First Coast Service Options, Inc.

JN Open Meeting

Thursday, September 12, 1 p.m.

Topics:

DL38726 – Transurethral Waterjet Ablation of the Prostate

CORPORATE PARTICIPANTS

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PRESENTERS

Dr. Terrence Regan - Advanced Urology Institute

Barry Templin, EVP, Technology & Clinical Development - PROCEPT BioRobotics

Dr. Ali Kasraeian, Kasraeian Urology – PROCEPT BioRobotics

Dr. Inderbir Gill, Keck School of Medicine of USC-PROCEPT BioRobotics

PRESENTATION

Patti Reidenbach

Good afternoon. I'm Patti Reidenbach, your Webex host for today's First Coast JN open meeting. Before we get started, I want to remind everyone that this meeting is recorded. At this time, I'm going to turn the meeting over to Contractor Medical Director Dr. Benita Jackson.

Dr. Benita Jackson

Thank you so much. Good afternoon. I'd like to welcome everyone to First Coast's September open meeting. My name is Dr. Benita Jackson. Joining me today are my First Coast and Novitas colleagues, Dr. Anitra Graves, Dr. Patrick Mann, Dr. Dave Sommers, Dr. Jennifer Davis, and Dr. Vishnu Potini. Please be aware that First Coast is recording this virtual open meeting to comply with the CMS guidelines. By remaining logged in and connected via telephone or webinar, you acknowledge that you have been made aware of this virtual open meeting as being recorded and you are consenting to the recording. If you do not consent to being recorded, please disconnect from this virtual open meeting. We are holding today's open meeting to provide you with an opportunity to present your comments on revisions made in response to a LCD reconsideration. Open meetings allow interested parties the opportunity to present information and offer comments related to new proposed LCDs and/or the revised portion of a proposed LCD during the 45-day comment period.

The proposed LCD topic for today's meeting is DL38726 transurethral waterjet ablation of the prostate. During today's meeting, interested parties will make presentations of information related to the proposed LCD. Please remember today's call is being recorded, and we request that all formal comments be submitted in writing before the end of the comment period on October 12. We encourage you to submit full text published evidence supporting your recommendations that have not been previously submitted. This is a critical component in effecting any change. At this time, I would like to turn the meeting over to our medical policy nurse Alyssa Smith, who will provide a brief overview of the proposed LCD, DL38726, for transurethral waterjet ablation of the prostate.

Alyssa Smith

Thank you, Dr. Jackson. This local coverage determination, LCD, is a result of a reconsideration request and efforts of expanding access to care. The proposed policy is available for review on our website as well as on the CMS Medicare coverage database website. Transurethral waterjet ablation is a minimally invasive procedure that uses a high-velocity stream of water and image-guided robotics to dissect and remove problematic prostatic tissue. This form of treatment is an alternative to the gold standard transurethral resection of the prostate known as TURP and aims to provide a safer option with fewer adverse effects. After review of the reconsideration request and submitted literature, evidence supports removal of the previous age limitation, which was for those less than 80 years of age, from this policy. The coverage and limitations to coverage are currently in alignment with other MAC jurisdictions and are listed within the policy. Dr. Jackson, I will turn it back over to you.

Dr. Benita Jackson

Thank you so much. Our first presenter for the proposed LCD, DL38726, is Dr. Terrence Regan from Advanced Urology Institute. Please go ahead and state any conflict of interest.

Dr. Terrence Regan

Yeah, I have none. So I'm Terrence Regan, urologist in Palm Coast, Florida, long-term CAC representative from the Florida Urologic Society. And thank you for the opportunity to present and thank you for the reconsideration of this LCD and your commitment to evidence-based medicine. I consider myself a general urologist, but I find this procedure has really allowed us to offer effective, safe, and efficient treatment options for patients with enlarged prostate, especially those greater than 100 grams, 100 to 150 ccs, which otherwise were problematic and generally had to have much more invasive procedures or have staged procedures. So I find it a very excellent tool for our prostate tool kit. But there are some probably unintended consequences of the LCD that allow beneficiaries who are otherwise good candidates not to be able to have this procedure. One of my concerns is that, really, the failure to take into account urinary retention, both in the current proposed LCD. Currently, patients need to have a flow study that just not demonstrates low flow, but also has to be 125 ccs of urine voided. The problem is for those patients who are in acute or chronic urinary retention just aren't going to be able to urinate that volume. And so that leads to a problem for these patients technically being excluded from this procedure.

There have been a number of studies that have shown that waterjet ablation of the prostate has excellent outcomes in terms of urinary retention with 96 to 98 percent of patients in retention who have this procedure being catheter-free from one to five months. My proposal would be, for those who have catheter-dependent urinary retention who failed at least two voiding trials on medical management or can't tolerate medications be eligible for waterjet ablation. Next slide. So I'm not advocating MRI necessarily for just sizing the prostate, but what I see is I get a number of referrals for patients to have this procedure. They've previously been evaluated for elevated PSA. They've had an MRI of the prostate. The prostate's already been sized. But now to conform to the LCD, they need to have a transrectal ultrasound of the prostate, which is an invasive procedure, which if the prostate's already been sized, there's really no reason to do this procedure except to make sure that they qualify for the LCD checklist. And there's a number of studies that show that, actually, MRI was more accurate than transrectal ultrasound for an estimation of prostate volume when compared to radical prostatectomy specimens, although I think that they're pretty fairly equivalent, period. The fact that we still have to do transrectal ultrasound to meet the LCD is a little unnecessary for our beneficiaries.

My proposal, if size limitations-- and I want to make just a brief comment here that I agree with-- the number, I think, the presenters who are going to follow me who would like to feel that the size limitation should be lifted from the LCD-- I agree with that. But if that size limitation is still present, then the size may be determined by MRI or transrectal ultrasound if the MRI has already been performed for other reasons. Next slide. This is a little bit different. The LCD patients must have a negative biopsy within six months if the PSA is 10 or greater and not have prostate cancer. I believe there's going to be a presentation about why waterjet ablation is safe for patients with low or intermediate-risk prostate cancer, but I would defer to Dr. Gill and Dr. Kasraeian in that regard. However, there's growing level of evidence, including a systematic review and meta analysis, that show that patients who have a negative MRI and low PSA density, specifically less than 0.1, their risk for clinically significant prostate cancer is 4% or less. And so for patients who-- and I get this-- in my practice, patients referred to me for this procedure, they've had an MRI for a elevated PSA. They've had a negative MRI, but their PSA is above 10, but their PSA density is less than 0.1. To qualify for the procedure, they have to have a biopsy, which is an invasive procedure, also could lead to the detection of clinically insignificant prostate cancer and the difficulties that arises for both patient and clinician.

So my recommendation that if this restriction is still on, that negative biopsy, PSA greater than 10, or negative MRI and PSA density less than 0.1 within the last six months, I think that would help avoid unnecessary and invasive procedures for the beneficiaries. That's really the extent of my comments because I know we generally just have 10 minutes. But I look at these from a practical standpoint as a general urologist who sees a number of patients referred to me for this procedure and find that although the LCD is well intentioned, the current and proposed LCD unfortunately excludes some patients who are perfectly reasonable for this procedure, period, if they choose to do so. And oftentimes, it then would subject them to potentially more invasive procedures to either get them catheter-free or get them to void and improve their quality of life. Again, thank you for allowing me the opportunity to present. Thanks.

Dr. Benita Jackson

Very good. Thank you, Dr. Regan. Our next presenters are Barry Templin, executive vice president technology and clinical development from PROCEPT BioRobotics, as well as Dr. Ali Kasraeian from Kasraeian Urology, and Dr. Inderbir Gill from the Keck School of Medicine of USC, who are also presenting on behalf of PROCEPT BioRobotics. I believe Barry Templin is up first. Please state your name along with any conflicts of interest you may have when you begin your part of the presentation.

Barry Templin

Thank you. And thanks to the panel and Dr. Regan about your opening comments as we support those as well. My name is Barry Templin. My conflict of interest is I'm an employee of PROCEPT BioRobotics. I'll let Dr. Kasraeian and Dr. Gill, when they come on to do their sections, announce their conflict of interest. And you can go to the next slide. So just a brief background, Aquablation was approved by FDA about seven years ago. There's approximately 400 robots in the United States where over 1300 surgeons are doing this procedure. In Florida, specifically, there are 63 robots with 167 surgeons currently doing this procedure. So the agenda is very similar as the opening presentation, which is the removal of the upper age, which thank you for the draft policy, we agree with your edits there. We will get into what I consider as causing a bit of a confusion which is the voided volume greater than 125 for Qmax. We will talk about prostate size, and then we will conclude with the known prostate cancer exclusion. So if you can go to the next slide, please. So just using as an outline the proposed edits. And yes, we will follow this up with written correspondence as you have requested in the beginning of the meeting. Next slide.

This one, just to document age, we agree with the current edits of the draft policy. Next slide, please. All right. So to be specific around here-- and I can give a little bit of the history as to why this was there because I designed the early studies. In order for us to have a secondary endpoint around Qmax, we needed good flow studies. In order to have a reasonable assessed uroflow, you needed a decent amount of voided volume in order to have a proper number. However, we didn't think in years to come this would exclude our catheter-dependent retention patients because for that particular patient, it's impossible - and the surgeons will speak on this - for them to actually conduct this test. So in theory, their Qmax is zero. But can they conduct a uroflow test? The answer is no because they can't void 125 when that catheter is removed. And this is starting to pop up. I'm sure you all are familiar with RAC audits, that they're going after this and saying, "Well, it's a retention patient, you didn't do a uroflow." But the surgeon's notes in their chart suggest this was an impossible task to do. So that's the reason why. Next slide, please.

It's similar information that was shown, so I'm not going to dwell on this, which is there is plenty of successful literature out there that Aquablation is a good procedure in retention, both in acute and chronic retention. Next slide, please. Going all the way back to 2020, when the original LCDs were created, there originally was an exclusion for high PVR. The committee at the time removed that. In the spirit of-- retention patients were allowed to be treated. However, I think it was honestly probably an oversight that we didn't look at this parenthetical following the Qmax. So I just wanted to bring this to everybody's attention that this was something from November of 2020 that still is agreed upon with the panel. Next slide, please. There are some new literature, and again, similar to the up-front publication, we will make sure that all these manuscripts are sent your way. But you can see here a high rate of retention patients being included in the real-world use of Aquablation. And finally, I'm going to invite, next slide, please, Dr. Kasraeian to first comment and then Dr. Gill to comment on the-- I'll call it the burden of having a catheter-dependent patient to attempt to do a uroflow study. Dr. Kasraeian?

Dr. Ali Kasraeian

Hi, I'm Ali Kasraeian. I hope you can hear me well. I'm a urologist in Jacksonville, Florida. I have the honor of being a speaker for PROCEPT and was actually part of the first cases outside of clinical trials about six years ago now. And we're actually looking at our six-year data. 56% of our patients that we do Aquablation procedures on are in retention, and that's their primary reason for getting evaluated. 42 to 46 percent of those patients, over the years, have been catheter dependent. So that's about half of our patient population of close to 200 patients now that we're operating on are catheter dependent. So the opportunity to get a uroflow on these patients sometimes becomes very challenging because it is close to zero. What's nice about this, in our experience, we have yet to have a single patient return to a lifestyle of catheterization due to an obstructive etiology. And in fact, we've only had one patient return to catheterization, and we re-evaluated him, and he had actually a bladder function issue years after his Aquablation procedure. So that's almost a 99-point-something percent success rate of this procedure agnostic of the size of the prostate, which we'll get into later on. So this Qmax is something that keeps our patients sometimes from getting a procedure that can be very effective of managing their prostate regardless of retention, not having retention, and/or the size of their prostate. So thank you.

Barry Templin

Thank you. Dr. Gill, any comments? And I know there might have been some troubles with Webex.

Dr. Benita Jackson

Yes. And Dr. Gill, please state your name along with any conflicts of interest.

[silence]

Barry Templin

I am not hearing him. So shall we move ahead in the interest of time and hopefully, we can get this corrected for the back end of that presentation?

Patti Reidenbach

We're in the process of getting him moved over. Give me a minute here.

Barry Templin

Okay

Patti Reidenbach

Okay. Dr. Gill? Dr. Gill?

Dr. Inderbir Gill

Hi.

Patti Reidenbach

Hi. Okay.

Dr. Inderbir Gill

Hi. We can start--

Barry Templin

We can hear you.

Dr. Inderbir Gill

Can you hear me?

Barry Templin

Yes.

Patti Reidenbach

Yes.

Dr. Inderbir Gill

Okay. Great. Sorry--

Dr. Benita Jackson

Yes. Thank you. Dr. Gill, please state your name and any conflicts of interest you may have as you begin your part of the presentation.

Dr. Inderbir Gill

Surely. My name is Inderbir Gill. I'm chair, department of urology at the University of Southern California in Los Angeles. I have no conflicts of interest regarding this presentation. I'm sorry. I was not allowed to unmute myself initially when I was talking. So I agree with the comments made by my two colleagues who preceded me. I mean, I'll just keep it simple. If the patient can't pee, we can't get a uroflow. Pretty simple. And so if the guy is in retention, has a catheter, etc., then the uroflow rate is non-existent. And they do benefit very nicely from the Aquablation procedure. Our rates of patients who come in with retention for Aquablation are lower than what Dr. Kasraeian mentioned. I would say it's in the range of about 5 to 10 percent. But they respond beautifully to Aquablation. So actually, this procedure is very much indicated for them, and not have them-- not giving them the ability to have this procedure would be a disservice. Thank you.

Barry Templin

Thank you. Okay, we can move on to the next slide, please. The next topic is around prostate size. Our request is to remove the size restriction altogether. The rationale behind us is you see this first published data by Helfand et al. He will be speaking at tomorrow's meeting, so if there's overlap, I'll let him elaborate on this. But you can see here that the outcomes are similar to the large category, which was our water two study. We've been talking about that for years, and now has five-year follow-up. And then the average column represents the water study, the 30 to 80-gram prostates, and you can see very similar responses from efficacy and safety in these two populations. If you go to the next slide, it has a breakdown of the IPSS reduction, which again, you want to lower the IPSS, which is a measurement of symptoms in these patients. And when you get to Qmax and flow rate that we were just talking about, you want this to increase for this patient. And you can see very similar numbers and dramatic increases in this patient population. The next slide is just a collage, if you will, of all the published literature. And again, we'll follow up with any of the new things, which the one on the left out of Mount Sinai is probably the newest piece of literature. It just came out a few weeks ago with four-year data from Mount Sinai. And here, you can see broad ranges of sizes. They were 38 to 330. The middle publication, 41 to 270. The lower middle one is actually a data set from Dr. Kasraeian's lab, 27 to 223.

So again, there's lots of evidence to suggest that the broad utilization across ranges, and this also has aligned with our FDA label for years. Our FDA label does not have a size restriction unlike some of the other BPH technologies. So this would come into alignment with our FDA label. So I'm going to have Dr. Kasraeian make a brief comment on this, and then we'll move on to our fourth topic after that.

Dr. Ali Kasraeian

Thank you. Again. As you see here, one of the beauties and one of the things that actually drew me to Aquablation as a wonderful way of managing men with BPH is that it's agnostic to size or even the shape of the prostate. So for us, our range has even kind of grown since that publication, from a small prostate size of 23 ccs to our biggest prostate, which was 457 ccs. And fortunately, all of those men have been able to have a procedure that benefited them in terms of their urinary function as it related to an obstructing prostate. And when we look, this size requirement issue, again, becomes a problem for getting men who could most benefit from a procedure like this where you can manage big prostates in a very minimally invasive manner with very, very low risk of side effects and importantly, minimal impact, if none, on sexual function, which is important to many of these men. And a big reason why many men have avoided some of the other treatments that are available to them for bigger prostates, simple prostatectomy, a much more invasive holmium laser enucleation, which almost eliminates ejaculatory function and is a bit more invasive. So this allows us to offer them a less invasive option that they now present to managing their BPH, which they've ignored for a long time. For us, about 10% of our patients approach 200 grams or more and 17% are larger than 170 grams. Thank you.

Barry Templin

Thank you, Dr. Kasraeian. Okay. We can move on. I think click through to two slides ahead. We'll move on to the next topic, which is the known or suspected prostate cancer. Again, mirroring some of the comments in the opening presentation here, our ask is to remove this limitation altogether, and I'm going to get into the reasons why. So if you go to the next slide, this is a table from the NCCN guidelines where it suggests even a patient with diagnosed prostate cancer, the best solution for them is to go on active surveillance or observation based on their lifespan. As these men get older, it is very likely that he's going to develop LUTS due to BPH, and there's a quality of life aspect where they can sit on the sidelines, if you will, for their prostate cancer-appropriate treatment, however, they need to take action against their LUTS. And we can talk about that. So if you go to the next slide and here's where we get into a little bit of the data. So the first bullet point here is a couple of years ago, we conducted a study where we measured circulating tumor cells - that's what CTC stands for; we should have spelled that out for you - where we measured that. These were known patients with prostate cancer who also had BPH. We measured pre-op. We measured minutes after the procedure, then post-op day two, and post-op day seven. And you can see from the graphic on the right, you can see there was a small transient spike the day of the procedure, and by day two and day seven, it was back to normal.

This was the anchor of our submission to FDA in 2023 to remove the contraindication of patients with known prostate cancer. That was successful, and that was approved in August of 2023. So that contraindication no longer exists on our label. In addition to that, you see the second and third bullet point there is there's a lot of literature around radical prostatectomy and the surgically induced circulating tumor cells. And again, they've not seen that accelerate cancer evolution from those surgeries. And so we think, again, another proof point that the acute disruption of circulating tumor cells does not have long-term negative effects. And lastly, if you kind of take our data in perspective, which we've treated around 60,000 men, and approximately 10 to 12 percent of them come into the OR-- whether they know they have prostate cancer or not, as a post-procedure pathology report, they will diagnose them with cancer. And we've not seen any negative oncologic effects, and this would be approximately 7,000 patients that have been treated in our cohort. So if you go on to the next slide, I will invite Dr. Gill to add comments in his perspective as an expert in this particular topic.

Dr. Inderbir Gill

Thank you. Barry. Can you hear me?

Barry Templin

Yes. Thank you.

Dr. Inderbir Gill

Okay, great. Thank you. So yeah, active surveillance is now our preferred treatment option for men with low and low-intermediate-risk prostate cancer, which would be grade group 1 and grade group 2. And these are typically older men. And as a matter of natural history of prostate as an organ, it does increase in size over time and causes obstructive symptoms, thereby compromising the ability of men to be able to void properly. So men who are on active surveillance are going to have obstructive voiding symptoms in a good percentage of them. And then what are we going to do with these folks? They have low-risk or low-intermediate-risk prostate cancer for which they are being on active surveillance, and now they can't void well, so what are we going to do? We can give them medications. Medications can help them be better. So that's always our first step. But quite a few are refractory to medicines or medicines do not give them good enough benefit. So then what are we going to do? Well, we can do a transurethral resection of the prostate or we can do laser ablation. All those typical treatments that we do for, quote-unquote, "BPH." Aquablation fits right into that category. And certainly, for the larger prostates, as already alluded to, it is actually a superior method because it is faster, quicker, not that much urologist skill dependent since it's robotic and allows the benefit of transurethral removal of obstructive prostate tissue in a superior way compared to other treatments such as TURP laser, etc., which do depend upon the skill of the physician.

And the final point I will make is that-- Barry has already shown you data regarding over 7,000 men having been treated this way with prostate cancer without any untoward sequela. The CTC data also have been presented. And the only thing I'd add to that is our experience with Aquablation for benign prostate is excellent. And that's the reason we are now actively considering offering men with prostate cancer, grade group 2, grade group 3, for Aquablation. We don't burn any bridges when we do Aquablation. So we have had a few men in whom Aquablation was done and then they were diagnosed with prostate cancer requiring a radical prostatectomy. And we are able to do that nicely without any compromise of outcomes. So I think for the reasons of-- that men with active surveillance are men on active surveillance for low and low-intermediate-risk prostate cancer, quite a few of them are going to have difficulty voiding. They will need surgical intervention after they have failed medications. Aquablation, in my view, is a superior option to taking care of the obstructive symptoms in these men with low-risk prostate cancer. We don't believe there are any untoward sequela of doing Aquablation in somebody with low-intermediate-risk prostate cancer. And for sure, it does not burn any bridges in case subsequent radical therapy is needed. So for all these reasons, I personally feel, and my team does at the University of Southern California, that men on active surveillance who are having difficulty voiding are excellent candidates for Aquablation.

Dr. Benita Jackson

I'd just like to let you all know we've got eight minutes left for your group presentation.

Barry Templin

Okay. All right, next slide. We may be able to give you all time back. So this is our concluding slide. So I'd like to first thank the panel and all the presenters for the proposed edits. And again, we spoke about age, which we aligned with in the opening comments. Our recommendation is to strike or remove the prostate size limitation not only based on published data, but also to align with our FDA label. We talked about the burden. Having to void a minimum of 125 ccs for a catheter-dependent patient is unnecessary because almost theoretically, their Qmax is zero, which does meet the requirement of less than or equal to 15 mils. And then the most recent topic we covered, which was removing the restriction to treat men on, essentially, active surveillance or observation with prostate cancer who are suffering from obstructive disease and symptoms with LUTS. So at that point, I believe we are done. And I don't know if the format opens the floor for questions or the meeting will conclude at that point, so I will turn it back over to you.

Dr. Benita Jackson

Thank you. Since there are no additional presenters, I would like to thank everyone for their participation in today's open meeting and remind you to submit comments in writing before the end of the comment period on October 12th, 2024. This meeting is adjourned. Thank you.

Barry Templin

Yeah. Thank you.

Dr. Terrence Regan

Thank you.

Dr. Ali Kasraeian

Thank you.

[silence]