National Government Services, Inc.

Moderator: Dr. Ola Awodele

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Coordinator: Welcome everyone, and thank you for standing by. I would like to advise you that today's call is being recorded. If you have any objections, you may disconnect at this time. All participants will be in listen only mode until the comment sessions of today's call. I would now like to turn the conference over to Marc Duerden. Thank you so much. You may begin.

Dr. Duerden: Hi, this is Dr. Duerden from National Government Services, and we'd like to welcome you to the open meeting today. As the operator told you, this meeting is being recorded. And to facilitate the transcription of these minutes, we would like for you to introduce yourself by name when you first start your presentation. I also would like to remind you that if you're going to be making comments that we would like for you to articulate any conflict of interest that you may have, prior to the reporting of your comments.

For the speakers that have already been identified, I believe we already have their conflicts of interest that'll be identified, so you can refer to them in your presentation. If you go to the next slide I'd like to introduce the contract medical directors that are with us today, and that's Dr. Awodele, Dr. Boren, myself, Dr. Mullen, Dr. McKinney, and Dr. Noel. And what I'd like to do now is turn the time over to Dr. Noel, so that she can start with the proposed LCDs, starting with salvage high intensity focused ultrasound treatment for the prostate. Dr. Noel?

Dr. Noel: Thank you, Dr.Duerden. We have several LCD drafts to go through today, so we'll get started. Just as a reminder that those who are giving presentations today, have 10-minute limits. If you reach your 10-minute limit we will warn you a minute before that occurs, and then we will cut you off when it gets to 10-minutes. So the first up is DL 38262, salvage high intensity focused ultrasound treatment in prostate cancer. This was a reconsideration request.

And in actuality, we received three reconsideration requests from providers this year. These three requests were somewhat related and were sent in with some duplication of the literature provided to the contractor for review. The requesters wanted coverage for HIFU, for primary treatment of prostate cancer, in either the whole gland or the affected side of the prostate, or have the policy retired. After reviewing the literature provided along with societal

guidelines, no changes were made to the coverage guidance of this policy. There are no plans to retire this policy at this time. Next slide

HIFU has not been compared with other standard treatment approaches in randomized trials, nor is it included in guidelines for the initial management of males for prostate cancer from expert groups. Clinicians should inform patients considering HIFU, that the treatment option lacks robust evidence of efficiency, and then even though - excuse me, efficacy. And even though HIFU was approved by the US FDA as existing technology for destruction of prostate tissue, it has not been approved for the treatment of prostate cancer, given the lack of long term data on outcome. Next slide.

The role of ablation techniques as an alternative to radical prostatectomy or radiation therapy for the definitive treatment of prostate cancer, remains uncertain. Potential advantages in men with localized disease include the ability to destroy cancer cells using a relatively non-invasive procedure as well as sparing normal tissue. These procedures are associated with minimal blood loss and less pain in surgery. And there is a more rapid post treatment convalescence.

Although HIFU most commonly, has been used to treat the whole prostate gland, it has also been used for partial gland ablation, limiting (atypical) treatment in parentheses, in an effort to minimize potential complications. However, this may increase the risk of cancer persistence. Longer term follow up is required to assess both functional and oncological outcomes before this can be considered a standard approach. Next slide.

At least some reports would suggest local HIFU may be less effective in treating anterior prostate cancer lesions as compared with posterior tumors. One approach to ensuring that all diseases included in the treated field is MRI-guided local HIFU. While one early report of 101 individuals with intermediate-risk prostate cancer is promising, follow up is limited and additional studies are needed to evaluate the long term functional and oncological outcomes from this approach. Next slide.

Although the FDA has approved prostate HIFU as a minimally invasive treatment approach to ablate prostate tissue, HIFU is not included in several international guidelines with the initial management of men with prostate cancer. One of these, a joint guideline from the American Neurological Association and the American Society for Radiation Oncology, decide if urologic oncology, which was - excuse me, endorsed by the American Society of Clinical Oncology states that clinicians should inform patients considering HIFU that this treatment option lacks robust evidence of efficacy, and that even though HIFU is approved for the obstruction of prostate tissue, it is not approved explicitly for the treatment of prostate cancer.

Furthermore, if HIFU is performed limiting (atypical) treatment to minimize morbidity, increases the risk of cancer persistence. Similarly, as noted above, a German guideline on focal therapy for prostate cancer, states that education about focal therapy includes HIFU, should state that the equivalent of focal therapy to standard therapies for localized prostate cancer, is not proven. They recommend that focal therapies, including HIFU, be limited to patients with unilateral localized low risk prostate cancer, who refuse both standard therapies and active surveillance. Next slide.

Now we're going to hear from one of our speakers, Dr. Derek Lomas. Are you present at the meeting, doctor?

Dr. Derek Lomas: I am here.

Dr. Noel: I'll let you take over and do your presentation. Thank you.

Dr. Derek Lomas: Perfect. Thank you for allowing me some time to speak. My name is Derek Lomas. I'm Assistant Professor of Urology at Mayo Clinic in Rochester, Minnesota; here today to speak on the topic of HIFU or high intensity focused ultrasound. My area of expertise is in prostate cancer diagnosis, screening, imaging, and focal therapies for prostate cancer, including high intensity focused ultrasound. I trained here at the Mayo Clinic, but I actually did a fellowship in London, in the UK, working under three of the world experts in prostate ablation and HIFU.

During that time I was introduced to the technology, saw some of the safety, the benefits, the effectiveness of the technology when used in appropriately selected patients. This therapy in the UK was covered under their government medicine scheme, the NHS, and accessible to any patient that would quality for the therapy. Since coming back to Rochester a few years ago in Mayo, I have attempted to build a HIFU practice in order to offer this therapy to appropriate patients. Unfortunately, coverage for HIFU is not universal across all Medicare patients, and varies depending on which jurisdiction they choose to get their treatments. We can go to my next slide.

No conflicts of interest that are pertinent. Next slide. I won't spend too much time here, but a little bit about the mechanism - for HIFU the ultrasound probe is placed in the rectum, which generates sound energy which is focused to a point within the prostate. This generates heat which destroys the tissue including the cancer within its field. It's much like a magnifying glass in the sun. If you focus it just right you can burn a hole in something like a piece of paper. But if your hand was right in front of that magnifying glass you wouldn't feel it.

So using the same principle we're able to offer this minimally invasive treatment free of any incision, to ablate the prostate. Next slide. So the current coverage determination is limiting use and coverage for those only

having salvage treatment following radiation failure, and has several other stipulations as well. And Medicare patients in our region seeking HIFU for primary treatment of prostate cancer, are denied coverage for the procedure, due to this current determination.

However, if we have these same patients that travel to another region that does not have a coverage determination restriction in place, they can get Medicare coverage for the procedure. And in fact, that's what I've seen in my practice. We are a multi-site institution. I have several patients that were good candidates for HIFU, that have gone down to our site in Arizona, which is covered by a different jurisdiction. And the procedure has been covered and they've been able to have the treatment.

I've also been able to offer it to Medicare patients willing to pay out of pocket for the procedure. But unfortunately, both of these are limiting access to the therapy, which means large out-of-pocket expense or travel is required. And not all patients can cover that. Next slide. Data - so I want to spend some time sharing the data that I think supports high intensity focus ultrasound as an option for appropriately selected candidates for localized prostate cancer.

In my practice I use HIFU as a focal therapy, meaning I destroy usually half of the prostate or the half that contains the prostate cancer, sparing the rest of the surrounding structures, importantly the urethral sphincter which is important for urinary function, and the neurovascular bundles, which are important for sexual function. I'd like to share with you a couple of studies that I think show that if the states' effective approach with lots of patients. So, next slide.

So this first study, over 1000 patients out of the UK, and in five years they found that 91% of those patients were able to avoid radical treatment surgery or radiation therapy. Next slide. This study - so this was a study out of the center I trained at in the UK, this was 625 patients, and the primary outcome was failure-free survival, meaning patients that hadn't needed to move onto surgery, radiation, had cancer spread, or pass away from prostate cancer.

At one year of course outcomes were great, but at five years outcomes were very good - 88% of men had not failed therapy. And importantly, 98% of these men achieved pad-free urinary continence, and no patient was wearing more than one pad a day, compared to prostatectomy where maybe up to a quarter or more of patients may have leakage depending on technique. Next slide.

So this is from the same group in the UK. I think I'm the seventh author on this study. This is almost 400 patients who underwent focal HIFU. Seven-year failure-free survival is now 70%, suggesting good medium to long term follow

up. This is over a 15-year experience. Another important aspect is it was very well tolerated; very low rates of high complications or high risk complications. Next slide.

A lot of people comment that say well that's European data. That doesn't apply to America. Well, our group out of USC in California looked at their experience with 100 patients using focal HIFU and we can see the two-year freedom from radical treatment was 91%; continence, zero pads was 100%; and there were no significant changes in sexual function scores. So these outcomes seem to be translatable across the Pond. Now one of the - next slide.

One of the - oh, this is systematic review, polling a bunch of papers together. Now we have 4200 patients. And again, rates of in field failure or treatment failure, 22%. And again, continence rates excellent, and sexual function are excellent as well. Majority of complications throughout those over 4000 patients, were early and low grade. Next slide.

So one of the, you know, comments, will always be well, there is no randomized control trial. And as we know in surgery, those are very hard to do to randomize patients, certainly to blind patients. And many things in surgery happen in advance without a randomized control trial. But we do have matched pair analysis where we compare patients that - with similar background, and we compare again, to each other.

And there was no difference in need for salvage therapy in this match pair analysis, between surgery and radiation or surgery and HIFU at five years. Functional outcomes however, were better with HIFU. HIFU had half the rate of erectile dysfunction and about half the rate of incontinence. Next slide. Another matched pair analysis out of the UK group, again failure-free survival at five years equal between the two groups. Next slide.

So primary focal HIFU or HIFU in general, appears to be a safe procedure with low complication rates and preservation of urinary and erectile function. It has good early and intermediate term outcome, and the evidence is building. I think HIFU should be available to appropriately selected patients and coverage should not be restricted to salvage use. I would propose that our Medicare jurisdiction be brought in line with the remainder of the jurisdictions throughout the country who are not restricting the use unnecessarily.

Allow the providers to carefully select the patients that might benefit from appropriate use of this technology. And I think me sending patients to Arizona or opening a HIFU center at our satellite center in Iowa, just to treat these patients and have them covered, is probably not the best answer. And thank you for allowing me to comment.

Dr. Noel: Thank you. I appreciate your comments. If you could forward anything in writing to our comments mailbox, I would appreciate it. We just found out that there is a problem with our comments mailbox and we're trying to get that fixed. We may need to extend the date that we're accepting comments. It was set up to be November 12th, but we will extend that if we have any difficulty opening that mailbox up. Our next presenter is Dr. Thomas Frye. Dr. Frye, are you available?

Dr. Thomas Frye: Yes. Can you hear me?

Dr. Noel: Yes. I can. Go ahead, sir.

Dr. Thomas Frye: Thank you so much for this opportunity. As the slide says, Im Thomas Frye. Im an Associate Professor of Urology at the other Rochester, the University of Rochester in New York. I have specialized training in urologic oncology from the National Cancer Institute in Bethesda. And my clinical focus is mainly on localized prostate cancer. Next slide. I have nothing to disclose - no financial interest in any HIFU companies or any support for this talk. Next slide

Just a brief agenda. You know, I want to, similar to Dr. Lomas, give a brief overview of HIFU at the current publications, where state where I think the limitations of the current LCD are, some recommendations, and then potentially a request to meet with the NGS medical staff, policy staff to discuss these options further. Next slide.

So I think the real question is where does primary HIFU fit within the proposed salvage LCD, and it really doesn't. And my patients that I see with localized prostate cancer, who would be good candidates for this, are limited because the current language limits it to patients who've only had salvage therapy. And it's not systematically covered around the US, where some of my colleagues are in different jurisdiction, are allowed to get this treated.

And, you know, currently the only way that these patients could potentially get it in our area, is if they paid out-of-pocket for this. And ethically, I think it's wrong that these patients would have to pay for their treatment of cancer, out-of-pocket. You know, this is not a cosmetic-type operation we're doing here. This is a quality of life and oncologic surgery.

You know, like I said, only - NGS is the only Medicare carrier that has this restrictive policy in place. And it really restricts patient who are looking for different options to treat their cancer. And I think we have good data now, to support this. And, you know, similarly, I think it's somewhat inconsistent with our current AUA guidelines, and I will show that in a bit. Next slide.

So just briefly, you know, as mentioned in the last presentation, you know, HIFU is benefited the ability to precisely treat tissue. And what this allows us

to do is to map out the prostate and to treat where the prostate is, leaving the unaffected prostate tissue untreated, thereby minimizing the side effects. Next slide. You know, and I think that if we look at this, I often get really frustrated with the comment that there is insufficient data, or the safety profile has not been there, because I think it's just not true.

We've got 15 plus years of clinical data that's done all over the world. There have been 80,000 plus patients treated with this. And when we look at it from a patient benefit, it's an outpatient procedure; there's limited recovery; and really multi patients are back to normal activities once the catheter comes out in a few days. The side effect profile is certainly much better than surgery and better than radiation. And it's repeatable. And I think that that's a key point with these sorts of focal technologies, where we're treating just where the cancer is.

We can redo HIFU. They have other options. We haven't restricted them if a cancer were to come back somewhere else within the prostate. Next slide. So this is what the key is. You know, I always talk to my patients that this is customizable. This is personalized medicine for their cancer. This is not one size fits all. And that's the benefit and beauty of a treatment like this. The more prostate tissue we treat the more side effects a guy might have. So why put them through that?

And essentially, if we can get good margins around the cancer which we're able to do, then we can effectively treat the cancer and minimize the side effects. And it's able to treat anywhere along the posterior or lateral parts of the prostate. But the main advantage is maintaining the quality of life while getting good long term cancer control. Next slide.

I just wanted to highlight that the clinical data is highlighted in red, are all studies that are included in the current LCD. And I don't want to go through all the details of this; you can look at this on your own, but essentially it's safe; there's minimal incontinence; the erections are spared; and it think usually anywhere between 70% to 80% of men are free of needing radical treatment approximately five years out. And that's what both my patients were interested in this. Next slide.

Just looking at a couple of these papers, and Dr. Lomas did highlight on these, but, you know, I think this is a really interesting study here, because, you know, the initial introduction brought up a point that there are no randomized trials. A randomized trial in prostate cancer is very difficult. It's a long and protracted disease. To show any benefit of treatment requires at least 15 to 20 years of follow up. Along with that we'd have to have significant equipoise in treating these patients if they were to be randomized between a radical treatment such as surgery, versus a focal therapy treatment.

And if you want to talk about randomized trials in prostate cancer, there's no randomized trial. The pivot trial is a randomized trial doing observation for surgery. And there's no long term benefit of surgery versus observation, except in a very select group of intermediate patients. So that doesn't limit our patients from receiving radical prostatectomy, even though it's a randomized control trial, so there's no long term benefit.

So what's the next best step? I think it's the propensity score match study like this. It matches up the clinical factors, and what did it show? Patients who are in a radical prostatectomy cohort versus a focal therapy cohort, at eight years out there was similar oncologic control. So this is a paper I quote to my patient a lot. And I think that what that tells us is I don't know what the data is going to show at 15, 20 years out. But what I can tell them is pretty decent intermediate results like this that at eight years you have a similar cancer control with focal therapy, as you would with radical prostatectomy. Next slide.

I think that this is the longest reported study out there from the UK. In almost 1400 men, 15 year experience, you know, I think that the highlight here from a patient perspective, is that adverse events are very low. This is a very safe procedure. And again, the freedom from needing any - freedom-free survival or not needing any additional radical treatment at five years out, is about 75%. Again, I think it's, you know, really good intermediate control data that we have here that we can report to our patients. Next slide.

You know, lastly I think that if we look at, you know, a systematic review like this, almost 4000 patients, 50 plus articles - it's safe, there are pretty consistent results; there's about a 25% chance of an in field recurrence over time. You know, and that's in line with the recurrence rates after radical prostatectomy. If you look at all comers to radical prostatectomy, about 25% will have a failure at some point in their life.

But again, these patients maintain their quality of life along with the long term cancer control. I did - in my patients I just don't see the incontinence. And the erections are preserved, you know, in 80% plus of the time. When I just looked at my data it was at 90% plus of the time my patients were still able to have erections sufficient for intercourse, after a treatment like this. Next slide.

When we talk about guidelines, the guidelines are very important for us in oncology. And if you look at the most updated American Neurologic Association in combination with the Radiation Society guidelines, you know, they believe that it should be - ablation may be considered in select appropriately-informed patients. So I think that...

Dr. Noel: Dr. Frye? You're...

Dr. Thomas Frye: Yes?

Dr. Noel: ...into your last minute.

Dr. Thomas Frye: Okay. Thank you. I think I'm almost done

Dr. Noel: All right.

Dr. Thomas Frye: So I think the needle is starting to shift a little bit within our guidelines. And we rely on these to appropriately treat patients. Next slide. So I think that just in conclusion, I think that we've gone through these, but, you know, hopefully we give this serious consideration. I think the data has changed, our guidelines have changed. You know, and I think that it's time for patients in our jurisdiction to start being offered this as a case-by-case definitive treatment. Next slide. And I think that is it. Thank you.

Dr. Noel: Thank you very much. Is Dr. Silver available?

Dr. David Silver: Can you hear me okay?

Dr. Noel: Yes, I can. Go ahead and start, sir.

Dr. David Silver: Great. Thanks so much for allowing me to address this public comment session. I have some prepared remarks. My name is David Silver. I am a Urologic Oncologist in Brooklyn, New York. I'm a graduate of the Albert Einstein College of Medicine. I did surgery and urology residencies, followed by urologic oncology fellowship at the Memorial Sloan Kettering Cancer Center.

I'm currently the Chief of Urology at the Maimonides Medical Center, the largest hospital in Brooklyn, New York, with 711 beds, and one of the largest house staff training centers in the country, with over 26 ACGMA accredited residency and fellowship programs, including our own five-year program in which we train the next generation of urologists. I'm also the Director of the Maimonides Prostate Center, a subsidiary of our ACS accredited cancer center.

Now at the Prostate Center, my colleagues and I see over 500 new prostate cancer patient annually. Many of these patients have prostate cancer limited to the prostate. The majority will choose standard whole gland treatments - radiotherapy, surgery, or in some cases, surveillance. However, an increasing number of these men find the risk of the quality of life side effects and standard treatments, mainly incontinence and impotence, to be unacceptably high.

And these men request alternative treatments in the form of partial gland therapy. At our center we have offered high intensity focused ultrasound or HIFU ablation, to carefully selected patients since 2019. This treatment

destroys only the portion of the prostate containing the tumor, spares the unaffected normal part of the prostate, and as you have heard from my colleagues, decreases the risk of quality of life side effects.

In the past three years, we've successfully treated over 70 patients with HIFU, achieving positive and durable results, consistent with the published literature that you heard presented. As expected, the patient satisfaction is quite high. Now I and others, have advised NGS in several communications, of the international data supporting partial gland therapies in general, and HIFU in particular, some of which were presented previously, specifically this is not a new experimental treatment, but one of proven efficacy, both in the whole gland and partial gland setting, both for salvage treatment, and as primary therapy.

Nevertheless, NGS has inexplicably persistently reaffirmed an outdated, out-of-step, and unfair coverage policy, LCD L38262, the policy in question, limiting reimbursement for patients, incurred by Medicare, within its geographic area, only to salvage situations, namely radiotherapy failure alone. I'm speaking here on behalf of my patients, 85% of whom have Medicare or Medicaid, whose HIFU treatment has been denied by NGS consistent with this policy.

On their behalf, I request retirement of this NGS policy. Now here are my reasons. First, this policy is outdated. At the time of this local coverage determination back in 2020, evidence was presented indicating efficacy for local salvage of radiotherapy only. As you have heard, since that time, recognition of the significance of the index lesion as a driver of tumor behavior, coupled with the broad acceptance of surveillance for low grade prostate cancer, has resulted in a significant shift in the treatment paradigm for localized prostate cancer. That is primary ablation of the index lesion where surveillance of remaining low grade disease is increasingly utilized.

Simultaneously, additional evidence has accumulated both domestically and abroad, of the efficacy of HIFU as an initial primary treatment. Now, NGS was advised of this evidence, including observational and matched pair studies, again, which you just heard. In fact, the localized prostate cancer guideline panel of my professional society, the American Urological Association, as well as two additional societies, the American Society for Therapeutic Radiation Oncology, or ASTRO, and the Society for Urologic Oncology, or SUO, after reviewing this same evidence, recently updated their guidelines in favor of ablation in general, and HIFU in particular, stating as you saw, the panel believes that ablation may be considered in select appropriately informed patients.

This is a direct quote from the guideline. However, NGS analysis of this evidence emphasized only the short term of follow up and the unknown long-term outcomes, failing to recognize that HIFU unlike other ablative

therapies, can be readily followed by surgery or radiotherapy, should this become necessary. Despite this, the coverage policy limiting HIFU to salvage radiotherapy failure remains inexplicably in force.

Now, second, this policy is out-of-step with other Medicare Administrative Contractors or MACs. Effective January 2021, CMS final rule established the CPT code for HIFU and set reimbursement levels for both facilities and physicians, irrespective of primary or salvage treatment setting. Of the 12 MACs ,currently NGS alone has an LCD restricting HIFU coverage to salvage after radiotherapy failure.

To my knowledge, the only other MAC with a similar coverage for salvage HIFU, WPS, has decided to retire, allowing shared decision-making between the patient and physician on what treatment is appropriate for that patient's tumor. Today, my colleagues practicing in other jurisdictions, confirm that their local MACs cover prostate HIFU ablation, without regard to whether the setting is primary or salvage. This regional intransigence is similarly inexplicable.

Finally, this policy is just flat out unfair. Women with breast cancer can choose to have whole breast or partial breast treatment for localized breast cancer. In contrast, the current coverage policy for localized prostate cancer limits treatment choices for men, to whole gland surgery or radiotherapy, with surveillance, or no gland therapy as the only covered alternative. Why are women allowed to choose how their breast cancers are treated, but men with Medicare administered by NGS, aren't allowed a similar choice.

Furthermore, why does NGS reimbursed prostate prior ablation, a more invasive therapy, with a parallel evidence base and guideline support, without any restrictions? In my opinion, since many private insurers do appropriately reimburse HIFU as a primary treatment for prostate cancer, and since, as I mentioned, other MACs cover primary prostate HIFU, NGS clinging to a policy that restricts HIFU treatment to patients with radiotherapy failure, is clearly discriminatory. Why? I cannot imagine.

In summary, NGS policy limiting prostate HIFU ablation to the salvage setting, is outdated, out-of-step with other MACs, out-of-line with the latest guidelines, and simply unfair to patients. This policy should be retired immediately. Thanks for your attention, and the opportunity.

Dr. Noel: Thank you, sir. And we will take your comments under consideration during our comments. Now, I need to ask if there's anybody in the general audience that wishes to make a comment on this LCD draft, before we move to the next one?

Coordinator: Yes. And if you would like to share a comment at this time, please press star 1 on your phone and be sure your line is unmuted as you record your name.

Again, to share a comment, press star 1. One moment as I wait for any to come through. And I am showing no comments at this time.

Dr. Noel: Okay. We'll move on to the next LCD for reconsideration. Water vapor thermal therapy/BPH reconsideration request, summary of evidence. The indications of coverage in this LCD were expanded to allow coverage for prostate volumes of 30 to 120 CC's, based on the analysis of several studies. Previously, the amount allowed was below 120 at 80 CC's. Do we have any comments on this draft in the general audience? There were no speakers on this topic.

Coordinator: And again, for any comments at this time, please press star 1. And I am again showing no comments at this time.

Dr. Noel: All right. And then the last draft is DL 33398, transcranial magnetic stimulation reconsideration request. NGS co-hosted a (CAC) meeting with multiple other contractors on 9-29-21. The panelists reviewed the literature that was submitted as part of the LCD reconsideration request, to expand the policy to include coverage for OCD diagnosis. The literature was reviewed and noted to be challenged by small sample sizes, high risk of bias, and many studies with lower quality study design, with a lack of control arm or blinding short follow up, four to five weeks for most studies, with lack of any long-term outcome data, and lack of real world application of the technology.

Overall, the panels felt there was potential improvement for OCD with TMS, and it appears to be safe. But limitations in literature are substantial as described. There is - next slide, please. There is currently insufficient evidence to show use of TMS for OCD, as reasonable and necessary for the treatment of illness or injury in the Medicare population. TMS studies have heterogeneous populations, vary in frequency inside of stimulation, have mixed results in short follow up.

The investigations are in their infancy with one randomized double-blind controlled study looking at 99 patients with a 12% dropout rate and a four-week follow up. With the exception of (Roth et al.), the patients in the literature submitted for LCD reconsideration, were participants in the (Carmy, et al.) trial of 2019. There was insufficient information to support coverage of TMS to treat OCD. The ability of TMS to improve outcomes in patients with OCD, is yet to be determined. Do we have any speakers for this topic? Scott Blackman, are you available?

Scott Blackman: Hello?

Dr. Noel: Mr. Blackman?

Scott Blackman: Yes. You have to open my line. I'm here.

Dr. Noel: I can hear you. The operator has to open your line.

Coordinator: Sir, your line is open. You're speaking in the conference.

Scott Blackman: Okay.

Dr. Noel: Yes. We can hear you.

Scott Blackman: You can hear me. Great. Thank you. Next slide, please. Okay. My name is Scott Blackman. I'm the Director of Market Access for BrainsWay. I'm also a member of the Clinical TMS Societies Insurance Committee. Next slide, please. My goal today is to briefly go over the review that NGS did for TMS, for OCD, and point out some of the limitations; a brief background on the treatment continuum; a comparison of the TMS coils; and also a review of the evidence and patient selection criteria that would be appropriate. Next slide, please.

In general, NGS reviewed seven of the ten studies that we submitted a year and a half ago, back in March. None of the four additional studies that we've sent in, in the past year and a half, have been included, to include the NGS reconsideration dated August 1st. The challenge has been that the evidence summary that you just pointed out, combined all OCD TMS coil studies between 1980 and currently, for OCD treatments. And they reached a conclusion that based upon all these other trials that were small with mixed protocols, there were mixed results.

The figure eight coils have not been studied using the FDA-cleared DTMS for OCD protocol. Yet all the studies that didn't use this protocol, were included with mixed results and mixed protocols, to make a decision of mixed results. So ultimately, DTMS with the H7 coil for OCD, is the only FDA cleared system based upon effectiveness studies and improvement treatment protocol. It should be reviewed separately. Next slide, please.

As you mentioned, all the studies you reviewed lacked standard protocol with the exception of DTMS that was approved. The studies were small, low quality ratings, a high risk of bias; there was short term follow up; different brain regions; a variety of frequencies from low, medium, and high; lack of real world application; and what's clinically meaningful. Next slide, please.

So the question that you really have to ask, is since DTMS is the only one that had effectiveness trials to gain clearance, you should really be looking only at the demonstrated parameters within the protocol - brain region, stimulation frequency sessions, and duration, in order to assess coverage for your Medicare patients. Next slide, please. Number one, there is a protocol that was approved by the FDA by DTMS. The medial prefrontal cortex and the anterior singular cortex, were the brain regions that were simulated at

20 Hertz, 29 sessions for about 18 minutes each, and with a brief provocation. Next slide, please.

This is an analysis of all the evidence you reviewed. The challenge with your analysis is that you're lumping all these protocols with the effectiveness protocols by DTMS seen in green on the bottom. If you look at meta analyses that basically analyze and summarize all the TMS studies, they got the same response. When you're adding in all these non-approved protocols with the mixed outcomes, mixed brain regions, mixed frequencies, and different numbers of sessions, you're still getting mixed results. And those are highlighted in yellow by red.

And I don't know if you can see my cursor, but you'll notice the frequencies were anywhere between 1 and 20 Hertz. Brain regions are everything. And of those meta analyses, only one of them included a DTMS trial. And that was only our pilot trial, and it was an interim analysis of only 43 patients, not the actual trial, the multicenter pivotal trial used to gain clearance by the FDA. Next slide, please.

In general, I want to make Medicare aware that OCD is not a depression. It's not a short term episode. It's a chronic disease. It usually takes 14 years or longer before somebody actually seeks treatment. The challenge is, is that OCD has a lot of co-morbidities with anxiety, mood disorders, and major depression. And even 50% of those patients will have suicidal thoughts. But reality is, if you don't treat the OCD, it can be a limiting factor to patients getting well with the other disorders. Next slide, please,

In terms of being appropriate for the Medicare population, Medicare covers about 62 million beneficiaries, but of those beneficiaries, over 9 million patients with disabilities are under age 65. If you look at those patients under 65, 34% of those patients qualify due to mental disorders. And of the patients under age 65, nearly 2/3 or 65%, have cognitive and mental impairment. Next slide, please.

Ultimately, the patients appropriate for DTMS for OCD would be a very small portion. In fact, if you look at NGS, of the 11 million patients that they take care of, or beneficiaries, only about 24,000 might be appropriate. And those are the ones that would actually be having treatment for OCD. And more importantly, the ones that wouldn't respond to their first line psychotherapy or meds. Next slide, please.

The challenge is that there are limited treatments. SSRI, is only four of them, and one tricyclic. And then, psychotherapy. The challenge is only 50% of them might get a response, but the other 50% don't get a response. But yet they still go on and they're not getting well. From the treatment continuum., where do they go after they failed us? They go onto more intensives. They stay in

residential facilities, inpatient or outpatient facilities for a longer period of time. Next slide, please.

The challenge also is that these therapies lack durability. There's been no proven long-term effect of this past a month for medications. The same thing with psychotherapy. Next slide, please. Specifically, if you look at this picture, brain regions which are stimulated, it's a circuit disorder. But specific brain regions that we use in the protocol to identify effectiveness to treat OCD, in the center picture you can see in pink, the dorsal medial anterior singular cortex, or DACC, is actually located deeper in the brain, about 3 cm subdural.

If you look at the picture on the left that in the front left of the blue, is the medial prefrontal cortex which is not as deep. It's actually shallow. Next slide, please. All the TMS coils are not the same and they don't stimulate as deep or as broad, as the DTMS. If you look in the center, the BrainsWay 7 coil approved for OCD, can stimulate 3 cm subdural. That's below the skull. That's four times deeper than the coil on the left which is the Figure-8 coil, which only goes .7 cm subdural.

And all the way on the right, the DB80 coil, which is also cleared for OCD, only goes 1.2 cm. But more importantly, not only does the H7 coil go deeper, but broader, ultimately stimulation a lot more neurons, stimulating a much greater intensity of that circuitry, for OCD. Next slide, please. This is an electric field diagram comparison of all three coils. The H7 is on the top, the Figure-8 on the bottom, and the DB80 is in the middle. Orange or red is actually good. And what this actually shows is that the red are neurons being fired at either 80 to 100 volts per meter. Because that's what it takes to fire a neuron.

And as you can see in the H7 coil, on the top in the red, much greater depth and breadth of stimulation of these neurons is occurring, much greater than the DB80 and the iron core. Next slide, please. Most importantly, I mentioned the anterior singular cortex. That's shown in blue. Stimulating this region of the brain has been implicated in OCD. In the H7 on the far right, you can see the orange at the top, much greater depth and breadth of firing of the neurons to reach the ACC, as well as the medial prefrontal cortex.

And if you look at the DB80, they have very little intense stimulation as shown in the red. And the yellow shows a moderate amount of stimulation. So the coils are not all the same. And next slide, please. So the point I just want to stress, is that only the DTMS coil has gained FDA clearance based upon effectiveness studies. There are no effectiveness studies with either the (Mag Venture) DB80 coil or the (NeuroStar) Figure-8 coil, using the FDA-cleared protocol.

It was only based on (benchtop) modeling of electric field stimulation to show that they were roughly about the same. That's how they gained

substantial equivalents. So the reality is, if you want to compare trials to show effectiveness, you have to have effectiveness trials with these other coils. And you should not confuse the outcomes of the other trials or studies they had, with small patients and different protocols, with the actual effectiveness studies that were shown to the FDA, to gain clearance. Next slide, please.

In terms of evidence, I just want to highlight the four in green. These are ones that were submitted but were not reviewed or included in your review. I want to specifically look at, on the right, the (Harmela) trial, which looked at the real world evidence and the long-term of durability of DTMS for OCD, as well as the analysis of what treatment would be most effective for patients that fail their first line treatment...

Dr. Noel: Mr. Blackman, you have less than 30 seconds left.

Scott Blackman: Thank you. Next slide. Next slide, please. DTMS in the multicenter trial, showed 38% response or 30% improvement; real world showed almost 60% response. Next slide, please.

Dr. Noel: Mr. Blackman, your time is done.

Scott Blackman: Okay. Can I summarize? May I summarize, at least?

Dr. Noel: You may summarize. I'll give you 20 seconds.

Scott Blackman: Thank you. Next slide, please. Durability was two years - the durability was two years with almost 90% of patients have durability for a year or longer, and improvement in functional disability. Next slide, please. Next slide, please. Next slide, please. In summary, you have almost 90 million people being covered for OCD, to include Palmetto, Medicare, and also (Centene), which covers DTMS and the two largest Blues, Healthcare Services and (Highmark), and now Cigna Evernorth with 70 million...

Dr. Noel: All right. That concludes your presentation. Sorry. Operator, can you please check to see if there is anybody else that would like to make a comment on this topic?

Coordinator: Absolutely. Again, if you would like to share a comment at this time, please press star 1 on your phone, and be sure your line is unmuted. Again, for any comments it is star 1. And we have a comment from (Carlene MacMillan). Go ahead. Your line is open.

Dr. Carlene MacMillan: Thank you. My name is Dr. Carlene MacMillan. I'm a psychiatrist in New York City, and co-chair of the Clinical TMS Society Insurance Committee. I just wanted to state that we're strongly in favor of expanding coverage with TMS, to include the OCD diagnosis, in light of the recent research (unintelligible) H7 coil. I have treated many patients with severe OCD with this coil, who truly

found this to be lifesaving. And unfortunately, my Medicare patients have not been able to access this, resulting in ongoing disability as well as high overutilization of medical services, for various thematic complaints that are related to the OCD. Thank you for your consideration.

Dr. Noel: Thank you for your comments. And if you could forward that into writing, to our comment mailbox, we would much appreciate that. That goes even for our plan presenters. If there is no one else with comments on this topic, I will turn the meeting over to Dr. Awodele, about SFR.

Dr. Awodele: Good afternoon. This is Dr. Awodele. And the next draft up for comments, is noninvasive fractional flow reserve for stable ischemic heart disease revision. And that is DL39075. This is being brought to the open meeting, to discuss a revision of the existing policy based on 2021 AHA, ACCA, FC check as they (unintelligible) guidelines for the evaluation and diagnosis of chest pain executive summary.

Within these guidelines, the committee gave a moderate strength of recommendation to expand the role of FFRCT in special clinical settings, as an alternative distress tests. Next slide, please. The FDA-approved FFRCT technology may be considered reasonable and necessary in the management of patients with intermediate risk patients with acute chest pain and no known coronary artery disease with coronary artery stenosis of 40% to 90% in proximal or middle coronary artery on CCTA. Or intermediate risk with acute chest pain and known coronary artery stenosis of 40% to 90% in a proximal or middle segment on CCTA.

Or stable non-obstructive coronary artery disease with persistent symptoms requiring further testing, and 40% to 90% stenosis on CCTA. And not in conjunction with stress testing. That is unless FFRCT was not high quality, and alternative study is needed. And intermediate and high risk is as defined in the 2021 AHA, ACC, ASC, chest, (SAEM), SCCT, SCMR guidelines for the evaluation and diagnosis of chest pain. Next slide, please.

So we are now - the policy is going to reflect that FFRCT is considered not reasonable in the following clinical circumstances. Prior placement of prosthetic valves, known severe aortic stenosis, prior placement of grafts in coronary bypass surgery, suspicion of acute coronary syndrome where MI or unstable angina has not been ruled out, intracoronary metallic stents, status posts, heart transplantation, a recent MI which is described as 30-days or less, prior pacemaker or defibrillator and leave placement, nearly diagnosed systolic heart failure with no prior less heart catheterization.

Left main coronary artery disease with intermediate coronary stenosis. The kind of lumen reduction less than or equal to 30%. Non-obstructing stenosis, which is less than 50% of all major epicardial vessels on CTA or catheterization in the past 12 months in the absence of a new symptom

complex. Its turnaround times may impact prompt clinical care decisions. High risk defined by lessening stenosis, is greater than or equal to 50%. I think that may - thanks. Also to note, is that this service should be performed in patients with stable coronary symptoms.

It should not be performed until after the base study in CTA has been completed and interpreted. It should not be used - it's not for use basically, in the high risk patients or when myocardial infarction has not been excluded. If higher grade stenosis that is greater than 90% or present, thi study is not medically necessary as the patient should proceed to catheterization. And low grade stenosis that is less than 30% do not require additional confirmatory data.

I think that might be - okay, well I think that's it. Okay. FFRCT should be performed as an alternative to stress testing. Based on this recommendation, a new requirement has been added to the draft LCD, that the FFRCT will not be covered in conjunction with stress testing. If extensive plaque is present, a high quality CCTA is unlikely and stress testing is preferred, while the FFRCT offers a benefit of another test, not needing to be performed at a separate time.

Clinical judgment will be necessary to limit the clinical circumstances that a high quality FFRCT study will be expected. If FFRCT is not high quality that is to not be read, and stress test is selected as alternative study, then eligible for coverage. Changes that have been made to the policy essentially, are number one, expand the notice range to 40% to 90% and alter vessel specific limitations to align with guidelines; two, it removes the limitation on BMI based on new data; number three, it defines intermediate and high risk by 2021 guidelines; number 4, it allows FFRCT as an alternative, but not in conjunction to stress testing.

Okay. Is that the last slide? Yes. So Operator, could you please open the line if there is anybody on the line - we didn't have any presentation requests on this, but let's check and see if there is anybody on the line that would like to comment on this draft LCD. Thank you.

Coordinator: Absolutely. Again, if you would like to comment at this time, please press star 1 on your phone, and be sure your line is unmuted as you record your name. Again, to make a comment, please press star 1. And I am showing no comments at this time. You may proceed.

Dr. Awodele: Okay. Thank you. Absent of any comments current on the line right now, at the end of the meeting we will be letting everybody know what either the temporary box to send comments are, or what our decisions or plans are in extending comment period. Thank you. I will hand over to the next presenter, which I believe is Dr. Duerden?

Dr. Duerden: It's Dr. Duerden, and I'll take over.

Dr. Awodele: Dr. Duerden, sir.

Dr. Duerden: That's okay. The next draft LCD that is before us, is the sacroiliac joint injection and procedure policy. And by way of background, this policy development was started with a multi jurisdictional subject-matter expert and advisory committee meeting, which was held for this policy development, on March 10, 2022. The teleconference was hosted by National Government Services, CGS Administrators, Meridian, Palmetto, and Wisconsin Physician Services.

As you may know, the sacroiliac joint is a unique but very challenging joint complex. And the pattern of innovation is not as specifically clear for the posterior and anterior aspects of the joint. In fact, pain from the SI joint can be quite variable and cause varying degrees of pain. The literature for sacroiliac joints is also limited by very few placebo-controlled randomized trials; by the lack of long-term data; several inconsistencies in the diagnostic criteria; the assessment of the outcomes in those studies; and the unique - and the techniques that are used for the procedures resulting in a very high heterogeneity between the studies. After careful evaluation of the medical literature and utilization of the best evidence, which we were able to obtain. We've made some determinations in regard to coverage and guidelines.

These coverage guidelines in the LCD and the draft LCD, are supplemented by the knowledge that was shared by our subject-matter expert trial which I alluded to back - that was held in March of 2022. SI joint injections will be considered medically reasonable and necessary when all of the following criteria are met, and these are six criteria. The first is, is that there is a moderate to severe low back pain primarily experienced over the anatomical location of the SI joints, between the lower level of the iliac crest, and the (gluteal) fold. And the low back pain has a duration of at least three months.

And the low back pain is located below the L5 level without associated radiculopathy. And the clinical findings or the imaging studies do not suggest any other diagnosed or obvious cause for the lumbosacral pain. And at least three positive findings of provocative maneuvers such as the Faber's test, Gaenslen, thigh thrust, SI compression, SI distraction, and the Yeoman's test. And the low back pain persists despite a minimum of four weeks of conservative therapy.

When an SI joint injection is performed as a diagnostic injection, the diagnostic injection used to be used to determine if the ideology of the pain is from the SI joint complex, and is considered reasonable and necessary as a diagnostic test, when the patients meet all of the criteria above, the six criteria referenced previously, and the following criteria - that is the SI joint

injections must be performed under CT or fluoroscopic image guidance with contrast; and ultrasound guidance may be considered if there is documentation that there is a contrast allergy or a pregnancy involved. Otherwise, ultrasound guidance is not acceptable. It's to be CT or fluoroscopic studies.

Additional diagnostic criteria include the SI joint injections that are not performed for other musculoskeletal - sorry, SI joint injections are not performed with other musculoskeletal injections in the spine, and the documentation should show a direct causal benefit between the SI joint injection and that not related to other musculoskeletal injections or treatments.

And the diagnostic SI joint injection provides at least a minimum of 75% of the primary or index pain with the diagnostic injection, meaning that the diagnostic - I'm sorry, the positive diagnostic response is defined as greater than 75% sustained and constant pain relief, for the duration of the local anesthetic, and greater than or equal to 75% sustained or constant pain relief for the duration of the anti-inflammatory steroid which was injected. And this measurement of improvement of greater than or equal to 75%, needs to be measured by the same pain scale that was used at baseline. Next slide.

In the billing of these diagnostic injections it is important to note that no more than two diagnostic joint sessions, either bilateral or unilateral, should be performed. When the diagnostic SI joint injection is performed, a KX modifier should be appended to the line for all of these injections. The KX modifier will only be used for the initial diagnostic injections.

Repeat diagnostic injections beyond the first one or two SI joint injections, which are required to perform the diagnosis, and after the beginning of treatment, are not considered reasonable and necessary. Any subsequent SI joint - sorry, any subsequent diagnostic SI joint injections are not considered reasonable and necessary when the initial diagnostic block did not produce a positive response of greater than or equal to 75% pain reduction. Next slide.

When you're determining the efficacy of the diagnostic injections, the pain scale must be done using the same pain scale as I previously stated. But the pain scale must also be obtained with a baseline injection that is done pre-injection on the day of the SI joint injection. And it needs to be performed post-injection on the day of the injection. And the post-intervention to pain scale, needs to be performed on the days following injection, to substantiate and corroborate that the pain scores were consistent with the pain relief for the duration of the local and/or steroid, which was used.

So let me just explain that a little bit more clearly. When the second post-intervention pain scale is to be done, it is to look for and be assessed, following the time that the anesthetic and steroid response would have been obtained, and to obtain that information but using the same diagnostic pain scales. The pain scales which can be used to measure pain or disability, must be documented in the medical record.

Acceptable pain scales include but are not limited to, the verbal rating scale, the numerical rating scale, the visual analog scale for pain assessment, the disability assessment scale, the Oswestry Disability Index, the Oswestry Low Back Pain Disability Questionnaire, the Quebec Back Pain Disability Questionnaire, the Roland-Morris Pain Questionnaire, the Back Pain Functional Scale, or the Promise Profile.

Now let's move to the next slide, which is the discussion regarding therapeutic SI joint injections. Therapeutic SI joint injections will be considered medically reasonable and necessary for patients who meet all of the following criteria - the patients must meet all of the above criteria, which is for covered indications for SI joint injections. And I'll reference you back to the initial six criteria, which was discussed previously.

Continuing on, therapeutic SI joint injections also require that the diagnostic SI joint injection provided a minimum of 75% pain relief of the primary index pain, with the diagnostic SI joint injection, i.e. it's showing that there is a positive diagnostic response which is defined as greater than or equal to 75% sustained and constant pain relief for the duration of the local anesthetic, and greater than or equal to 75% sustained and constant pain relief for the duration of the anti-inflammatory steroid which was used, and measured by the same pain scale that was used at baseline.

Likewise, the measurement of pain which was taken pre-injection on the day of the diagnostic SI joint injection, the post-intervention pain scale on the day of the diagnostic injection, and the days following the diagnostic SI joint injection are done to substantiate and corroborate the consistent pain relief, was obtained for the duration of the local anesthetic and the steroid that was used.

Therefore, if you go to the next slide, when performing subsequent therapeutic SI joint injections, these would be considered reasonable and necessary when the subsequent SI joint injections are provided at the same anatomical side as the first therapeutic SI joint injection; and the therapeutic SI joint injection produced at least a consistent 50% pain relief, or at least 50% consistent improvement in the ability to perform previously painful movements, and activities of daily living, for at least three months, from the proximate therapeutic SI joint procedure.

And this is compared to the baseline measurements for the ADLs and/or the painful movements, or the pain relief using the same pain scale. Subsequent blocks not meeting this requirement, are not considered reasonable and necessary. The SI joint injections must also be performed under CT or fluoroscopic guidance imaging, for guidance with contrast. And the exception is that ultrasound guidance may be considered reasonable and necessary when there is a documented contrast allergy or a pregnancy prohibiting the use of the CT or fluoroscopic imaging.

Finally, there are no more than four therapeutic SI joint injections, unilateral or bilateral, will be in reversed for a rolling 12-month period of time. And the final slide and final point of this, is that SI joint de-innervation, also called radio frequency ablation or RFA, is considered investigational and therefore not reasonable and necessary. So the requirements are that the SI joint procedures should be performed in conjunction with conservative treatments.

Patient should be part of an ongoing and actively participating in a rehabilitation program, home exercise program, or functional restoration program. SI joint injections may be performed unilateral or bilateral if clinically indicated within the same session. In regards to the documentation requirements, the documentation must also include the radiographic films or fluoroscopic images of the procedure, in at least two views, and those will need to be retained in the medical record. And the documentation should also include a specific assessment of the duration of pain relief being consistent or inconsistent with the agent used for the injection, and the specific dates the measurements were obtained using the same pain scale you found at baseline.

For the functional assessment, they must show - sorry, the documentation must show clinically material improvement with the painful movements and the ADLs. So there needs to be specific information and documentation regarding the baseline, as well as the improvements of those activities of daily living or the previously painful movements. I'd like to also now address the limitations. It would generally be not considered medically reasonable and necessary for the treatment of SI joint injections, to extend beyond 12-months. Use beyond 12-months requires the following.

The pain is severe enough to cause a significant degree of functional disability or vocational disability, measured by objective scales. Next, the SI joint injection provide at least 50% sustained and constant improvement of pain and/or 50% sustained and constant objective improvement in function, using the same scale at baseline, for at least three months. The documentation also needs to provide the rationale for the continuation of SI joint injections, including but not limited to, the patients who are at high risk as surgical candidates, patients who do not desire surgery, and/or they have

a recurrence of pain in the same location that was sustained and consistently relieved with the SI joint injections for at least three months.

Finally, the primary care provider should be notified regarding the continuation of these procedures in prolonged repeat steroid use, following the administration, to allow for systemic care delivery, treatment surveillance, and multidisciplinary bio Psychosocial rehabilitation. Go to the next slide. SI joint injections involving the use of anesthetic, corticosteroid, or contrast agents, is encouraged. But it does not include injections of any of the biologics, such as platelet-rich plasma, stem cells, amniotic fluids, etc., and/or any other injectants.

Another limitation is that it is not considered medically reasonable and necessary to perform multiple blocks such as epidural steroid injections, empathetic blocks, facet blocks, trigger point injections, etc. during the same session as the SI joint injection procedures were performed. SI joint injections to treat non-specifc low back pain, axial spine pain, complex regional pain syndrome, widespread diffuse pain, chronic pain syndrome, and/or pain from neuropathy, are considered investigational.

SI joint injections used as part of a series of lumbar spine or musculoskeletal injections to treat non-specific or chronic low back pain, is not considered reasonable and necessary. And finally, patients with coexisting psychological conditions or depression-related illnesses, should be treated and stabilized prior to proceeding with the interventional procedures. Multidisciplinary biopsychosocial, rehabilitation principles, should be provided for these patients. That concludes the presentation for the SI joint injection draft LCD. And I will open the line up for comments or ask the operator to open up the line for comments.

Coordinator: Absolutely. Again, if you would like to share a comment at this time, please press star 1 on your phone and be sure your line is unmuted. Again, that's star 1 for any comments at this time. And we have a comment from Scott Stayner. Go ahead, please. Your line is open. Scott Stayner, go ahead, please. Your line is open.

Dr. Scott Stayner: Oh, sorry. My name is Scott Stayner. I'm an interventional pain physician in Minneapolis, Minnesota, and member of the American Society of Interventional Pain Physicians. The one comment that I had just about the sacroiliac - that was just read about sacroiliac joint injections. I often use them as a diagnostic tool to determine if a patient would benefit from an SI joint fusion. I usually do a lateral approach.

And a 3-month interval between two injections seems a bit long to me, because some people don't respond to the steroid, but it's helpful to know if they respond immediately to local anesthetic. And if they get a few hours of pain relief and you do that, you know, a couple of times, that's a pretty good

indication if you rule out other things like facet joints, etc., that's a good indication that the sacroiliac joint might be the pain generator. And the 5-year data for SI joint fusion is actually quite good, along with radio frequency ablation for at least six to 12 months is also another option if they don't respond well to the steroid portion of the sacroiliac joint.

Dr. Duerden: So, Dr. Stayner, I appreciate your comments and I really appreciate the time that you're taking to present at the open meeting. I do have a question for you. When you're only assessing for the use of the local anesthetic and you're specifically treating the SI joint, how do you know that you're not just getting a benefit from the injection of the ligaments structures and not the actual joint instability problem when you're only assessing for local anesthetic?

Dr. Scott Stayner: Well, you do it in combination with physical exam assessment, and then you use of course, contrast dye in your injection, to show that you're in the joint space itself. Now I would concede that sacroiliitis is somewhat of a diagnosis of exclusion, but there are many patients, especially those who have had fine surgery and have, you know, the facet joints are fused, and you perform sacroiliac joint injections.

They don't get long term relief but the short term relief and I do a infusion for them and they do quite well, presumably because of the laxity of the joint, ligaments allowing the bones to rub together; the iliac crest or the ilium and the sacrum. And then when you fuse them together then they sit tight like they - prior to the loosening of the ligaments.

Dr. Duerden: Okay. Thank you. Do you have any additional final comments, sir?

Dr. Scott Stayner: Are we going to be talking about SI joint radio frequency ablation in a separate?

Dr. Duerden: No. It comes - as part of this LCD as you may refer to back about three slides, SI joint denervation, also called radio frequency ablation under this policy, is going to be considered investigational and not reasonable and necessary. Would you like to address that point?

Dr. Scott Stayner: Well, I think that it should be - I think it should be allowed for us. The data for at least three - well six to 12-months after SI joint radio frequency ablation I wouldn't call it excellent evidence, but at least moderate evidence shows that it is effective. And lateral branch block of the S1, S2, S3, along with the L5 dorsal ramus, is a pretty good indicator of whether roar not a patient would benefit from that radio frequency ablation.

And I just pointed out to you that I'll do the SI joint fusion for these patients, which is covered, albeit you have to show that you - at least the guideline that we have out here, say that you have to do two sacroiliac joint injections and they have to have 75% pain relief for the duration of, you know, the

duration of the local anesthetic. But waiting three months to get that diagnosis, seems a bit long to me.

With the radio frequency ablation, and what I was going to say is I wish that there was something in between just doing a sacroiliac joint injection and an SI joint fusion, to treat sacroiliitis and that's the sacroiliac joint radio frequency ablation procedure.

Dr. Duerden: And how do you account for recommending the radio frequency ablation when there is variability with the innervation of the SI joint, in particular the anterior and the posterior variance that occurs with the innervation? How can you - how do you find...

Dr. Scott Stayner: I'll concede you can't get the anterior innervation of the joint, but if you do diagnostic lateral branch block and dorsal ramus block, the L5 dorsal ramus and the patient gets significant pain reduction for the duration of the local anesthetic, I think that's enough evidence to at least try ablating those nerves. No will they get complete pain relief? We're not sure. They get no pain, you know, will they get complete pain relief with the ablation? Maybe not. But significant pain reduction has been observed in many studies. And in my own practice that seems to be the case as well.

I'll have patients that you'll do the facet joint de-innervation, and still have some residual pain. And then you treat the sacroiliac joint and their back pain is pretty well controlled.

Dr. Duerden: Okay. Thank you, Dr. Stayner. I would encourage you - well, all comments need to be submitted in writing. First of all, we appreciate your verbal comments, but we would also like to encourage you to submit these comments in writing, and also provide the references that you alluded to in your comments.

Dr. Scott Stayner: Okay.

Dr. Duerden: Operator, is there anyone else that's needing to talk or be able to present for this draft LCD?

Coordinator: I'm showing no further comments at this time.

Dr. Duerden: Okay. I will close discussion on that draft LCD and open the discussion for the draft LCD on pain management which is being revised. The simple part of this one is, is that all references to the SI joint injections, have been removed from this - the current LCD on pain management, so the draft LCD, which is going to now be described as pain management revised. We'll just simply have the absence of the IS joint injection. And I will open up the meeting for comments and ask the operator to open up the line for comments.

Coordinator: Yes. Again, if you would like to share a comment at this time, please press star 1 on your phone and please make sure your line has been muted. If you need to make a comment, please press star 1. We have a comment from Eric Grahling. Go ahead, please. Your line is open.

Dr. Eric Grahling: Hi, yes. Thank you. Good afternoon. Thanks for putting this meeting on. I'm President of the Connecticut Pain Society, a member of ACIP, and I am the CAC member for pain management in Connecticut. I practice interventional pain management in a private practice setting. I've done that for 15 years and - hello?

Dr. Duerden: Dr. Grahling, you're still with us.

Dr. Eric Grahling: Okay. Thank you. I'm hearing an echo. I guess I'm puzzled by the - this - again, this LCD as was with the facet and the epidural is incredibly restrictive. Its owners in terms of the documentation requirements, you know, having just for an example, to save two pictures of an SI joint injection in the medical record, we don't even have to do that for an epidural steroid injection, and that's a more invasive, higher risk, more involved injection. So that puzzles me.

But I don't, you know, unfortunately I've lost faith in having been in the CAC process for over a decade. I don't really think, and my membership would agree, we don't really think that what we sort of propose and try to fight for, and ends up being a difference in these hearings. But, you know, just so you know, with the facet treatments and the epidural treatments and the egregious restrictions thereof, you know, our opioid prescriptions have gone way up in the last two or three years, since these new LCDs have been incorporated.

And I know that wasn't the intent by any means, of the carriers, but that's the reality. So I just wanted to make a point and get that on the record. Thank you.

Dr. Duerden: Thank you, sir. I appreciate your comments. And Dr. Grahling, I always appreciate you attending our open meetings. And just for clarification, I believe you are referring to the draft LCD on SI joint injections as opposed to the pain management revised draft LCD. But I understood the direction that you were taking. So thank you, sir.

So as we come to a close for this open meeting, I again, want to express my appreciation to all of those speakers, particularly the busy physicians who have taken time out of their schedule, to present to us, and we really do appreciate your comments. The comments are taken under advisement and incorporated into all of the other guidelines and other National Society

recommendations, subject-matter expert panels that have been convened in regards to these draft LCDs.

As we conclude this meeting, as you recall, Dr. Noel indicated that comments need to be submitted in writing, and we are having some difficulty with the submission of that. But the official comment period is now open and will extend until November 12, 2022. And that these draft comments or policies are now open for comments, and we will accept everything in writing for those comments that need to be submitted.

The current recommended location for the submission of these comments, is PartBLCDComments@Anthem.com. It is my understanding as well, that we're still - we may be having some technical difficulties with accepting comments on this email address, so therefore I'm going to provide a second email address. And that is NGSCMD@ElevanceHealth.com. I'll repeat that. That's NGSCMD@ElevanceHealth.com.

As we close this meeting, I just wanted to reiterate the comment period is open until November 12th. And this will bring to the conclusion of this open meeting today. And we thank you for your attendance. Thank you very much.

Coordinator: That will conclude today's conference. And we thank you for participating. You may disconnect at this time.

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