care for type 1 and intensively managed type 2 diabetes patients. The American Diabetes Association that amends their standards every year has recommended that CGM is a tool to improve glucose control and to mitigate against hypoglycemia.

The American Association of Clinical Endocrinologists or AACE devised their clinical standards in 2016. And against all the benefits of using CGM to reduce costs, as well as medical consequences of hypoglycemia and poor diabetes control, and it was the same for the Endocrine Society in 2016 as well, whereas the standard to improve diabetes outcomes includes the use of CGM.

For slide three, this is the FDA approved indications for our therapeutic CGM. It's indicated for adults for up to 90 days. The system provides real time glucose readings, glucose trend information, alerts are released to detect or predict episodes of high and low glucose values.

The data can be shared with up to five care providers in real time. And the data is also retrievable by patients and healthcare providers, and can be used to adjust diabetes regimens and behaviors. The device is used as a non-adjunctive device to replace information obtained by standard home blood glucose monitoring devices. And it does require calibration.

So slide four, this shows the components of the Eversense CGM system. There's the sensor, the smart transmitter, the mobile app on the smartphone, as well as a Cloud-based data management system. This sensor lasts for three months, and it's fully implantable. The transmitter is worn over the sensor on the arm and held in place with a silicone based adhesive.

And it has the unique feature of allowing for on body vibratory alerts if somebody does not have their smartphone with them at the time, and the transmitter can be easily taken on and off. And again, this system allows for sharing with up to five care providers.

Slide five, this shows how the Eversense system works. The on body training limiter wireless powers the implanted sensor that placed in the subcutaneous space. And the antenna on the sensor receives the energy and powers the sensor. The indicator polymer on the on the sensor fluorescence when glucose is present in a reversible reaction, and the sensor then sends back the raw data to the transmitter that calculates the glucose value.

That value is then sent to the mobile device where it's displayed, and trends and alerts can be shared. And of course, this can be shared with up to five partners.

Slide – the next slide, slide six shows the Eversense procedure. This is a procedure for both inserting and removing the subcutaneous sensor. They're both done in a sterile field set up and it is a brief office procedure done in the

health care provider's office. For the insertion of small five millimeter incision is made after numbing with local anesthesia.

A sterile tool is inserted to create a pocket where the sensor is then placed and then the skin is closed with Steri-Strip and a small bandage is placed on top. There brief removal procedure is also done under sterile conditions involving anesthetizing the area. Making a small five to six millimeter incision inserting the clamp, grasping the sensor, removing it, and then the incision is closed with Steri-Strip and a small bandage is placed on top.

This next slide, slide seven, shows an example of how the system is used by a patient with intensively managed diabetes. This report is generated by our data management or DMS system. And this example is from a 91-year-old patient with long standing diabetes.

It's your that she wears the transmitter almost all the time, therefore is getting CGM information almost all the time, 93 percent. And the glucose levels that are displayed below show that there are a number of values that she can use as well as her healthcare provider can use to understand her diabetes management.

It gives a main glucose value, hers happens to be excellent that gives an estimation of the hemoglobin A1c. So particularly now in the time of COVID and the inability to see patients and many patients concerned about going to laboratory for hemoglobin A1c determination. This value can be used during the virtual health care visits, as well as these other glucometrics and the endocrinologist or healthcare provider, and the patient can then amend the diabetes regimens to improve outcomes.

The goal of glucose management is to have this in target range, the glucose values between 70 and 180 milligrams per deciliter to be greater than 70 percent of the time. This patient far exceeds that. And then there are other metrics that show the high and low percentage values as well as measures of glycemic variability.

It's also all displayed on a glucose profile, where you can see the overlay of the glucose values for the time period displayed so that the patient can understand their glucose control.

Now, if we go to slide nine. Now, let me comment briefly on the coverage criteria. So for our therapeutic ICGM coverage, I do want to point out that many beneficiaries are actually not performing blood glucose monitoring as frequently as four or more times a day, as suggested by the JDRF, Mr. Bushman's explanations. And therefore, we'd like to have you consider amending this criteria in that the four or more times of measurement are very onerous for the patient and the healthcare provider to obtain.

So in conclusion, I want to thank you for your attention. I'd be more than happy to answer any questions if you may have them. And again, thank you on behalf of Eversense, the first long term implantable CGM system.

Dr. Noel: Are there any other folks on the telephone that would like to make a comment on the implantable continuous glucose monitor policy?

Operator: Again, if you'd like to ask a question, press star one on your telephone keypad. Again, if you would like to ask a question, press star one on your telephone keypad.

Dr. Noel: I'd like to give one last opportunity for anybody to make comments on any of the LCD drafts that were presented today before we close the meeting.

Operator: Again, if you would like to ask a question or make a comment, please press star one on your telephone keypad. Again, if you have a question or comment, please press star one on your telephone keypad.

Dr. Noel: Having no further comments, I'd like to remind everybody that written comments are due by July 11th to Medicare policy comments at WPSIC.com. And I'd like to thank you for attending today. The meeting is adjourned.

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