National Government Services
Moderator: Carolyn Cunningham
October 15, 2020
12:00 p.m. CT

Coordinator: Welcome and thank you for standing by. I would like to inform all participants that your lines have been placed on a listen-only mode until the question-and-answer session of today's call. Today's call is being recorded if anyone has any objections you may disconnect at this time. I would now like to turn the call over to Dr. Cunningham. Thank you, you may begin.

Dr. Carolyn Cunningham: Thank you very much. Welcome everyone, we're going to begin our meeting.

Our first presentation will be the draft policy for Magnetic Resonance Image Guided High Intensity Focused Ultrasounds for Tremor. Dr. Haug.

Dr. Haug: Thank you Dr. Cunningham and good afternoon. We added tremor dominant Parkinson's disease or TDPD to the existing MR Guided Focused Ultrasound LCD based on a new RCT, published RCT and subsequent FDA label expansion. The criteria you see here reflects both the FDA label and manufacturer's requested language.

By way of some background, tremor is a common motor feature of Parkinson's disease and TDPD is a clinical subtype distinct from akinesia rigidity and postural instability gait disorder subtypes. And also this tremor dominant subtype may be more resistant to dopamine replacement therapy than other motor symptoms.

I mentioned the published RCT that's the blind study cited at the bottom of the slide, is a small perspective sham-controlled trial published 2017 has demonstrated statistically significant improvement in hand tremor in these tremor-dominant PD patients at 3 and 12 months.

This was followed as I mentioned in 2018 by expansion of the FDA indication to include TDPD with medication or prior medication refractory tremor patients. As with essential tremor, MR guided focused ultrasound is considered an alternative when not a surgical candidate for deep brain stimulation.

We received no presentation for this policy. Operator, do we have any comments on this policy? Operator could you hear me?

Coordinator: I do apologize. What was your question?

Dr. Craig Haug: We received no presentations for this policy ahead of time but I wanted to ask if there are any comments on this policy from the people that have dialed in.

Coordinator: Sure, if you would like to ask a question on the policy please press Star 1. Again, that's Star 1 if you would like to ask a question. One moment. We do have a question, one moment. Our first question comes from Eric Grahling, your line is open.

Dr. Eric Grahling: Thank you, good afternoon everyone. Good morning to some. I apologize this is not a question about the specific LCD but rather are there known issues right now with respect to the Webex? It is not coming up on my computers.

Woman: There's no known issue that I have heard of. I do see people in Webex, so I believe it's functioning properly.

Virginia Muir: Dr. Grahling did you register for the web…

Dr. Eric Grahling: I sure did, yes ma'am.

Virginia Muir: Yes, did you get a confirmation email?

Dr. Eric Grahling: I did yes.

Virginia Muir: So yes, so if you select join event and that's not working for you?

Dr. Eric Grahling: Correct. I'll get by just with the audio, but I appreciate it and I'm sorry to have to interrupt the meeting like that.

Virginia Muir: We can certainly send you the slides through email if that will help you.

Dr. Eric Grahling: Much appreciated, thank you.

Virginia Muir: Sure.

Dr. Craig Haug: Operator, are there any other questions.

Coordinator: There are not.

Dr. Craig Haug: Okay thank you then. The comments on this policy for this open meeting are now closed. The next policy on the agenda is colon capsule endoscopy or CCE. Next slide please.

Colon capsule endoscopy or CCE involves a wireless camera housed in a vitamin-sized capsule that is swallowed and then it takes pictures as it travels down the GI tract. The pictures are transmitted to a recorder worn by the patient and then subsequently strung together to create a video.

The evidence, the published evidence supports the request that we received that CCE may be a suitable alternative to optical colonoscopy or CT colonography in a very select group of patients for whom a diagnostic optical colonoscopy for suspected polyps was either unsuccessful or relatively contraindicated. Next slide.

This slide details the draft criteria for either surveillance with diagnostic CCE in a setting of either an incomplete optical colonoscopy or when optical colonoscopy is contraindicated and are based largely on the FDA approved indications. Next slide.

Exclusion criteria mostly reflect the manufacturer's generic pill cam limitations like the eye obstruction, cardiac pacemakers, swallowing disorder, etc., but also emphasized that CCE for colorectal cancer screening is not a Medicare benefit regardless of family history or other risk factors.

We did receive one submitted comment on this policy and operator if you could if Dr. Bergwerk rather is, if his line is open to comment if he's there. Dr. Bergwerk can you hear me? Can you speak?

Coordinator: Dr. Bergwerk if you are on the line please press Star 0. One moment. Dr. Bergwerk's line is open.

Dr. Ari Bergwerk: Hello.

Dr.Craig Haug: Good afternoon Dr. Bergwerk. We can hear you.

Dr. Ari Bergwerk: Hi can you hear me well?

Dr. Craig Haug: Yes, please proceed.

Dr. Ari Bergwerk: Excellent. Hi my name is Ari Bergwerk, I'm a physician, I'm a pediatric gastroenterologist. I work part time in practice and part time as a medical advisor at Medtronic. Thank you for allowing me present at this meeting. I believe you received a presentation. Can you advance the slide?

Dr. Craig Haug: Operator advance one more please.

Dr. Ari Bergwerk:Thank you good. So I'd like to thank you for inviting me to present and we appreciate the effort that went into the panel's development of the proposed LCD colon capsule endoscopy.

In particular, NGS recognizes that PillCam Colon 2 qualifies for Medicare coverage as a diagnostic test and is safe and effective as well as reasonable and necessary for defined (patients) population. The proposed LCD indicates that colon capsule endoscopy is not a Medicare benefit colorectal cancer screening regardless of family history or other risk factors or developed chronic disease. And Medtronic supports this limitation since PillCam Colon 2 is not FDA cleared for colorectal cancer screening.

And, Medtronic respectfully requests the NGS to move forward with coverage for colon capsule endoscopy based upon the FDA approved indications which are two one, it may be used for detection of colon polyps in patients after incomplete conventional colonoscopy with inadequate preparation and a complete evaluation of colon was not technically feasible.

And, two, for detection of colon polyps in patients with evidence of lower GI bleeding. This applies only to patients with major risks for a colonoscopy such as for moderate sedation but who could tolerate colonoscopy with sedation or anesthesia in the event that a clinically significant chronic abnormality was found at capsule endoscopy. Thank you very much.

Dr. Craig Haug: Thank you Dr.(Bergwerk.

Dr. Ari Bergwerk: Sure.

Dr. Craig Haug: Operator can you see if there are any other comments on the line on this policy.

Coordinator: Thank you as a reminder if you would like to a comment, please press Star 1. Again, that's Star 1 if you'd like to make a comment. And, at this time, we have no one looking to ask a comment.

Dr. Craig Haug: Thank you operator. And at this time the comments on this policy for this open meeting are now closed. Sorry back to you Dr. Cunningham.

Dr. Ari Bergwerk: Thank you.

Dr. Carolyn Cunningham: Thanks Craig. Next is select minimally invasive GERD procedures and Dr. Boren will be presenting.

Dr. Steve Boren: Thank you. This was a request to update LCD on select minimal invasive GERD procedures. We were asked to include Stretta.

We evaluated a number of papers we received. There were 43 of them. Thirteen had been previously evaluated by NGS and then included in the bibliography so they did not add any new support for Stretta. There were eight that were considered to be positive coverage documents by the submitter.

None of them were from Medicare contractors but rather commercial insurance plans which used contract language as part of the decision making process rather than evidence-based method that Medicare required thus none of these added any support to Stretta.

Many of the remaining 22 articles were old, others were small studies or had short follow-up periods. Many pertained to patients who were not reflective of typical Medicare beneficiaries. The methodological quality and design of the studies were, most of them were poor, some were unpublished or not found in PubMed of the National Library of Congress under National Center for Biotech Information.

A 44th article review from Cochrane base was mentioned by one of the submitted articles it was mentioned and reviewed and that article with very strong evidence against Stretta.

Do we have any presenters? Do we have any people on the lines who have comments on this also?

Coordinator: As a reminder, if you'd like to make a comment please press Star 1.

Dr. Steve Boren: Okay if there are no people making comments we will close this one policy, thank you.

Dr. Carolyn Cunningham: Thank you Steve. Next is heavy metal testing and Dr. Boren will present this too.

Dr. Steve Boren: Thank you. We were asked to add zinc testing for the diagnosis of depression to our heavy metal testing.

Zinc deficiency is characterized by growth retardation, loss of appetite and impaired immune function as well as hair loss, diarrhea, impotence, hypogonadism in males, eye and skin lesion and weight loss, delayed healing of wounds and taste abnormality in more severe case.

Zinc nutritional status is difficult to measure adequately using laboratory tests. Plasma or serum zinc levels are most commonly used indices for evaluating safety efficiency but these levels do not necessarily reflect cellular zinc status.

It's been suggested that zinc and other micronutrients might influence depression. A recent meta-analysis assessing the relationship between zinc deficiency depression included there is insufficient evidence demonstrating a causal effect.

Furthermore, the authors noted that the relationship between serum zinc levels and depression could partially be explained by reversible causation where depression influences the intake bioavailability or the biological regulation of zinc therefore a zinc assessment and supplementation for the treatment of depression is not considered to be medically necessary.

Do we have any presenters on this? Operator, do we have anyone on the line who wishes to comment on this?

Coordinator: As a reminder if you'd like to make a comment please press Star 1.

Dr. Steve Boren: Well if there aren't any comments this concludes the discussion and presentation for heavy metal testing. I will refer back to Dr. Cunningham.

Dr. Carolyn Cunningham: Thank you Steve. The next and last policy is facet joint interventions for pain management. Dr. Duerden.

Dr. Marc Duerden: Thank you Dr. Cunningham. If you go to the first slide this is a reminder to those that are going to be presenting and/or commenting for this LCD, we need to have written comments regarding your presentations today and such that, so that they - I recognize there will be verbal comments made but we appreciate and we will only be considering written communications.

Now if you can go to the first slide. This entire LCD has been reformatted following the 21st Century Cures Act format and with a recent assessment of the evidence-based medical standards that are present.

This was augmented by a multijurisdictional CAC meeting that was held on May 28, 2020, where all the noted Medicare Administrative Contractors were present, as well as, the group of ten subject matter experts. You can go to the next slide.

Because facet joints interventions for pain are known to be rather challenging due to the variability of the medical literature, the lack of consensus among even the experts and the differences in the societal guidelines and the historical patterns that are done in the community this demonstrates that there is a high risk for overutilization, therefore it was felt that a clear understanding of facet guidelines was necessary, therefore because of this we have used the best available evidence that has been determined and we have been able to facilitate that and supplement that with the subject matter experts that were held at that multijurisdictional CAC. You can go to the slide for definitions.

Just briefly I want to touch on some of the definitions that are going to be used in this presentation. The first is there's an abbreviation IA and that's intra-articular facet joint injections; MBB is medial branch facet blocks; RFA, radiofrequency facet ablation also known as facet joint denervation. And then something that is important to recognize is the term spine region because there's going to be two spine regions that will be defined in this policy that is the cervical thoracic region and the lumbar sacral region. You can go to the next slide please.

The first discussion I would like to have is the discussion about diagnostic facet procedures. This diagnostic facet procedure whether it's a medial branch block or an intra-articular facet joint injection, the primary objective is to confirm the diagnosis of facet joint syndrome, that's very important and why this policy needed to have some updating to really help facilitate that to help our practitioners or physicians that are doing these procedures that they're going to use this as a way to diagnose facet joint syndrome because if that is positive the goal is actually to proceed to the radiofrequency ablation procedure and that is the primary treatment goal that is found to be recognized in the medical literature as the end goal.

To in order to be considered positive response this article clarifies and this is actually not much of a change from prior LCDs that there must be at least 80% of relief of the primary index pain, the pain that they had just prior to the injection and that'll be based on the duration of whatever agent was used in that procedure since many people use different things.

Also, another aspect is, is that there needs to be at least 50% consistent objective improvement in the ability of the individuals to perform painful movements or activities of daily living. And this would be over a period of time that is outlined in the LCD. You can go to the next slide.

Wanted to clarify a second point regarding the diagnostic facet joint procedures and that is that after the initial facet joint injection is done we recognize that a need and the medical literature recognizes the need that a second diagnostic facet procedure is medically necessary so you can confirm the validity of that initial diagnostic facet joint procedure so that that needs to be documented as being done at the same level as the initial procedure and have the same consistent positive responses that were defined in the previous slide.

Also, new to this policy is that in most cases we recognize that there will be two initial diagnostic injections. This policy allows a maximum of four diagnostic injections per rolling 12 months so that the identification and assessment of a pain generator can be provided. Because sometimes it is possible that when an initial injection was done that the one or two levels that were injected were not the exact pain generators so additional diagnostic procedures may be necessary and we recognize that.

Also new to this policy is the billing with the KX modifier so we can distinguish a diagnostic injection when it is performed. Now if you can go to the next slide.

That slide is regarding the therapeutic facet joint procedures. As I pointed out at the very beginning of the discussion this, the therapeutic facet joint procedures are going to be limited because the intent is to get the individuals, the patients, the beneficiaries to the radiofrequency ablation procedure.

So, if you have a therapeutic facet injection then you're not actually going to try to get to that RFA procedure therefore we recognize that there is and the medical literature recognizes that there is a need first to document why the beneficiary may not be proceeding to get an RFA procedure. But, then there's also a limit in the number of therapeutic facet injections that are going to be provided and that is four therapeutic injections sessions per spine region and those will be reimbursed at a rolling 12-month interval. You can go to the next slide.

So it is the - when it comes to radiofrequency facet injections then the beneficiary has, needs to have sufficient documentation to show that the radiofrequency procedure provided consistent and objective 50% improvement in the pain for at least six months before a second RFA procedure will be covered.

The limitation therefore for the radiofrequency injections are going to be per each covered spinal region no more than two radiofrequency sessions will be reimbursed for each rolling 12 months. Go to the next slide.

I'd like to just touch briefly upon the facet cyst aspiration component. This is a rare thing, but it does occur and therefore we included this in the facet policy. And this - when a cyst is to be injected and treated it needs to have two particular inclusion criteria, first there has to be the use of the diagnostic imaging study and clinical evidence to show the corresponding nerve root of the facet joint has been impaired and we have to have clinical and physical symptoms related to that synovial facet cyst and those need to be documented. When those two indications are met the cyst aspiration can be repeated once and only if there's 50% or more improvement and that can be done at least every three months.

Now the, if you go to the next slide and these are just, I'll just touch briefly on them. This facet joint LCD is going to have some particular key limitations and guidelines to indicate how these procedures need to be performed. We're requiring imaging. We are not going to allow general anesthesia or sedation since it is general societal guidelines as well as the consensus guidelines of our CAC members that routine sedation for facet joints are not needed. One or two levels either unilateral or bilateral will be allowed per session per spine region and the retreatment of those can be done without repeat diagnostic blocks if the treatments are within the past 24 months.

And then also just briefly touching again on the therapeutic injections these are not covered unless there is justification in the medical documentation particularly why a radiofrequency ablation procedure cannot be performed. Now you can go to the last slide.

In this LCD, it also indicates that facet joint procedures in individuals with generalized pain conditions such as fibromyalgia or other chronic centralized pain syndromes are not, is not considered reasonable and necessary but may be considered on appeal.

And then finally, it is not expected that these patients will routinely present with the specific pain in a particular facet joint and they will not need multiple facet blocks on the same day as an injection, i.e. such as a trigger point injection, epidural injections, etc.

There is not expected that these individual beneficiaries will need three levels procedures, one or two level facet joint injections will be considered reasonable and necessary. And also the routine performance of repetitive injections will trigger a focused medical review.

And I know there are at least two presenters. I don't have their order so operator I will turn the time over to you and Dr. Cunningham to determine who will be our first presenter.

Dr. Carolyn Cunningham: I think Dr. Desai is listed as the first presenter. Are you with us Dr. Desai?

Virginia Muir: Yes Dr.Cunningham our presenters for this policy were expecting it to come up around 2:00 p.m. so it's possible that some of them are not online yet. Dr. Gharibo was one, Dr. Desai and Dr. Stout maybe if any of those presenters are here we could start with one of them.

Coordinator: I do have Dr. Gharibo on. Your line is open doctor.

Dr. Christopher Gharibo: Hi thank you for the invitation and I would like to - I just want to be able to see my slides I'm sorry. Okay great thank you.

So I am Dr. Christopher Gharibo. I'm the Medical Director of Pain Medicine at NYU Langone Health. I put together this presentation in collaboration with Dr. Sanjay Bakshi who is with Ortho Manhattan in New York City as well and in collaboration with our other colleagues through New York State Society of Interventional Pain Physicians. Next slide please. There's no relevant conflict of interest for Dr. Bakshi and myself. Next slide please.

Now with respect to the diagnostic determination of the, of success of a facet medial branch block I would like to emphasize that the pain world is clearly moving towards functional restoration rather than percent pain reduction. And I think for best clinical outcomes and for best specificity and sensitivity we need to have both available to us and the designation should be a specific percent pain reduction of less than 80% which we would agree with or the functional restoration of something that was prior and that was painful to begin with before the medial branch block that can be assessed during the duration of the local anesthetic.

And the reason to keep it or is extremely important because there are many of our patients that don't have a good concept of percentages, percent pain reduction or even numerical pain intensity. They describe their pain in terms of limitations of range of motion, sitting intolerance or standing intolerance or even this is a pain provocation that can be measured in terms of the lumbar range of motion. And that can be assessed immediately after the performance of the medial branch block.

So moving towards functional restoration is also in line with for example FDA goals in terms of analgesic outcomes focusing more on function rather than pain reduction and visual analog scale scores as well as other parallel coverage determinations that apply to epidurals, other clinical studies that are being performed that are based on treatment of chronic pain conditions. Next slide please.

So there are multiple reasons to not rely on the local anesthetic percent pain reduction and focus more on function and I think us as a clinical advisors encourage you to move in that direction because false positives can occur due to local paraspinal muscular effect, local or systemic absorption, proximal dorsal ramus local anesthetic effect and blockade of the dorsal root ganglion blockade or the patient's simple miscomprehension of their percent pain reduction.

False negatives can occur where patient let's say gives us a 40% pain reduction but their range of motion is now full during the duration of the local anesthetics whereas prior it was limited to about 10, 20%. And now they're able to sit for a prolonged period of time beyond let's say 15 minutes whereas prior they were not able to do that at all. They were able to sit for example in the recovery area after the nerve block for a 30, 45-minute duration.

So therefore, we certainly in agreement with the designation between 80% reduction in the pain or at least 50% consistent objective improvement in the ability to perform previously painful movements, ranges of motion and activities of daily living. Next slide please.

So in addition to that all imperative or (between percent) pain reduction and functional improvement, we would also would like to emphasize that the second diagnostic block can be separated from the first diagnostic block after some minimum and significant healing has occurred, and that minimum timeframe can be a week. By a week timeframe any muscle damage, any bleeding, any soft tissue or skin pain that is occurring has pretty much resolved and the patient can be retested for the second medial branch block in (a week) time but not any sooner than that.

With respect to a repeat radiofrequency procedure our society believes and Dr. Bakshi and myself believe that a repeat medial branch block was necessary before we perform another neurodestructive procedure such as a radiofrequency ablation. And the reason behind that being simply because low back pain although it may appear to be the same, it has a whole range of different ideological factors that are just very difficult to ascertain and pin down in a clinical exam that we should not move based on an assumption but we should move based on objective repeatable data at the time of the pain recurrence and the repeat medial branch blocks can be repeated at that time.

And the last comments I want to make is that these injections are performed generally speaking under fluoroscopy not so much under CAT scan or MRI. I don't know if I put that point out of context on that slide. As well as another point being that there is a subset of patients although the majority of patients are going to require one or two level facet there is a very small subset that is going to require three level facet denervation on one side for example. And it's, the incidence of that is probably 10, 15, 20% or so if that, but these patients tend to have a multi-level facet disease and in a very small subset that may involve three separate facet nerve blocks and radiofrequency ablation.

Thank you for this opportunity and I'm happy to take any questions. And I believe Dr. Bakshi is on the line as well.

Coordinator: As a reminder if you would like to make a comment, please press Star 1. At this time, we have no comments.

Dr. Marc Duerden: Operator can you place the second presenter on the phone please.

Coordinator: Dr. Desai if you're on the line please press Star 0. I do not believe he's dialed in yet.

Dr. Marc Duerden: Then operator I would like to then open up the line to anyone else who would like to make a comment.

Dr. Steve Boren: Marc did you want to check and see if Dr. Stout is on?

Dr. Marc Duerden: I apologize.

Virginia Muir: Dr. Stout did say she would not be available 'til 2 o'clock but maybe, you know, we could, the operator can still try.

Coordinator: And Dr. Stout if you are on the line please press Star 0. At this time, neither are on the phone line but if you are Dr. Stout or Desai please press Star 0. We do have someone who'd like to make a comment or question would you like to go to that?

Dr. Marc Duerden: Yes please.

Coordinator: Thank you Eric your line is open.

Dr. Eric Grahling: Yes, I thank you very much. This is Eric Grahling, I'm a pain management physician in central Connecticut. I'm the President of the Connecticut Pain Society and I am the Connecticut Representative for Pain Management to the CAC. I appreciate everyone's effort and time and being here addressing this very, very important discussion.

I have no relevant conflicts of interest. I work in a solo private practice office and I spend a great deal of time helping people with facet joint pain, you know, the goals of which are to restore ones mobility and functionality, decrease the need for other interventions and decrease the need for medications which in many beneficiaries there are various side effects which aren't tolerated in an older patient population.

And additionally in light of the ongoing opioid epidemic which we're dealing with here in Connecticut and I'm sure every other state we want to minimize the usage of the medications which in chronic pain, you know, have equivocal evidence in terms of the efficacy and in terms of relief and of the pain as well as functionality.

I do have some concerns and I speak on behalf of the Connecticut Pain Society regarding the presentation and the draft LCD mainly in terms of limitations. For instance, on the presentation that was just made regarding, I have page 21 or slide 21, facet joint denervation. This addresses the frequency limitation.

The third bullet point and I'll read this frequency limitation, "For each covered spinal region no more than two radiofrequency sessions will be reimbursed per rolling 12 months." This needs to be - there needs to be clarification because many of us including myself for radiofrequency ablations we do one side at a time. So maybe left side and then the following week right side and there are different reasons for that.

But that being said if we do that in this case generally the standard of care is radiofrequency ablation shouldn't be performed any more frequently than six months per level per side. So if we look it as written here this is of concern because if I were to do a two-level lumbar radiofrequency lesioning on the left and then one on the right that beneficiary as per this statement would only be eligible for one treatment per 12 months. And that would run into major issues because oftentimes the radiofrequency treatment will only last six months, nine months.

And so the question is what do we do with these patients who have responded very favorably to a very, very safe, you know, nonsurgical intervention, what do we do if they aren't getting sustained relief for one year. So that's an issue.

And additionally as the doctor from New York pointed out, you know, limiting the levels to one or two level lesioning is of concern because there is, and it's a minority, but there is a significant percentage of patients who have three and sometimes even four level facet joint mediated pain and that's proven by a diagnostic medial branch nerve blocks under fluoroscopy.

And so the question arises as to what we do with the patients whereby, you know, we do the radiofrequency lesioning they're say 50% improved, their functionality's improved yet they're still having to rely upon Vicodin or a opioid to help manage the other 50% of their pain which arguably could be eradicated by ablating a couple of more facet joint levels. So that's the consideration we need to be mindful of.

And in the LCD draft regarding from the draft not the presentation we were just shown but the LCD draft under limitations Number 6 it does say two levels joints either unilateral or bilateral and four joints - I apologize that's the revision. Let me see this. Pardon me.

Okay the proposal under Number 6 for limitations, one or two levels either uni or bilateral are allowed per session per spine region. The need for a three-level procedure may be considered under unique circumstances and with sufficient documentation of medical necessity on appeal. Our society is

recommending the language, and obviously I'll put this in a written format, but that be revised that it state that for, you know, two joints per bilateral procedures and up to four joints for unilateral procedures are allowed per session per spine region.

So I will put this obviously in a letter and submit it humbly but I thank everyone for their time and of course I'm available to answer any questions and help in any way I can.

Dr. Marc Duerden: Thank you Dr. Grahling. In addition to the submission of your recommendations, we would appreciate that it be accompanied with the appropriate literature to support those recommendations.

Dr. Eric Grahling: Absolutely thank you.

Dr. Marc Duerden: Thank you sir.

Coordinator: Thank you and we do have Dr. Stout on the line now, would you like me to open her line?

Dr. Marc Duerden: Yes please.

Coordinator: Excuse me this is the operator would you like Dr. Stout's line open, she has called in.

Dr. Marc Duerden: Yes, please if you could open up Dr. Stout's line we would appreciate it.

Coordinator: Thank you, Dr. Stout your line is open.

Dr. Alison Stout: Thank you can everyone hear me okay?

Dr. Marc Duerden: Yes

Dr. Alison Stout: Okay thank you. I'm Dr. Alison Stout, I'm a physiatrist practicing in Washington State. I am here representing the Spine Intervention Society. These slides were put together by the Health Policy Division and do represent the views of the Spine Intervention Society as a whole.

I want to thank everybody for having the opportunity to present this. Just for a little background I'm in Washington state which is under Noridian which our LCD looks much like this proposed LCD and so I'm quite familiar with practicing under it. I'll have a few personal comments of my own and I'll disclose that those are my own person comments when I get to those. Next slide please. I have no relevant disclosures. Next slide please.

All right so looking at the proposed LCD when looking at diagnostic facet joint procedures we do, SIS does strongly agree with requiring a second diagnostic facet procedure to confirm the validity of the initial diagnostic facet procedure.

On that same point though, we feel that the second diagnostic procedure does not really need to be delayed for two weeks. Outside of any global periods, you know, that are required between facet procedures two weeks seems to not have a medical basis.

My suspicion, my personal suspicion is that was carried over from epidural steroid literature and that has, you know, with repeated steroid injections are recommended to be two weeks apart. So SIS is recommending 48 hours after the diagnostic procedure they could consider having a second because we're really just looking at the anesthetic phase relief.

This is important at least in my center where we do have patients that will often travel from great distances and planning to spend say, you know, a week to get to an answer at least of what their options for treatments would be and whether or not even if they're a candidate for radiofrequency neurotomy and so that sort of two week delay could create quite a burden on patients that are traveling to treatment centers. Next slide please.

All right criteria for second and diagnostic facet procedure, yes obviously we agree they should meet those criteria for the first diagnostic procedure and that it should be at least 80% relief of their index pain with the duration of relief being consistent with the anesthetic used.

The part about 50% consistent objective improvement in the ability to perform previously painful movements in ADLs is a nice consideration. There are many patients who have columns with a VAS score have trouble separating out numbers of for pain scores and functional measures are good, however this leaves a lot of vagueness, how do you measure this, how do you quantify this reliably. There's some risk of overutilization with that and this is where I'm going to bring in my personal experience, it's going to create a problem with any audits that are performed.

We're a large center that gets referred a lot of radiofrequency treatments. We were audited and under Noridian there was the qualification of adequate physical therapy, flash, you know, conservative care but that was never, initially that wasn't defined. And with a lot of back and forth came up with eight visits of physical therapy whether that's, you know, valid scientifically or not but that was what was decided which at least gave us a clear thing to be able to use clinically. So, that's just a side point there about the functional measures. Next slide please.

So therapeutic facet joint procedures SIS feels that requiring two diagnostic medial branch blocks prior to a therapeutic intra-articular injection is unreasonable and really not necessary. And this is because an intra-articular injection at least historically is often done with local anesthetic in steroid and therefore considered both diagnostic and therapeutic at the same time.

And since there's a percentage of patients that will obtain relief from a single intra-articular steroid injection in select patients that this by combining the anesthetic and the steroid this could result in significant cost savings over the three-step needed to perform radiofrequency neurotomy. Next slide please.

For therapeutic facet joint procedures SIS strongly believe that medial branch blocks are diagnostic procedures only and should only use local anesthetic. These are not considered therapeutic procedures. The idea of putting steroid along the medial branch nerves does not have any construct fluidity. There's not going to be a - there's no documentation of an inflammatory medial branch neuritis as a cause of this type of pain. So we stand that medial branch block should remain as diagnostic only rather than therapeutic.

And again, bringing up the criteria of 50% consistent improvement in movements or ADLs again the vagueness of that could create some problems or difficulties managing these clients. Next slide please.

Therapeutic facet joint procedures under this if a patient obtains at least 50% relief from a therapeutic facet joint injection it seems unnecessary to require that they are not a candidate for radiofrequency neurotomy meaning, you know, especially if we allow the use of intra-articular anesthetic and steroid injections of the facet that could conceivably the initial treatment and appropriate to repeat in patients that improve from that by at least 50% for three months.

And then if they didn't receive relief from that for three months, then they could go on to diagnostic medial branch block and then go on as appropriate to RF and that would save steps for the patients as well as create a cost savings especially for those patients that do respond to the intra-articular steroid portion. Next slide please.

So for the radiofrequency neurotomy portion of the proposed LCD yes we agree that they should have two diagnostic medial branch blocks or intra-articular diagnostic blocks that result in at least 80% relief of their index pain consistent with the duration of anesthetic. And again same point about the 50% improvement in movements in ADLs. Next slide please.

Some limitations on the radiofrequency proposed LCD repeating medial branch blocks after 24 months of pain relief or greater from radiofrequency neurotomy is not really necessary if patients have experienced more than 24 months of relief from a radiofrequency neurotomy and this does occur, a repeat procedure should be permitted at the same level to reinstate relief.

You know, rather than requiring another two sets of medial branch blocks which is again more cost and obviously more burden to the patient, you know, a potential alternative would be maybe a visit documenting that the pain is in the same location or a pain diagram of the patients that document it is in the same location understanding that two years is a long time to be able to say it's the exact same pain just over the phone for some patients. But it seems like it's going to result in more patient burden and higher cost to require two sets of medial branch blocks to repeat something that appears to be the exact same pain generator.

There is also an area of inconsistency with Statement 6 in the list of procedures considered not reasonable and necessary and it will be then denied and that diagnostic injections or MMBs at the same level as the previous successful RFN procedure. I think this is just a wording thing. I don't think that's the intention of the proposed LCD. It just looks, it could be, the way it's written it could be mistaken to say that somebody who had 24 months of relief cannot have a repeat RF and cannot have a repeat medial branch. So we're suggesting a wording change there. Next slide please.

Requiring documentation of why radiofrequency neurotomy should not be performed in patients being treated with therapeutic intra-articular facet injections just create unnecessary work for the physician that will not result in improved patient care. And I mentioned this before so if we're allowing diagnostic intra-articular injections, you know, adding steroid to that to allow a diagnostic and therapeutic injection without someone technically being quote not a candidate for radiofrequency neurotomy could actually result in less treatment episodes and decrease cost and, you know, for that one proportion of patients that get better with intra-articular injection of steroid. Next slide please.

Under provider qualifications SIS would like the consideration for placing healthcare professionals with physicians. The reason for that is because of patient selection is actually pretty difficult in these cases. We think it'll actually result in overutilization if this is opened to say a naturopath and PAs and assuming that also, you know, chiropractors are healthcare professionals. This, that inability to really select patients based on known anatomy and prevalence of the disease and other potential causes of the pain generators is an important consideration.

The other point is that these are actually difficult procedures technically. And a professor who's done a lot of anatomical and clinical research on medial branch anatomy and radiofrequency neurotomy, you know, he says, you know, lumbar medial branch is the most difficult simple procedure that was ever dreamt up because, you know, especially in the Medicare population there is some very difficult anatomy and you need a lot of experience to be able to address that even just for the medial branch

blocks not - and then even more so for a successful radiofrequency neurotomy that requires very precise placement and adequate treatment to result in pain relief for these subjects. And then, of course, dealing with any potential complications is an issue as well. Next slide please.

So that's the end of the SIS recommendations for changes. Obviously, this will be in the written comments as well but if there are any questions that come up before then Belinda our Senior Director of Policy and Practice can answer those questions or I can answer any questions now if anybody has any. Thank you.

Dr. Marc Duerden: Thank you, Dr. Stout. Did Dr. Desai was he able to join us?

Coordinator: Yes, one moment. Dr. Desai your line is open.

Dr. Desai: Hi good afternoon, hi this is Dr. Desai. So I don't, I have a very brief statement on behalf of the American Academy of Physical Medicine and Rehab.

So I think generally speaking we just wanted to make two comments, one we echo the comments of the prior speaker Dr. Stout with regards to the Spine Intervention Society and their comments. And generally speaking we also wanted to express an appreciation for the opportunity both to comment on this LCD but also with the general sort of spirit of the LCD I think is in line with what we were hoping for and the opportunity to both collaborate and communicate regarding next steps is something that we very much appreciate. So, I wanted to just make that very brief statement.

Dr. Marc Duerden: Thank you Dr. Desai. Operator we'd like to turn the line over to any final commentors.

Coordinator: Thank you and as a reminder please press Star followed by 1 if you'd like to make a comment. One moment please.

Dr. Steve Boren: Dr. Duerden, Dr. Boren here, could I make two comments, two clarifications please.

Dr. Marc Duerden: Certainly.

Dr. Steve Boren: Naturopaths are not recognized by Medicare so this is not an issue. And by national regulations chiropractors can only perform three CPT codes which are all chiropractic manipulation so they would not be eligible either for this, thank you.

Dr. Marc Duerden: Thank you Dr. Boren.

Dr. Christopher Gharibo: This is Dr. Gharibo can I make a comment?

Dr. Marc Duerden: Yes, sir we'll open up your line.

Dr. Christopher Gharibo: Thank you Dr. Chris Gharibo from New York City on behalf of American Society of Interventional Pain Physicians. I'd like to emphasize that baseline percent pain reduction and function linked percent pain reduction is still percent pain reduction. And given we're moving more towards a functional restoration being our ultimate goal that that is a much more relevant metric that is also being looked at in studies as well.

And 50% improvement in function being okay for repeat radiofrequency should also make it okay to proceed to radiofrequency after 50% improvement in function-based pain for the initial set of medial branch blocks that later proceeds onto medial branch block proceeding onto radiofrequency ablation.

I'd like to - extremely important for the Medicare population is that there is a subset of patients where false negative results are being produced especially in the elderly because they cannot understand the concept of percent pain reduction. So it is essential for our aging population to get a functional assessment during the duration of the local anesthetic whether that's a positive facet loading that has later become a negative facet loading or whatever that ADL limitation may be.

To serve those patients with less mind-altering medicines there needs to be a recognition of that false negative and there needs to be recognition of functional restoration that is provided by these medial branch blocks which they do provide, which they should go on to proceed with radiofrequency if there is a 50% pain reduction during functional maneuvers.

And, furthermore, as far as the repeat radiofrequency goes, you know, two years out location may very much be the same and the diagrams may very much look the same. But, I think we all know that there is a whole range of diagnoses that can cause same exact pattern of low back pain and referral patterns. And before a neuro-destructive procedure is performed, a repeat at least a single medial branch block should be done before RFA.

And the last comment is 48 hours is still soft tissue healing phase for repeat medial branch blocks and that now we're going to reinsert our needles into and try to gauge an assessment whether the second medial branch block was effective. So I think in order to improve the specificity and overall reliability of the repeat medial branch block, at least a week should be allowed to elapse.

Dr. Marc Duerden: Thank you, Dr. Gharibo.

Coordinator: And we do have…

Dr. Marc Duerden: Operator…

Coordinator: …other comments on the phone.

Dr. Marc Duerden: Thank you. Go ahead and open them up one by one please.

Coordinator: Yes, thank you. All right the next comment is from Sanjay. You may go ahead.

Dr. Sanjay Bakshi: Yes, hi this is Dr. Bakshi. I'm also on the American Society of Interventional Pain Management. And I think all the points so far have been excellent.

I agree on all three points that Dr. Gharibo just mentioned. I think, you know, two weeks for in between diagnostic blocks is a long time, but 48 hours may be too short. So I think a week is a good timeline between the, you know, between the two diagnostic procedures.

And also, the point about, you know, judging the functional capacity as well as, you know, repeat medial branch block after two years I think all those I agree with completely. So those are my comments.

Dr. Marc Duerden: Thank you, sir.

Dr. Sanjay Bakshi: Thank you.

Coordinator: Thanks. Thank you. The next comment is from Eric Grahling, you may go ahead.

Dr. Eric Grahling: Thank you, very good presentations. I am very much supportive of Dr. Stout's recommendation regarding healthcare professionals being switched to physicians.

I know in my area there are many, well no, there are several non-physicians who are, and I can't speak to whether or not theirs are Medicare beneficiaries but they are chiropractors that are doing under ultrasound facet blocks and doing them out as such and unfortunately I've seen that.

I do have to say on behalf of the American Society of (Interventional) Pain Physicians, ASIP, there is some evidence to show that medial branch nerve blocks can be therapeutic and I will submit those studies to the, to you all for your review.

And additionally, the concept of an intra-articular facet joint injection being diagnostic is a very controversial concept. I know when we had our expert meeting back in May, we all voted on that and I don't believe that there was high confidence in the intra-articular facet injection as being a truly diagnostic testing modality. And I think that's all I wanted to say for now, thank you again.

Coordinator: Thank you and currently there are no further, sorry there are no further comments at this time.

Dr. Marc Duerden: Having no further comments, I'll move to close the discussion on the LCD and turn the time over to Dr. Cunningham.

Dr. Carolyn Cunningham: Thank you Marc. I failed to mention in the beginning that Dr. Awodele and Dr. McKinney are also with us. Do you have anything for the open meeting?

Dr. Awodele: No not from me, thank you Carolyn.

Dr. Carolyn Cunningham: Anything else from those on the phone? Thank you all very much. The comments period ends November 7, 2020 and we welcome your comments. Thank you very much. Thank you, operator.

Coordinator: That does conclude today's conference. Thank you all for participating you may now disconnect.

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