Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Spinal cord stimulation

November 17, 2023

DISCLAIMER

Note: The following is the output of automated transcription. Although the transcription is largely accurate, in some cases it is incomplete or inaccurate due to inaudible passages or transcription errors. It is posted as an aid to understanding the proceedings at the meeting.

Sheila Rege	Who's going to go ahead and take a role call to make sure everybody can speak?
Val Hamann	Yeah I have that Sheila so let's start with Dr. Bramhall. I don't believe I have seen him yet. Then Daniels, Clinton Daniels.
Clint Daniels	Hi, good morning can you hear me?
Val Hamann	Yes
Clint Daniels	Alright I'm, I'm the chiropractic section chief for VA Puget Sound and I have no conflicts for this topic as well.
Val Hamann	Thank you. Janna Friedly?
Sheila Rege	As committee members can we introduce ourselves mention our, our role and then also if we have conflicts.
Janna Friedly	I'm Janna Friedly I'm a physiatrist and chair of the department of rehabilitation medicine at the University of Washington and I have no financial conflicts with this topic.
Val Hamann	Chris Hearne. Conor Kleweno.
Josh Morse	I saw Chris in there.
Val Hamann	Yeah I did too.
Josh Morse	Yeah, okay.
Conor Kleweno	Conor Kleweno orthopedic surgeon at Harborview Medical Center, University of Washington. No financial conflicts with this topic.

Val Hamann	Christoph Lee.
Christoph Lee	Christopher Lee professor of radiology at the University of Washington I have no conflicts.
Val Hamann	Laurie Mischley.
Laurie Mischley	Present. I have no conflicts to disclose. I'm a naturopathic physician and a epidemiologist and nutrition researcher at UW and Bastyr, no conflicts.
Val Hamann	Sheila Rege.
Sheila Rege	Sheila Rege radiation oncologist and no conflicts thank you.
Val Hamann	Jonathan Sham.
Jonathan Sham	Jonathan Sham surgical oncologist and hepatobiliary surgeon at the University of Washington and Fred Hutch no conflicts.
Val Hamann	Tony Yen.
Tony Yen	I'm Tony Yen I'm a hospitalist at Evergreen, no conflicts.
Val Hamann	And then I did let in Dr. Bramhall.
John Bramhall	Yes, hi, uh present I work at Harborview at the University of Washington system. I'm an anesthesiologist by trade and I'm an associate medical director there and I have no conflict of interest for this subject.
Val Hamann	And then we'll go back to Chris Hearne.
Chris Hearne	Sorry I didn't unmute myself previously I am a nurse practitioner, I work for Swedish I work in the hospital medicine department and I have no conflicts of interest.
Val Hamann	And then our clinical expert Joseph Strunk.
Joseph Strunk	Hi, I'm Joe Strunk. I am an anesthesiologist and pain physician at Virginia Mason Medical Center where I practice pain and spinal cord stimulation. I have no financial conflicts of interest.
Val Hamann	And that is it Sheila.
Josh Morse	Val, how many committee members is that today.
Val Hamann	We have 10.
Josh Morse	Excellent thank you so much.

Sheila Rege So we do have a quorum, correct?

Josh Morse Yes

Sheila Rege Perfect. If we could reproject our schedule, our agenda again, I do not have any chair remarks except I'm going to have Josh address it in his program updates if anybody has trouble kind of what the mechanism would be to let our staff know that uh we're having trouble. And we are trying not to use the chat we're trying because people may be listening in on the telephone so we're trying our hardest to have everything kind of verbally done if possible. With that Josh I will hand it over to you.

Josh Morse Excellent. Here's the agenda you'll see we have a few minutes here for a program update and a brief background we'll go over some of the technology used today that we plan to do from 9:15 to 9:40 we'll then do the previous meeting business and if we finish that at all early we'll then jump right into the next part and then followed by public comment so agency medical directors and public comment. We have a number of people interested in commenting today so I'll try to be super-efficient here, hopefully that didn't jinx my plan. So are you seeing the appropriate screen here for the intro slides?

Sheila Rege Yes.

Josh Morse Great.

Sheila Rege Oh no no we're just seeing health technology assessment we're not seeing your slides Josh. Now we are. Oh wait, now it is saying we will begin at 9 am. Is that what you wanted?

Josh Morse (HCA) That's what I want. We're in the slide presentation. Thank you. So welcome. This is the Health Technology Clinical Committee meeting. This is an open public meeting and here are some meeting reminders. A transcript of the proceedings will be available after this meeting. We are recording the meeting. It'll, it's available on the Health Care Authority website for the HTA program. We have disabled chat for this meeting. And we ask that you please refrain from using the hand raise function feature unless we ask you to do so and we're going to do that here in just a moment. So some background on this program, the health technology assessment program is administered by the Washington State Health Care Authority. This program brings evidence reports to the Health Technology Clinical Committee to make coverage decisions for selected medical procedures and tests based on the evidence for their safety, efficacy, and cost effectiveness. Some program background further. So multiple agencies are participating in this process to identify topics and implement the policy decisions. That includes the Health Care Authority programs of the uniform medical program and the state Medicaid program also known as Apple Health. The Department of Labor and Industries and the Department of Corrections also uses the outputs from this process. These state agencies implement the determinations from the clinical committee within their existing statutory frameworks. The purpose of this process is to ensure that medical treatments, devices, and services paid for with state health care dollars are

safe and proven to work. This program provides resources for the state agencies that are purchasing health care. In this process, it develops scientific evidence-based reports on the medical devices, procedures, and tests for the Health Technology Clinical Committee. And our program supports the HTCC to make the determinations for the selected of medical devices, procedures or tests based on the available evidence.

There are multiple ways to participate in this process. We have a sign up where you can receive email notifications from our program. For each step of the process, and to contact us. And anybody is welcome to provide comment when the topics are proposed for review, during the key question development phase, on draft and final reports, and on the draft decisions. We welcome people to attend these public meetings and present comments directly to the clinical committee. Anyone may nominate technologies for review or for rereview. So public comment for today, so there's a limited amount of time available for day of signups. So we're going to ask you to please raise your hand if you're not already signed up. Many people are already signed up to provide comment today. If you have not signed up already and you wish to provide comment, please use the handwritten function now to indicate that you would like to provide comment. We're going to monitor that for the next 5 min. Attendees who are scheduled to provide public comment, will be temporarily reassigned as a panelist and provided the option to unmute and turn on their camera. When this happens, a popup window is going to ask you to rejoin the meeting as a panelist. There's going to be a slight delay when that occurs. We ask that you please limit your comments to the time that is allotted.
Staff are going to monitor the time and will indicate to you when that time is up and we're going to give you a couple warnings as you approach the end of the time there. When you're finished providing public comment, you'll be reassigned as an attendee. There'll be a pause and you'll then rejoin the meeting. So during the public comment period, you may see this slide briefly. We're gonna ask that you clearly state your name. Please declare any conflicts of interest you may have. In this, again, this might be showing during that comment so it says this is the public comment portion of the meeting. And again, we will ask you to please limit your comments to the allotted time. We do, back on this slide, we do have a limited amount of time for additional public comments today. So we may not, depending on the volume, which I do not know of people who raise their hand, we may not be able to accommodate everybody, but we'll do our best.

So, here's a summary of our agenda. We're going to go through the previous meeting business, including the minutes from the last meeting. There will be consideration of any comments on the draft decision for hyaluronic acid and platelet-rich plasma. We'll then address the SBRT or stereotactic body radiation, renal cancer comments that are carrying over from, can, discussion in July and then we will enter the process for the spinal cord stimulation review, which will start with the agency medical directors followed by public comment. Excuse me. Followed by the evidence report

presentation. We'll then move into the committee question and answer session with our contractor and then into the discussion and decision phase. After today's meeting, the program will publish the final determinations for topics that were addressed from previous meetings in the previous meeting business phase. We will publish any draft determination on spinal cord stimulations today, after today's meeting. Those, that that determination will be available for public comment for 2 weeks between now and the next time the committee convenes.

So, future meetings of this committee, we are currently working to schedule a meeting in January. Which would be a follow-up to today's meeting if we have a draft determination today which would be the normal process. We hope to reconvene to address that draft in January. Then in May, we have a meeting scheduled to review, this is actually a rereview of bariatric surgery. We're currently in the final key questions phase of that review and then June, we currently have whole genome sequencing scheduled for review. That is in a similar status right now where the final key questions have been completed. If you have questions or if you need to contact us during the meeting and the, the Zoom technology is not working for you,
you can email us at SHTAP, that is an acronym for the State Health Technology Assessment Program, at hca.wa.gov. And the, the complicated link that you see on this slide is where the program information is, but if you go to hca.gov, you can also find ways to navigate to that, to the health technology assessment pages. Sheila, that concludes my presentation and I think we are ready to move into the next phase unless committee members have any questions for me.

Sheila Rege I actually would like to. Take a few seconds to make sure, not just committee members but members of the public understand how to ask or how to give comments during the open public comment period, which is a 10 am. I, we will put our agenda back up. And Josh, if people have trouble because we're gonna disable the, raise hand, how do they email us or how do they reach us for problems?

Josh Morse They can email us at the SHTAP@hca.wa.gov email address.

Sheila Rege Perfect. Thank you.

Josh Morse You're welcome.

Sheila Rege Let us go to the previous meeting minutes. We could project that. I will entertain a motion to approve these minutes and we will have instructions on how to vote after the motion and second.

Janna Friedly I motion to approve. This is Janna Friedly.

Laurie Mischley This is Laurie Mischley. I second.

Sheila Rege Any discussion? If not, then, if we can get instructions on how to vote on this.

Josh Morse Yes, Val, can you? Provide some guidance on how you would like to hear voice votes.

Val Hamann	Yeah, so. We will go through just name by name, like we've done in other meetings. We will, I will Change up the order, so just be listening for your name to be called for that. Okay, so are we ready for previous business?
Sheila Rege	Yes, please.
Josh Morse	I think we are.
Val Hamann	Okay. Bramhall.
John Bramhall	Yes, I'm simply voting now by voice. Is that right?
Val Hamann	Yes.
Josh Morse	Yes, voting to approve the previous meeting minutes.
John Bramhall	Okay, you bet. I vote.
Val Hamann	Daniels.
Clint Daniels	Yes, approve.
Val Hamann	Friedly.
Janna Friedly	I approve.
Val Hamann	Hearne.
Chris Hearne	Approve.
Val Hamann	Conor, Kleweno.
Conor Kleweno	Approve.
Val Hamann	Lee.
Christoph Lee	I approve.
Laurie Mischley	Mischley.
Val Hamann	Rege.
Sheila Rege	Approve.
Val Hamann	Sham.
Jonathan Sham	Approve.
Val Hamann	Yen.

Tony Yen	Can I ask, do I? I don't think I attended the July 20 first meeting. Yeah.
Val Hamann	Oh yes, that is correct. You were only there for that small section. Yes. Okay, we have all of the committee members have given their vote.
Josh Morse	Minutes are approved, thank you. So then next, item of business from the last meeting is the hyaluronic acid platelet-rich plasma draft, excuse me, findings and decision you'll see here on this screen. The order, of the technology review starting from July, 2022 through to the public comment period on the draft determination which occurred here in July and August of 2023. There were no comments received on this draft determination. And this is the draft that, is for your consideration for approval from your July meeting.
Sheila Rege	This is HA and PRP for knee or hip osteoarthritis. Let's say I'll take any discussion or a motion to approve.
Janna Friedly	Motion to approve. This is Jana Friendly.
Conor Kleweno	Second, Conor Kleweno.
Sheila Rege	If no discussion, let's go on to votes.
Val Hamann	Yen.
Tony Yen	I was not at that meeting, so I will abstain.
Val Hamann	Correct, sorry. Yep, here we go. Okay, Sham.
Jonathan Sham	Approve.
Val Hamann	Rege.
Sheila Rege	Approve.
Val Hamann	Mischley.
Laurie Mischley	Approve.
Val Hamann	Lee.
Christoph Lee	Approve.
Val Hamann	Kleweno.
Conor Kleweno	Approve.
Val Hamann	Hearne.

Chris Hearne	Approve.
Val Hamann	Friedly.
Janna Friedly	Approve.
Val Hamann	Daniels.
Clint Daniels	Approve.
Val Hamann	Bramhall.
John Bramhall	Approve.
Val Hamann	Okay. And that is everybody.
Josh Morse	And the draft decision from HA-PRP is approved as a final decision. The program will publish this final decision for the agencies to implement.
Sheila Rege	Alright, now we need to move on to the SBRT renal draft findings and decision. I had declared a conflict so I am going to hand the chair role over to Janna, Dr. Friedly.
Janna Friedly	Right. So, thank you. So I will try to, summarize where we are at just a reframe. So we had reviewed this topic in the spring and had come to a no coverage decision for renal cancer for SBRT. That, they were subsequently, there were comments that were that were made on the draft decision that presented two studies that they would like for us to consider. And, and these are the, the, Siva, 2022, and the Uhlig, 2023 studies, these were actually included in the original evidence report. Here's the tables and how they were, how they were discussed as part of the report. And these, neither one of these were randomized trials. These were most of retrospective observational studies. The Siva had a prospective analysis as well. And it just, to remind people of the, of the 2 studies, the Uhlig study was a very large study and then had a, a propensity matching, that, compared SBRT to partial nephrectomy and thermal ablation and found that there was inferior overall survival in the SBRT group compared to the partial nephrectomy and thermal ablation. The other study, the Siva study, was another observational study, but did follow people for 2 or more years and found that in in patients with stage one renal cell carcinoma the majority of which 75% were deemed inoperable, that they, that they had improved outcomes with SBRT. So, this, this was a study, this study in particular we discussed at the last meeting and Dr. Sham provided some contacts that felt that we should think about this study despite the fact that it didn't meet our necessarily our criteria, but it was a, as we discussed last time, a very challenging, condition to study, and that you need a long period of time in order to, to see, outcomes and so this is a high, considered to be a high quality observational study and we were asked to review this. We did not have time at our last meeting to really discuss this at length to, see if we wanted to Change our coverage decision for renal cell carcinoma. So that's where we're at. And if maybe Dr. Sham or anyone else want to add any comments or, or clarifications to what I presented.

Jonathan Sham Yeah, I don't have much more to add based on or above what I said at the last meeting, essentially just highlighting the difficulty of studying, relatively benign cancers, as it were, not aggressive cancers given how long it takes for your primary outcome to develop. And also just, again, remarking on the, the point of, limited options for those who are deemed to be quote unquote inoperable understanding that's a flawed term in many regards. But, but essentially, giving people an option who otherwise wouldn't have one for treatment of another wise I guess less aggressive cancer, but again, nothing else to add beyond that.

Janna Friedly Okay, is there any other discussion? Or questions from the committee? So, and Josh, so you can help me reframe this, in terms of voting. So we currently have a no coverage decision vote.

Josh Morse Actually, if I could. So we do not have a decision on renal at this point. Where you had left off was a draft. I'm sorry and I may have spoken too quickly. I'm sorry, Janna.

Janna Friedly Yeah. No, no, that's okay. Go ahead. Yeah, we, we have a draft. We had a draft as, as a not covered benefit. So I think the question is, do, do we want to finalize that, or, revise, revise that? So I think the vote is, is to finalize this no coverage decision. Is that correct?

Josh Morse That is correct. Sorry.

Janna Friedly Just wanna make sure we're voting on it exactly. Okay. So we'll need, we will need a, a motion to approve, this, this no coverage decision.

John Bramhall As so moved, this is Bramhall.

Janna Friedly Do we have a second?

Tony Yen This Tony and I second.

Jonathan Sham And can I just get a clarification as we vote. So. Because it's obviously been some time that's passed since we looked at this last. So the renal is under the batched pathologies at the end, is that correct? So.

Josh Morse Okay. If you look at this screen here, so, what we did in July is we approved this draft as final, but we removed the renal from the draft pending this discussion. You had some discussion there you asked for some follow up on the studies which Dr. Friedly just reviewed to make sure that that evidence was in the reports and had been considered in the evidence base in June when the meeting occurred. The draft you see here is the draft that we talked about in late July with the renal added in here because we have actually finalized the rest, everything around that renal is, is currently completed. The only thing that's left is to consider, do you wish to leave this here is not covered with these other conditions or are you, 1 as a group, do you wish to go in a different direction?

Jonathan Sham I see. And so if we agree with everything but the renal, we would vote to not.

Josh Morse	You have already finalized. I apologize. You have already finalized everything but the renal. So really what's, the final would look like this if you choose to leave renal in the not covered benefit. If you choose to go somewhere in a different direction, you know, with renal that may Change how this final looks. Does that make sense?
Sheila Rege	So as we vote. So, so it's a process as somebody I'm not voting or anything, but as a process thing, just to clarify, the only request was reconsideration of renal.
Josh Morse	Correct.
Sheila Rege	And so. Josh is trying to help us by reminding us of everything else, but you are not voting on the other topics, you are just voting on renal cell, cover or not cover based on the discussion. Does that help you? Johnathan?
Janna Friedly	So if as we vote, if you approve, if you approve the vote, that means that it is approving a no coverage decision.
Sheila Rege	Josh, it may be helpful if you just highlight renal. So you were just doing SBRT all we voting on is SBRT is not a covered benefit for treatment of renal. That is the words. If Josh could just highlight that, SBRT is not a covered benefit for treatment of renal. So you're gonna vote just on the highlighted section. Josh, can you also highlight SBRT is not a common benefit for treatment of?
Josh Morse	We'll see if I have the skills for that.
Sheila Rege	Sorry, I just wanna clarify.
Josh Morse	No, it's a good idea. Thank you.
Sheila Rege	Okay, so this is the sentence you are voting on. I'm sorry, Madam Chair. I just wanted to clarify.
Janna Friedly	That's quite all right. I appreciate that. Thank you. Okay, should we move to a vote?
Josh Morse	You had a motion in a second to vote on non-covered, I believe.
Janna Friedly	So Val, do you wanna start up?
Val Hamann	Dr. Kleweno.
Conor Kleweno	I was not there for the original meeting, so I'll abstain.
Val Hamann	Hearne.
Chris Hearne	I think I may not have been present for the original meeting as well.
Val Hamann	Okay. Friedly.

Janna Friedly	Uh, I disapprove.
Val Hamann	Daniels.
Clint Daniels	I approve.
Val Hamann	Bramhall.
John Bramhall	I think I have to abstain. I missed this meeting. I'm sorry, I apologize.
Val Hamann	Lee.
Christoph Lee	I disapprove as well.
Val Hamann	Mischley.
Laurie Mischley	I disapprove.
Val Hamann	Sham.
Johnathan Sham	Disapprove.
Val Hamann	And Dr. Yen.
Tony Yen	Approve.
Val Hamann	Okay, so I believe we are, we have 4 votes to disapprove and 2 to approve. And the rest are abstained.
Janna Friedly	Okay. So that suggests that we need to now come up with a an alternative coverage decision based on that. So, do, do we need to go back then to the original voting of cover, cover with conditions. Josh?
Josh Morse	It's your choice whether you want to discuss potential conditional coverage and I've put a draft up here from July. This is the direction that, just based on the conversations you were having in developing. These were, I just copied and pasted for example from from this one as a start point and put in a renal here thinking you if you were to go this direction.
Janna Friedly	I'm not seeing the draft. I'm seeing the.
Josh Morse	Oh, apologies. Let me switch. So you, you can vote, you can either vote in advance do a straw poll on whether you want to go in the direction of conditional coverage or you can work on the conditional coverage right now and then do the vote after. Do a formal vote after.

Janna Friedly Yeah, I think we should just we should look at the cover. I think, and if there's anyone who believes that we should cover with no conditions, let, let me know, but otherwise I think it was clear from the discussion that there would be conditions. So we should, we should discuss with these, these conditions makes sense. I think, and Josh, would it be possible to simultaneously view the coverage with conditions for the other, for the other cancers so that we can see, I think we would like to be as consistent as possible in terms of the wording.

Josh Morse Yes, let me, let me figure out how to best switch between screens here.

Janna Friedly And I.

Josh Morse Are you, did that switch screens? Are you seeing the?

Janna Friedly Yeah, yeah, we're seeing those. So in these, I just wanted to highlight that in, in each of these, we except for pancreatic, I think we had included stage one or stage 2 or, you know, sort of what the risk is. So, Jonathan, maybe you can provide some context, at least from the study that I, that I saw was it was stage one and 2, were, was what was covered.

Jonathan Sham Yes, I completely agree. And that's what I was going to point out as. I think it makes the most sense for local therapy given an early stage cancer and that's what we have data for. So that's what I would, propose is covered stage one and 2.

Janna Friedly And so with the language, if you go up to the non-small cell lung cancer, I think that's the one that had, would, would it be the exact same stage one and stage 2 node negative. And these other criteria. Would that be the same?

Jonathan Sham Correct. And I would need to just double check that study. That it was one and 2. Again, that's what my recollections. I don't have in front of me though. I don't know if you have that Josh on what you just showed.

Janna Friedly I can pull that up as well. It was stage, it was stage one. So it was, in the methods. 2014 to 2015 national cancer database was. Oh, no, that's. That's the other one.

Jonathan Sham Yeah, I talking about the 2022 study.

Janna Friedly Sorry. Yeah, I apologize.

Jonathan Sham I just don't recall the inclusion material up top of my head and I'm happy to look that up, but I would just favor using their inclusion criteria and, given again, that's where the data we're basing our decision is from.

Josh Morse Those are from the Siva study. Is that?

Jonathan Sham Correct.

Josh Morse There not on this. Are you accessing that or would you like me to navigate to that?

Jonathan Sham I'm happy to take a look. Perhaps, maybe for efficiency sake, Janna, I'm happy to perhaps, drop something like we did before and then we can bring it back to a vote later or would you like to get that done now?

Josh Morse We actually have, we may have our vendor from this report from the Center for Evidence based Policy available to provide that. I don't know if Beth.

Beth Shaw Yes, yes, I'm here. So the first thing I'd just like to clarify is on the slide information that you've presented. So I don't know if we can just see that. That this is my error, I've just spotted it, that second bullet actually relates to pancreatic cancer. So the one that says it's more effective than chemotherapy that does not relate to renal cancer. So it's only that that's my area that I've just spotted from the presentation. In the report, what we say is based on the studies in this review we conclude that SBRT may be less effective than ablation so that it's that first bullet only that relates to renal cancer. So looking at the actual study details, that one comparative non-randomized study that, underpins that first bullet that's related to renal cancer was in stage one renal cancer only. The Siva study is the non-comparative study that looks at adverse events only. So that just talks about the toxicity and that's not reported in the GRADE table. But in terms of effectiveness, SBRT may be less effective for stage one renal cell cancer only.

Josh Morse Thank you, Beth.

Beth Shaw Thank you.

Jonathan Sham So I'm, I pulled up the paper here, Janna. So Lancet Oncology, 190 patients. 12 institutions, international study. And essentially the, the inclusion was that they were unfit or unwilling to undergo surgery. So it was actually not stage-based in their inclusion criteria looks like. Medium tumor size is 4 cm, but there's no specific stage that’s listed here in inclusion.

Janna Friedly Yeah. I'm looking at that as well. I think that it was just non-metastatic.

Jonathan Sham Yeah, they, they yield less local failure than multi-fraction. And it's not, it's not comparing it to, to ablation because these patients are unwilling or unfit undergo surgery.

Janna Friedly So then that's suggest if you could go back, Josh to your draft language, that sounds like that might be sufficient then is that. If you go to the renal cell one that you'd drop in. So that looks like that is consistent with the study. Okay. Should we, should we, is there any other discussion about these coverage conditions? Or should we move to a vote?

Jonathan Sham Motion to approve.

Clint Daniels Clint Daniels, second.

Janna Friedly	Okay. And then Val, can we start a vote?
Val Hamann	Daniels.
Clint Daniels	Approve.
Val Hamann	Friedly.
Janna Friedly	Approved.
Val Hamann	Lee.
Christoph Lee	Approve.
Val Hamann	Mischley.
Laurie Mischley	Approve.
Val Hamann	Sham.
Jonathan Sham	Approve.
Val Hamann	Yen.
Tony Yen	Approve.
Val Hamann	That's 6 to approve.
Josh Morse	Excellent. Thank you for the discussion. So this is a draft I would be most comfortable if the committee requests us to put this out again for a comment and then for a final approval at the next meeting. Janna, do you think that's the best course?
Janna Friedly	Yeah, that sounds great.
Josh Morse	Excellent. Thank you.
Sheila Rege	Thank you, Dr Friedly. Maybe, Josh, because we always like that 5 min, sometime. during this meeting. I don't know if you can incorporate this highlighted so the committee is happy with the wordsmithing room we kind of take a 5 min break and come back to it as protocol does committee wish to do that or are you Dr. Friedly are you comfortable with this?
Janna Friedly	I'm comfortable with this.
Sheila Rege	Okay, then we don't have to do that. Just wanted to give you the option. Okay.
Josh Morse	Thanks for that check. Okay, thank you. So back to.

Sheila Rege So now we go into the spinal cord stimulation. And, we are actually just on time before we start the, state agency utilization and outcomes, I would like to give our clinical expert an opportunity to just, I know he introduced himself with all the other committee members, but if you want to you can tell us a little bit about your practice and not anything on your thoughts on this procedure, but just in general, what you do so we get to know you because we know each other, but don't know you, Dr. Strunk.

Joseph Strunk Absolutely. Thanks, Dr. Rege. So I did my training at Virginia Mason and my both my anesthesiology training and my residency or and my fellowship training there in pain medicine. I've subsequently stayed on as faculty and now serve as the associate program director for our pain fellowship. So as part of that role and as part of my practice I work in our pain clinic where we see patients and perform assessments, evaluations, various procedures, which do include spinal cord stimulation. It would that is done through a multidisciplinary process that involves both those of us that work in the interventional side of things, but also some of our physiatry colleagues and even our neurosurgeons so it's a multi-disciplinary practice when it comes to spinal cord stimulation and it's, something that we do, for, for patients who meet the, meet those criteria as laid forth by their insurers and by the evaluation of our team and exhausting other, other pain modalities. So, that's kind of what I do and happy to be here and be part of this conversation. Thanks.

Sheila Rege Thank you. Now we'll move on to state agency utilization and outcomes. Thank you.

Christopher Chen Hey, good morning, everyone. Everyone hearing me okay?

Josh Morse Yes

Christopher Chen Great. And, Josh and Val, I'll be sharing my screen this morning. So, hi everyone. The, my name is Christopher Chen and I work as a medical director for Medicaid at the Health Care Authority. I'm an internist. And I'm here today to present to the committee agency medical director of comments for our rereview of the spinal cord stimulator topic.

So starting with some background, spinal cord stimulators have been around for a while. The first commercial implantable stimulator was developed by Medtronic in 1968. And the device consists of electrodes that are connected to a generator, and the electrodes are placed within the epidural space. Electrical impulses are sent to the electrodes with a remote control when patients feel pain. The older traditional spinal cord stimulator systems are low frequency with frequencies of 30 hertz to 200 hertz and newer technology involves high frequency. Otherwise, known as paresthesia free spinal cord stimulator systems with frequencies greater than 200 hertz up to 10,000 hertz. These impulses are transmitted as constant stimulation, tonic stimulation or inverse, also known as burst stimulation. The exact mechanism of action is unknown. There are a number of proposed hypotheses that involved pain basking or

neuromodulation. And spinal cord stimulators are generally performed in 2 procedures to test and implant the device. A trial with a temporary generator that lasts anywhere between 3 to 7 days, followed by an implantation of a more permanent generator. Although subsequent procedures to replace batteries may also be necessary. Common complications associated with spinal cord stimulators may include lead migration, lead fracture, implant related pain, infection, hematomas, seromas, and CSF leakage.

There are a number of conditions that are treated with spinal cord stimulators and before that will be discussing today as part of evidence report include chronic back pain with the subcategory of failed back surgery syndrome as well as complex regional pain syndrome and painful diabetic neuropathy. Chronic back pain, as you all know, is quite prevalent and affects about 8% of the United States adults with severe chronic back pain. Failed back surgery syndrome is defined as lumber spinal pane of unknown origin, either persisting despite surgical intervention or appearing after surgical intervention for spinal pain originally in the same topographical location and this affects about 10 to 40% of patients following back surgery. Complex regional pain syndrome is an array of painful conditions that are characterized by continuing regional pain that is disproportionate in time or degree to the usual course of any known trauma or lesion and painful diabetic neuropathy is a result of long-term uncontrolled diabetes leading to peripheral nerve damage and it's estimated that about 50% of diabetic patients will ultimately develop diabetic neuropathy.

A little bit on the background. FDA approval and oversight of spinal cord stimulators. There are currently about 12 devices that are approved on the market and about 30 to 50,000 implanted annually across the United States. Implanted spinal cord stimulators are considered class 3 devices. I did insert the product code here, LGW, because, much of this information is publicly available through the FDA, their MAUDE database and total product life cycles. So they're considered class 3 devices. Class 3 device approvals are granted on the basis of supplements to original pre-market approvals. So initially a pre-market approval is filed and modifications the device are approved on the basis of supplements that follow that initial pre-market approval. It's been documented that modified devices under this approval pathway may deviate significantly from the pre-market approval, which is a dynamic to keep in mind for spinal cord stimulators as I mentioned, they've been around for quite a while. So post, regarding post market surveillance, notably the FDA issued a Dear Health Care providers lender in 2021. And at that time, there was a rereview of medical device reports that were submitted between 2016 and 2020 for events from 2005 to 2020. That showed there were over a 100,000 medical device reports for spinal cord stimulator related to paying for the FDA including 77,000 patient injuries, 30,000 instances of inadequate pain relief, 29,000 device malfunctions, 8,000 infections ,and 428 deaths, about 30% of which occurred within 30 days of the device implantation. This represents a high number of events relative to the implantation date and we were unable to find exact incidences compared to implantation rate as that, that is not currently published or available. But the two categories of devices that have higher numbers events are hip prosthetics and insulin pumps and the implantation rate for those is estimated to be higher with approximately 450,000 hip prosthetics and about 400,000 insulin pumps for what we were able to identify. So relative to this, the implantation rate about 30 to 50,000 a year. This is, to be a relatively high disproportionately high number of events. There

have been 42 recalls since 2008 identified in the MAUDE database reflecting somebody's concerns.

So, spinal cord simulation was first reviewed by the health technology assessment program in 2010. At that time the decision was made that spinal cord stimulation for chronic neuropathic pain is not a covered benefit. Searches of spinal cord stimulators for medical literature were conducted again in 2014, 2016 and 2018 to determine if newly available published advice would change the original coverage determination. The technology was not selected for rereview at that time, but in 2022, HCA director selected spinal cord simulator for rereview based on published evidence that could change the original.

The scope of our discussion today, as I mentioned, it's these 4 conditions, chronic back pain, failed back surgery syndrome, complex regional pain syndrome, and painful diabetic neuropathy. Out of scope and not reviewed our dorsal root gangland stimulators, devices that are not approved by the FDA, patients who are younger than 18 years old, patients with prior use of spinal cord stimulator, pregnant individuals or other all other pain conditions. So, overall, the agency medical directors had high concerns for efficacy, safety, and cost of which I'll go into a little bit more. And in reviewing the evidence report, just want to share some additional considerations. The last review was in 2010. At that time included were 3 randomized control trials, one cohorts within 11 observational studies. The 3 review in 2023 has 13 randomized control trials. So there are more studies but we noted that there we're still lacking higher quality studies, well-powered studies or longer-term outcomes. Regarding quality, most studies are industry funded with a high risk of bias, including either significant industry involvement or other conflicts of interest. The studies are mostly relatively small, especially compared to the degree of implantation currently seen across the country and longer-term outcomes are insufficiently studied for the most part beyond 6 months, especially with high quality studies.

We're getting into the evidence report a little bit more today. You'll be hearing from the vendor regarding about 4 key questions that were asked. First is what is the evidence of short and long term effectiveness as spinal cord stimulator compared with medical and/or surgical treatment that does not include neuromodulation devices. What is the evidence of the safety of spinal cord stimulator compared with medical or surgical treatment that does not include neuromodulation devices? What is the evidence that SCS has differential efficacy or safety issues and some populations of interest? And what is the evidence of cost effectiveness compared with other options? So, regarding the, the first indication chronic back pain. And I guess maybe I'll just note that generally for the next 4 slides, you'll see, the forest plots that it pulled out from the evidence report. These were helpful for the agency medical directors to understand which studies in particular were driving the results and conclusions and helped home in on highlighting some key studies. And so for chronic back pain there are 3 parallel randomized control trials identified. The sample size for this was 477.

And the significant driver of the order of magnitude of effects for, for this indication, was one study by Kapural in 2022. And so on the forest plot on the right hand, side you'll see that this measures back pain scores on the scale for spinal cord stimulator versus conservative medical management for chronic back pain. And there was and diving into the Kapural 2022 study a little bit more. I'm highlighting some comments from a Cochrane review that was done by Traeger just recently in 2023. And notably for this study, there's a substantially different loss to follow up in the spinal cord stimulator versus the conservative medical management groups. And you'll see if there's loss in 76 randomized to the CMM group was 1 in that 3 months and 6 months and lost an 83 randomized to spinal cord stimulator was 15 at 3 months and 18 at 6 months. Also there was an enrichment type design for this trial, which was of concern, especially to the systematic reviewers. The sample selected initially for the study was selected on the basis of failing conservative medical management. The control group subsequently received treatment that they were doing poorly with and the quote. The intervention arm was given spinal cord stimulator and was followed up only if they were if they responded. That means that they were only included in the analysis of results if they responded positively to spinal cord stimulator. And so those that are in that sample size of 65 are only those who responded and there wasn't a subsequent treatment. There wasn't concomitant treatment to that given to the control arm, i.e. deleting those from the results who did not respond to conservative medical management and keeping those who did. It was kind of an atypical form of enrichment design and was felt to really disrupt the idea behind randomization. I'll also note that available in the CMS Open Payments database Kapural, for all received over $550,000 and payments from Nevro, which is the manufacturer of the device that was studied since 2016 and over 1.7 million dollars in research funding.

Regarding failed back surgery syndrome, there were 3 cross over randomized control trials with a sample size of 98. And we're highlighting here for you a study that was published in JAMA in 2022 by Hara and this was the only good quality study that was identified in our evidence review of the 13 randomized control trials. This was government funded by Norway. There were no conflicts of interest disclosures. There were independent and blinded outcome assessors. And the providers and patients were also blinded. This study did not demonstrate any significant difference in the disability index, pain, quality of life or physical activity level for participants that received placebo stimulation versus burst stimulation. And on the right hand side here is a graph of the Oswa tree disability index pain scores. These bars represent pain scores at the beginning at the end of the trial and you notice the distribution between placebo and burst is similar and does not demonstrate statistical significance in those outcomes.

For the indication of painful diabetic neuropathy, there were 3 randomized control trials with a total sample size of 312. There are no long term outcome studied here, only 3 to 6 months of follow-up. There were no functional outcomes reported and no blinding providers and patients as opposed to that study that I just mentioned. And the one study that we honed in on was Peterson, 2021and there was a high risk of bias

here. And I have a quote from the evidence report, that I'm sure the sponsor participated in the design of the study in collaboration with an outside expert advisory committee as well as the conduct of the study by supporting patient optimization in collaboration with the investigators and monitoring data at the sites. The sponsor participated in the analysis and interpretation of the data along with the authors and an independent biostatistician and the sponsor also participated in that preparation review and approval of the manuscript and the decision to submit the manuscript for publication in collaboration with authors. So significant involvement from the study sponsors.

For the next indication, complex regional pain syndrome, there was one crossover trial, of 33 and 2 parallel trials with a sample size to 104 and none of which had long-term outcomes. The Kemler study here, for conventional spinal cord stimulator, and physical therapy, this study was done in 2000 that this was small, it was unblinded and the only significant difference was on a visual analog pain scale, there were no functional changes, no changes in quality of life. Hmm. So, regarding the next key question safety. The strength of evidence across most outcomes was considered low. There was potential of risk of bias across the now non-randomized studies. And there really was a lack of consistency across studies on how the events were reported and how frequently they were reported. General concerns around spinal cord stimulator are that and I allude to this a little bit before that it's an implanted device with a risk of infection, morbidity, death, and a high risk for further inventions, including revision, removal with every implantation. A Kemler study in 2008 had a 5 year final follow up of patients in a randomized control trial. The complication rate at 2 years of follow-up was 38%. 9 of 24 patients with spinal cord stimulator implants underwent re-operation for 21 complications and at 5 years the complication rate persisted at around 40% with the 10 of the 24 patients undergoing re-operation as a result of 29 complications. This is not from the evidence report, but AMDG concerns are reflected in some other channels as well. So this is, I have a statement here just on the, from the professional society ASRA of pain medicine just showing us saying that complications are estimated to range from 30 to 40% for spinal cord stimulators. These are categorized as either biological complications such as infection, epidural hemorrhage, seroma, paralysis, CSF leakage pain, allergic reaction, skin breakdown, or device failures including lead migration, lead breakage, over/under stimulation, intermittent stimulation, hardware malfunction, and battery failure.

On the right hand side is a study that was from Australia and reported August 2022. And this, this is a comprehensive report that looked at the implementation removal rate and adverse events of spinal cord stimulators that reported to their therapeutic goods administration, their equivalent of the FDA, often known as the TGA. And they showed that almost 4 in 10 spinal cord stimulators that were implanted were ultimately removed. So a high degree of reoperation removal. And a number of

significant safety events, adverse events were also reported. These and these numbers the authors qualified in the report about 90 to 95%, 90 to 95% of events in Australia are estimated to not be reported to the TGA. So this, kind of just represents a sample of those better felt to actually be occurring.

Regarding the last few questions on cost, there were 8 studies in the evidence report that review that were reviewed and suggested that spinal cord stimulator may be cost-effective versus conventional medical management. However, the AMDG is noted that only 2 of these studies were based in the United States and 5 for industry sponsored. And of course, when it comes to cost, the United States stands out among other countries. But one particular study by Dhruva in 2022 was a propensity match population of 7,560 patients and cost were analyzed using administrative claims data. The total cost of care in the first year were identified to be $39,000 higher for patients who received spinal cord stimulator than conventional medical management and similar between SCS and CMM in the second year. Regarding cost, agency experience and Medicare reimbursement, so far as agency experience goes, there is no utilization for LNI or ERB because the HTCC decision that currently stands, we were unable to accurately estimate costs for Apple Health Medicaid because of complications related to estimating costs across inpatient, outpatient professional, data, and the ability to accurately identify those points that were specifically related to spinal cord stimulator. But, I do have some information here for you, related to Medicare reimbursement. And so on the top, are the professional fees and outpatient hospital reimbursement levels on the bottom table are the inpatient reimbursement levels for the procedure and I'll just highlight for CPT code 63650, which is a more commonly used method of percutaneous implementation of their stimulator electrode array. The total RVU for the procedure are 69. So it is a relatively highly reimbursed procedure and the procedure takes generally one to 2 hours. Current coverage of spinal cord stimulator across other payers. So Medicare does cover spinal cord stimulators. There's a national coverage determination made in 1995 that covers the service for late resort if not last resort for patients in whom other treatment modalities are tried and there's screening done before the operation, including a psychosocial evaluation and that they've done in sure you're the successful trial. So remember that spinal cord stimulators are generally implanted first of the trial and subsequently the permanent device. Aetna covers spinal cord stimulators for chronic back pain, complex regional pain syndrome, and painful diabetic neuropathy. They also require screening, including a psychosocial about evaluation, also require no untreated substance use disorder diagnosis, required that other modalities have tried it failed for 6 months, and that there is documented pathology and basis for the pain as well as the demonstrated Oswestry disability index of greater than 21%. And implantation is approved if that 3 to 7 day trial is successful with a pain reduction is of greater than 50%. As mentioned before Washington Medicaid, LNI, and ERB programs are currently consistent with the current HTCC for non-coverage.

Clinical practice guidelines. NICE had a decision in 2008 that spinal cord stimulation is recommended as a treatment option for adults with chronic pain of neuropathic origin who continued to experience pain for at least 6 months despite appropriate conventional medical management and who has had a successful trial stimulation as part of the assessment, as specified in one of their other recommendations.

The American Society of Regional Anesthesia and Pain Medicine issued a statement in 2023. This was less about recommendations of spinal cord stimulate implementation, but it was really focused on the trial because there was some debate going on about whether a trial was even necessary. But ASRA did issue this statement in 2023 that in patients with chronic lower back pain and/or leg pain, limb ischemia due to peripheral vascular disease, painful diabetic neuropathy, and/or common complex regional pain syndrome, a trial of spinal cord simulator should be performed prior to a definitive SCS implant.

So in summation, given our high concerns for effectiveness, cost, and safety, the, the recommendation of the agency medical director group is for non-coverage of spinal cord stimulator for chronic back pain including failed back surgery syndrome, painful diabetic neuropathy, and complex regional pain syndrome. Thank you and that's the end of my presentation. Happy to take any question.

Sheila Rege Thank you, Dr. Chen. That was very informative and comprehensive. Any questions?

Jonathan Sham Yeah, maybe I could start. Thanks for the great presentation, Dr. Chen. The data you in the trials you presented, you know, the data not only quality, but results seem to be pretty for, poor, but yet, you know, Medicare and these other guidelines include coverage. Could you like comment on that discordance and kind of why you think Medicare opted for coverage and why you think it's part of these other practice guidelines, given the status of the data?

Chrisopher Chen Thank you. You know, I think I'm obviously not being able to speak on behalf of Medicare, but I will just say that it's relatively frequently that people interpret the evidence, the same evidence in different ways, different parts of the evidence stand out to different stakeholders. And yeah, I think there's a number of reason that influence payers and purchase service to cover the technology, whether it be stakeholder interests or advocates, so yeah, I think, this is my general comments there. Sorry, I can't more helpful.

John Bramhall Chris, thanks. Yeah, again. Thanks so much for a really good presentation. I enjoyed that. Could you, do you mind just going back to, there's a fairly damning study that you quoted, the Norwegian study from what 2008, is that when it's from, sorry 2022.

Christopher Chen Uh-huh.

John Bramhall There you go. And there's a little graph there that seems to indicate, you know, no difference between sham and, and intervention. Could you, do you mind just stepping through that little graph? Do, did you recall the one that I mean?

Christopher Chen Yeah.

John Bramhall Okay. It looked like a little mountain. And I just, I wasn't quite sure of quite.

Laurie Mischley On page 12.

John Bramhall Yes, sorry to be indistinct.

Christopher Chen Yeah, it was kind of a novel. That was a novel way of just playing the data I thought too and

John Bramhall Yeah, there it is. That's it. So what's your, what's your take on the way that that's presented, what are they showing?

Christopher Chen Great, so. There were I think I total of around 90 patients in this study. And on the left hand side, are individuals who received the burst stimulation, or the trial intervention and then the test intervention is on right hand side were those who had placebo stimulation. This was one of the few studies that actually had pit providers and patients blinded and so they did receive placebo stimulation. And so on the on the vertical axis the Oswestry disability index which for those who are not familiar with a questionnaire reading a level of function across a number of different domains in 10 different categories and the bars here, so each bar extends from the patient's baseline score to their mean score that at the end of the treatment allocation period. So, they just kind of generally portray the distribution of those who see the burst stimulation versus placebo stimulation.

John Bramhall And so the key there is that the symmetry between the, let's say the orange or the yellow black does that symmetry a lack of efficacy of the intervention.

Christopher Chen Yeah.

John Bramhall Okay, all right. Thank you so much. Thank you.

Laurie Mischley I also have a question about this study. And do you know, are all of the people who were included in this study had already passed that 3 to 7 day trial period and we're deemed successful or was this all newcomers? Do you know who is included in that?

Christopher Chen I don't know. I think we could probably ask our evidence center that question, but I'm sorry I don't know that off the top of my head, Laurie.

Joe Strunk If you care, I could comment.

Laurie Mischley Please.

Sheila Rege Yeah, go ahead. And I think people are using the raise hand. So if we want to do that, I'll try and look for that.

Joe Strunk So in this study, what's actually interesting about the inclusion of these patients is that they didn't, they actually were included if they did complete a trial that showed greater than 2 points reduction in pain or 30%, which is not consistent with current clinical practice. So these were patients that most folks here, any, anyone here in the United States would not be implanting. And they also were randomized to a Sham versus a therapy that is known to be consistent with sham, so. Those are some of the,

	the biggest things that we look at in terms of clinical applicability of this study. In the current practice.
Janna Friedly	Could you clarify that, about the, that it's equivalent to sham, what specifically about the protocol makes it equivalent to sham?
Joe Strunk	So the actual burst stimulation pattern, which is the intervention arm that is used, has been studied in a, other, is it in a prior trial and should has been shown to be equivalent. It was a triple arm study that looked at a higher frequency stimulation pattern versus this burst pattern that was used versus sham and the sham and this current. The intervention arm in this study were actually shown to be that it is used in this study were shown to be equivalent.
Janna Friedly	It's not the frequency, it's the burst pattern.
Joe Strunk	It is the, the frequency of that burst pattern.
Janna Friedly	Okay, and what was the trial that you're referencing? The 3 arm trial?
Joe Strunk	Give me 1 second and I can give you the name.
Sheila Rege	While it's looking it up, anything from anybody else? The evidence? Alright, experts.
Josh Morse	Dr. Kleweno has his hand up.
Sheila Rege	Oh yeah, Conor, go ahead, sorry. You've been waiting patiently.
Conor Kleweno	No, no problem. Great, great presentation. Thank you. I had a question on the study. I believe it was from Australia where you had, I believe it was nearly one third or more, removal rate. And then there was on the third column was the complication rate, but I didn't know if you had any more additional granular information. I wasn't a reason for removal, was it? Because of a lack of efficacy or what?
Christopher Chen	Yeah, unfortunately I didn't have that available in the report.
Conor Kleweno	Okay, and then I would also just put a, I know you put some numbers there for RVUs and provide a reimbursement. I don't know if that's really in the purview of this committee to critique the ruck or and I know that reimbursements are sort of variable across providers and contracts, so just to comment on the numbers and RVUs put there, I would say.
Christopher Chen	The RVU values do hold across. As you know, they're associated with the code, until the level of reimbursement rates are kind of adjusted accordingly by payer.
Conor Kleweno	No, but what I'm saying is the number of RVUs is deemed by the ruck and you know without the context of what, how many our views and neurosurgical procedure is versus a urology procedure or you know it just it needs to be put into context, I would say.

Christopher Chen I'm sorry. Oh, did you have your hand up?

Joe Strunk I just wanted to come back to Dr. Friedly. It's Eldabe in 2021 and it's in the Journal of Neuromodulation.

Janna Friedly And I'm sorry, what was the author? Sorry, I apologize. I just wanna make sure I have it right.

Joe Strunk Eldabe.

Janna Friedly Okay, thank you.

Josh Morse Dr. Rege.

Christopher Chen Sorry, I'm not sure if I'm moderating. Okay.

Josh Morse Dr. Bramhall has.

Sheila Rege Dr. Bramhall has his hand up.

John Bramhall Yeah, so, sorry, I, this may be too early to get into the weeds of this, but Chris, it looks like, so to perseverate about this Norwegian study, it looks like we need to pay attention not simply to spinal cord stimulation but the modality, right? As we go through this through, the through, the through the day because it sounds from the way that you describe the study that does the spinal cord stimulation modality which is demonstrated to be not effective it's the same as sham. But there's an alternate spinal cord stimulation that, that uses a different frequency and a different distribution of energy. The, the, you're sort of implying that if that had been used, this Norwegian study from pretty recently, 2022, would, would have demonstrated a different result. So I just, I just want to clarify that and again, it may be too early to get into this sort of depth of it, but it looks like we're not dealing with a generalized problem we're dealing with something that may be very specific in the way that it's applied to, to an appropriate patient set.

Christopher Chen Yeah. And I think, and of course, kind of, not being, in clinical practice and individuals that performs these procedures but providing the agency perspective, and, generally kind of looking at the body of evidence, as well as coverage decisions over time and, and practice that has evolved. I think there is a perspective out there regarding traditional versus more modern technologies as spinal cord stimulators of varying levels of the frequency of the stimulation that's provided, the modality in which it's used and kind of referencing the tonic versus the burst stimulation. I think kind of with that perspective taking a critical lens at really whether over time any of the evidence has demonstrated kind of those broad things that were highlighted before around longer term outcomes, improvements in disability, function, equality of life. And I think generally applied to all those categories, whether traditional or modern or, or the various modalities. I think taking that lens we would still arrive at a similar conclusion around concerns of safety, efficacy, and cost.

Sheila Rege I don't see any other hands up, but I only have a limited number at any one time, so to keep scrolling anybody else for questions for Dr. Chen? Or can he get off the hot stand? That's kinda nice, you're not there in front of us in the room. Alright.

Christopher Chen Yeah. Just means I don't get the coffee. Yeah. Alright, thank you.

Sheila Rege Now we are actually we're actually a little early, I believe.

Josh Morse I think we're at we're a little behind on our agenda. Yep, we're about.

Sheila Rege Oh, look behind, sorry. Yeah. We need to go to the open public comment. But we're in that time frame, right? We go to 10:40.

Josh Morse Correct.

Sheila Rege So we will not, Josh, we look for you to give us advice. I'd like to not, I'd like to give everybody their time, if possible.

Josh Morse We will be. Yeah. No, we're 20 min behind at this point. Couple of minutes actually over that. I think we have. We have the room today to make that time up in the afternoon per our plan, but I do think it's appropriate to move up a common period.

Sheila Rege Yeah, let's do that.

Josh Morse So, Val will provide instructions. And we'll be managing the slides. We have, I believe 4 or 6 groups or individuals signed up in advance and then. I think we may have one additional commenter who signed up today. So, I think we're ready to start that, Val whenever you're ready to call up the first.

Val Hamann Yep, and it looks like they are ready. So I will share my screen and then once that starts, I will be, I have a timer on my end, so I will give you a heads up at 1 min and then again at 30 seconds and then once that time is up I will be cutting each public commenter off so we can stick to our time limit so here we go. And everybody can see those slides?

Josh Morse I can see them. Thank you.

Julie Pilitsis Thank you very much. Can everybody hear me?

Val Hamann Yes

Julie Pilitsis My name is Julie Pilitsis. I'm a professor of neurosurgery. I've been a chair of a department, a dean, and I'm currently serving as VP of medical affairs. But here, I'm representing the North American Neuromodulation Society, the largest, the largest group interested in this field and I currently serve as president of that organization. Next slide. So, you know, I think when we talk about chronic pain, we have so many people that are affected by this and you know one of the questions that came up during Dr. Chen's presentation was cost. And, you know, if we thought about all chronic pain patients and treating them the cost is astronomical as we all know.
I wanted to draw your attention to this right side of this screen where we're talking about looking at a market study of how many people actually would meet inclusion criteria if we just considered spinal cord stimulation for failed back surgery syndrome and that was only about a 123,000 people out of that huge 40 to 50,000 number. And then if we actually work up those people try conservative care and other options, only about 5,000 patients or 4.3 of the total were recommended for therapy. Another issue came up about cost was the data that Dr. Chen showed about the implants and I just like to say that this study also shows that you know at year one this is a device so it's always going to be more expensive than conventional medical management but as you go out in time 3, 6, 9 years this study shows that indeed it's more cost effective. Next slide please. There are a number of societies. Dr. Chen pointed out a couple of them, but there's about 13 societies that advocate for spinal cord stimulation for their patients the right patient at the right time in the right device.

Val Hamann 1 min remaining.

Julie Pilitsis And we would advocate for people to listen to these 95,000 the, physicians that are involved in these. Next slide please. As we heard, this is an NCD. It's also recommended by the US Health Service. I'm gonna skip ahead to the next slide because I think that's the key point. This looks at numbers needed to treat. So when we want to talk about efficacy.

Val Hamann 30 seconds.

Julie Pilitsis Pain is very difficult to treat. These are the hardest patients and look at these numbers needed to treat for drugs that we may all use. We look at SCS, it's 3.0, which is much better. When you're talking about chronic pain patients, really, you know, you have to think about who makes the difference and this is really important to consider just one last comment about the, the burst study that was recommended. That's like, you know, what the, the burst that they tested is like testing a cars speed if you had it in first year.

Val Hamann And time is up. We appreciate you. Yeah.

Julie Pilitsis Thank you.

Josh Morse Thank you very much for your comments.

Val Hamann And we are transitioning to the next speaker. And I have those slides ready. Is the next speaker ready? Looks like you Christopher, you are promoted. Okay, perfect. I will share those now, and then we will start your presentation.

Christopher Gharibo Good morning. I am a Christopher Gharibo. I'm a professor of anesthesiology, perioperative care, and pain medicine and professor of orthopedics at the New York University, Grossman School of Medicine. I'm also the medical director of pain medicine for the NYU LANGO health system. We deal with acute to chronic pain syndromes, and the entire spectrum of pain. And I am asking for this technology to be approved for a very select subset of patients where our backs are against the wall in terms of their pain treatment. And if their pain is not adequately treated, if something is not tried, they take extreme measures to control their pain. Now, next slide please. Now, my section on this covers our spinal cord safety, as well as inequities and access to pain medicine. From a safety perspective, I think we gotta keep the context of efficacy, safety, tolerability, and patient convenience in mind and keep in mind that we are prescribing psychoactive medications that often interfere with proper function and somebody feeling truly themselves. The, the safety factors can be subdivided into a mechanical and biological and most of the safety and the side effects that are experienced with spinal cord stimulation are device related.

So significant incidence of lead migration, hardware malfunction, lead breakage ranging from anywhere from about 2.9% to about 13.2%. When it comes to medical complications, there is the surgical risk of an infection of approximately 3% or so, but the other medical complications that can occur such as hematoma and paralysis and other more serious complications are extremely rare as low as .03% to about .3%. The most serious of them being an infection of about 3.4 percentage points and that held in other studies whether it's through.

Val Hamann 1 min remaining.

Christopher Gharibo The international neuromodulation society or through other studies. Next slide please. Next slide, please. There's considerable evidence to suggest that there's significant racial and ethnic minority disparity and access to proper pain medicine. Next slide, please. And we do know, that there's data to support that in a variety of different papers.

Val Hamann 30 seconds.

Christopher Gharibo Next slide, please. Where there is racial and socioeconomic disparity in spinal cord stimulator access in the most difficult subset of patients. Next slide, please. A good subset of this is for example complex regional pain syndrome patient where these patients resort to extreme measures to control their pain including amputation and some of the best studies in controlling pain in and that that we have achieved in achieving success with spinal cord stimulation is in the population.

Val Hamann And that concludes the time.

Christopher Gharibo Spinal question.

Sheila Rege	I would, like, and helping out staff, has everybody who speaking filled out a conflict form. If not, can you let us know in terms of conflicts if you, anybody who is speaking in the future and Dr. Gharibo, if you can, If you've had any reimbursement honorarium kinda like on the open public database which you would declare can, can with any of the companies that we may be kinda like would we do as committee members, would you like to mention that if you haven't I must have missed that?
Christopher Gharibo	I have any compensation as it pertains to spinal cord stimulation. So from spinal cord stimulator companies.
Sheila Rege	Thank you. And next speaker, we could also include that in your disclosure, please.
Val Hamann	And our next group is a group of manufacturers, did pool their time together. They also donated some of their time to, to the group after them. My computer is choosing to freeze. So I am and so sorry for that delay. I'm not sure why PowerPoint is not wanting to work with me in this instance. Josh, I don't know if you are able to pull up the manufacturer slides.
Josh Morse	Sure can can you just can you tell me which presentation that is? I'm happy to do it.
Val Hamann	It is labeled manufacturers in a public comment folder.
Josh Morse	Okay, I see. And it's the PowerPoint, is that right?
Val Hamann	Correct.
Josh Morse	Okay.
Val Hamann	And I will start the timer on my end. That's still working.
Nilesh Patel	Hello, on behalf of.
Josh Morse	That's coming up. We can hold for just a second and when I get your slides up Go from there.
Nilesh Patel	Okay.
Josh Morse	Apologize for the wait. I'm getting a message that. I cannot screen share, Val.
Val Hamann	Oh, I will. Yeah, sorry. I will allow that. Okay, go for it.
Nilesh Patel	Let me know when you want me to start.
Josh Morse	There's your slides there. So just let me know when you would like me to advance and we'll start. Thank you.

Nilesh Patel

Sure. Okay, on behalf of the SCS industry collaborators, my name is Nilesh Patel. I'm a board certified doctor in anesthesia and pain medicine with fellowship training from Cleveland Clinic where I also served on staff. A practice pain medicine for 25 years and I currently serve as a chief medical officer for Boston Scientific neuromodulation division and that is my conflict. If you go to the next slide, please, Josh. Just as we've seen rapid advancements in the treatment of chronic diseases such as hypertension, diabetes, rheumatoid arthritis, we've also seen meaningful innovation in this spinal cord simulation space, particularly in the last decade. Examples of meaningful and impactful innovation includes advancements in hardware software, firmware advancements in waveform, sensing, remote monitoring, programming, advancements in therapies addressing neuropathic as well as mixed and knows of your pain. Advancements in analytics allowing optimization of patient experience and patient outcomes. And this is important because advances have resulted in dramatic improvement in outcomes with responder rates going from below 50% in 2014 to about 80 to 90% today. And the level of evidence going from level 2 in 2009 peer reviewed published paper to level one in 2016 while earlier studies predating 2010. Reported superiority of SCS over conventional medical management contemporaries trials have shown superiority even over optimized medical management. Both our CTs and real world evidence from 2007 to 2022 that you see here basically has demonstrated improvements in pain, function, return to work, ambulation, mental health, and these studies have also shown cost effectiveness while avoiding and you know unnecessary hospitalizations, emergency room visits, and facility admissions.

Seminal trials, many of them are shown here, include the process, the problem is the proko, sunburst, whisper, evoke, Avalon, accurate, target, distinct, combo, and others have all shown favorable outcomes. Of course, in these trials, unlike the Hara paper, the devices were used by the physicians in the way in which SCS was intended to be used, including programming adjustments, including appropriate patient selection and these were personalized to meet the unique and changing needs of these patients. Remember there is complexity in pain requiring multiple different treatments. Remember there's also neuroplasticity requiring a dynamic approach to these patients. If you can go to the next slide. I'm glad the safety issues were brought up. Manufacturers remain committed to patient safety. FDA approval is based on proven effectiveness and safety. The MAUDE data being referenced by the, the HTA experts is problematic because the FDA itself cautions against the use of MAUDE when evaluating safety. We encourage the committee to review the FDA guidance in your deliberations. Coupled with well-designed RCTs, independent studies have also validated use.

Val Hamann

1 minute remaining.

Nilesh Patel

In failed back surgery, some complex regional brain syndrome, diabetic neuropathy, and in addressing these significant changes, the responder rates about 90% have been reported. So our recommendations for the state is to ensure that we provide access to these therapies. In today's day and age multi-discipline evaluation including psychological evaluation and trial with minimum 50% relief is generally a prerequisite to permanent implementation.

Val Hamann 30 seconds.

Nilesh Patel The coverage condition is recommended to the state of Washington. Manufacturers believe technologies must be used as intended and that SCS is recognized within the community including large payers such as Premera, Regents, Blue Cross pants, United Health Care in the state of Washington. And recognized by HHS best practices and CDC guidelines that came out in 2022. So doing so will align the policy objectives.

Val Hamann And that can include their time. We appreciate you.

Nilesh Patel Thank you.

Josh Morse Thank you for your comments.

Val Hamann And for the next group, we have, we received a number of individuals who are wishing to pool their time. So. I, my slides, I can work those again. We will have 3 individuals representing this group and all other requesters have pooled their time and they will have 24 min. Do we have Dr. Stanos, Stacey, and Xing I believe. Will be representing this group.

Josh Morse Yes, and I think they're listed. Do you have them? The Washington positions group elevated. Val, is that what you're seeking?

Val Hamann I believe Melanie is elevating individuals.

Val Hamann Okay, and they should be elevated now, so I will share your slides. Okay, I see you there. Perfect. And we're able to see those slides?

Steven Stanos Yes.

Josh Morse Slides on the screen.

Val Hamann Sounds good. Your time will start now.

Steven Stanos Yes, I'm Dr. Steven Stanos, executive medical director for rehabilitation and performance medicine. I'm also a past president, American Academy of Pain Medicine. I have no conflicts related to this technology. My colleagues and I represent the Washington State Physician Spinal Cord Stimulation Work Group who, they've all joined me here in this room today. We've also been joined by Pain Fellows and trainees from the University of Washington. We are a volunteer group of Washington main, pain medicine specialists advocating for spinal cord stimulation to be offered and being part of a treatment plan for our patients. Joining me is Dr. Brett Stacey, a professor of anesthesiology and pain medicine and division chief of pain medicine at University of Washington. Also, Fang Xing, a physician and pain management specialist at Swedish Pain Services here in Seattle. We as a group agree with a positive coverage decision for spinal cord stimulation for FDA approved conditions. Interestingly, we're very happy that we have Dr. Stacey and Dr. Xing with us today because they have

intimate spinal cord stim clinical experience and knowledge of not just old literature but recent literature and I think that was really highlighted earlier is a need for this discussion. Our simple goal is really to be an asset. To provide insight and knowledge, not highlighted by the vendors report, as well as what was mentioned with the Agency Medical Director's Report. We think it's important to first remember 3 things. First, there's an issue around this technology and I think we all can agree that technology has expanded significantly and evolved since 2010. Second, there's obviously it's been mentioned already, denying access to spinal cord stim really opens us up to significant questions around health equity. This, this decision impacts policemen, government employees, injured workers and people of sometimes lower socioeconomic stance that also would benefit from this treatment that no longer can, aren't allowed to receive it at this present time. The other area that I think is important, and I, again, this was brought up and we're excited to continue with this discussion, is just despite the best intentions, AAI the vendor, as well as the agency medical director Dr. Chen just agreed to, they don't really have within their scope of training and expertise the proper clinical perspective nor knowledge to judge these specific SCS technologies, it's mechanism action, nor the recognition of the current standard of care. So fundamentally, for example, AAI's methodologic search criteria of the literature failed to find the best of available clinical evidence. Instead, they included poor studies like Al-Kaisy and Sokal, that they themselves deemed insufficient to draw conclusions. One.

Josh Morse May I ask you, Dr. Stanos, I'm sorry to interrupt you, but are you wishing for us to be advancing your slides?

Steven Stanos No, we will in a second. Thank you.

Josh Morse Thank you. I'm sorry to interrupt. Thank you.

Steven Stanos Thank you. One positive study that they will highlight, which has already had a robust discussion is Hara, et al and that was really based on a bad clinical practice. It is not a good study. So I clearly disagree with Dr. Chen's assessment. That stimulation technology is not used today and was never used in the United States. Hence, all of these studies should be excluded from the analysis and not be used in any manner to form a basis for coverage decision. And we do want to caution as well as about bias being mentioned. These studies with spinal cord stimulation like any drug trial are done in close collaboration with the FDA during the developmental phase as well as the trial phase. Now to help better understand some key points, Dr. Stacey is going to review current technologies and highlight methodologic flaws in the vendor's report. Dr. Xing is gonna highlight the challenges around the use of placebo-controlled trials for spinal cord stim and the clinical rationale for using these well-designed comparative studies versus poorly designed sham studies. Importantly, he's also gonna review recent high impact efficacy studies, which we feel is very important. With the evidence and rationale we provide, we hope the HTCC is going to be able to make really better evidence-based and informed coverage decisions around spinal cord stimulation. With that, I turn this over to Dr. Brett Stacey. Thank you.

Brett Stacey

Thank you, Dr. Stanos. I am Brett Stacey. I do have no conflicts. Please, next slide. We've already heard how spinal cord simulation works. Electrodes are placed in epidural space, electrical energy is delivered to the spinal cord, that electrical energy changes pain transmission. In the evidence report there's a focus on pre 2015 technology which requires sensation to overlap the area of pain for pain relief. There are many parameters that can be adjusted during the course of stimulation. And this has changed dramatically in the last 8 years or so. Next slide. The new paradigms all have advantages over previous technology. The majority of them have no stimulation, no sensation whatsoever because they have new neuroanatomic targets with new mechanism's of action. One adjustment is the frequency. Now there are high frequency devices, typically above 1,000 kilohertz, most commonly at 1,000 hertz, most commonly 10,000 hertz. Next. There's also changing the pattern with bursts and that is the most steady burst pattern is 5 pulses and the rate of 500 hertz.
This results in no sensation and targets different substrates in the spinal cord. Next. There are other programming strategies including high dose and other sub-perception strategies that result in no sensation but deliver energy to the spinal cord that changes spinal cord physiology and pain processing resulting in better outcomes in traditional stimulation. Next. And we can also sense the response to the spinal cord 50 times a second and adjust the stimulation based upon how much the spinal cord is responding. All of these technologies next. All these have different mechanism's of action then previous traditional stimulation. They are not tied to a distracting sensation. The largest studies ever published in SCS focus on these new technologies. The implanted systems being used in the United States now, focus on these new technologies and newer data and technology should be the focus for this committee's review and decision making. Next.

The evidence report mentions the importance of clinical judgment and it also talks about using best evidence. And the best evidence seems to focus a lot on the study design rather than what is actually being studied in the granular details, which matter when we interpret the data. Next. So the placebo-controlled randomized trials for failed back surgery syndrome patients, there are 3 of them, are inadequately, clinically designed to give us any meaningful information. The fourth place simple controlled randomized trial 4, complex regional pain syndrome has shortcomings but still is a positive study. Let's review these next. Next.

We've heard quite a bit about the Hara study. It is the only paper in the evidence report rated as good with moderate strength of evidence as you can see from this table. It is a sham versus quote burst pattern crossover design conducted in Norway. Next. Study does not meet the standards of CMS or any insurer in the state of Washington. The trial period was not with what the patients were then later subsequently implanted. It was with traditional stimulation. So is testing one thing and implanting and treating someone with an implanted device with something else. Also, successful trial is defined as a two-point reduction in pain on the VS scale or a 30% reduction of pain. This does not meet the standard for any insurer in the state of
We've heard quite a bit about the Hara study. It is the only paper in the evidence report rated as good with moderate strength of evidence as you can see from this table. It is a sham versus quote burst pattern crossover design conducted in Norway. Next. Study does not meet the standards of CMS or any insurer in the state of

Washington. The trial period was not with what the patients were then later subsequently implanted. It was with traditional stimulation. So is testing one thing and implanting and treating someone with an implanted device with something else. Also, successful trial is defined as a two-point reduction in pain on the VS scale or a 30% reduction of pain. This does not meet the standard for any insurer in the state of Washington. After the implant, the using, the unusual design, a pattern of bursts which we will discuss in a minute and they did not make any adjustments whatsoever. As you heard from Dr. Patel, patient adjustment and patient feedback is important to optimize stimulation. Next. It makes no sense to try one mechanism of action for the test period and then use something else during the actual research study. It's as if we give someone metformin, an old school treatment for diabetes and are surprised when the outcome is different with the newer medications we have available for treating diabetes. Of course that would be the case. This is not consistent with the standards published for how to conduct a placebo randomized control trial of SCS. Importantly, the burst patterns studied it was 40 hertz, 4 spikes at a reduced amplitude has no evidence of efficacy. It's not recommended by the manufacturer. It's not available on current systems in the United States, It's shown to be ineffective in a randomized control trial with the placebo control. So this is comparing sham and effective treatment to ineffective treatment. This is irrelevant, clinically flawed, has no, no validity when thinking about a clinical treatment for our patients in the state of Washington, next.

There are 2 other sham placebo studies for FBSS, significant major limitations. The report highlights the design flaws of these and the report is absolutely correct about this. But I want to quickly mention the clinical limitations of these studies as well. Next. Al-Kaisy studies for different treatment areas, sham, 3 stimulation modalities, 2 of those are not clinically available in the United States. So 3 out of the 4 are not even valid treatments. This is not very helpful for determining treatment when you only have one quarter of the treatment arm being a possible treatment in our state. It's a small study, limited duration. Next. Sokal, 2020 is a is a worse study. It mixes failed back surgery syndrome and complex regional pain syndrome patients.
5 of the 18 subjects did not have a clinical trial, didn’t have a spinal cord stimulation implanted, they had a different type of system implanted. And it's, it's a mess. It's too small, very short treatment periods. This study should be set aside. Next slide. All of these 3 studies should be set aside. SCS, I mean, a study that has significant numbers on duration but does not look at effective treatment should be set aside. As parameters not used clinically should be set aside and underpowered trials should be set aside. Next.

There is a placebo controlled randomized trial that has a positive outcome in all modality studied versus placebo. That's because the 3 simulation patterns here 40 hertz, 500 hertz and 1,200 hertz. And burst, I mean all the stimulation patterns are actually valid stimulation patterns. They were all shown to be superior versus placebo. This study has some limitations in its design. It shows that if you study actual treatments we use now, you get positive outcomes. Next. There's an older study that receives some prominence in the report. It is looking at injured workers in our state using old technology we do not use now. It's a population-based controlled cohort. Rated is a good quality cost effectiveness study. It's workers comp patients. The failure rate in this trial is higher than almost any other study you can find. So that would point to poor selection. And the authors themselves talk about the lack of generalizability of the data because it is an injured worker cohort. Next. This is old technology, poor patient selection, and a special population. It should not impact our broader decisions for HCA patients. Next.

There are some things to build on, on the report, which I will highlight. CRPS has a positive study. The painful diabetic neuropathy has positive study. Failed back surgery, surgery syndrome has some positive data points. Next. These are front, these are positive signals in the evidence report. Next.
Next. Next, look at all these separations from traditional treatment. Next. Next, next. Next. Next. Next. We ask you to look broader and look at data that is current and contemporary looking at stimulation now there are longer term studies. Next, we think. When you do this and place appropriate guardrails around SCS, you will come to the conclusion that this is an appropriate treatment modality. I will yield my time to Dr. Xing.

Fang Xing

Alright, thank you, Dr. Stacey. Dr. Fang Xing, I have no conflicts to disclose. Next slide, please. As Dr. Stacey had mentioned, SCS is not one type of technology. These differences are as different as different classes of antibiotics, different classes of chemotherapeutics. This is a summary slide of all the mechanism’s and the different types of treatment parameters here. Next slide, please. So the AAI report, if you were to only look at that piece of document, you would fail to find the largest highest quality studies available from modern-day use of SCS. You'd also fail to see the breadth and scope of the totality of the research. This is a summary slide here. The green studies are the studies discounted or excluded in the report and the red studies below are the ones that Dr. Stacey just explicated. So instead of looking at Hara for failed back with a sham, strange burst stimulation pattern that nobody uses for failed back, look at the Evoke study, Mekhail published in Lancet Neurology in 2020 with 24-month durability study. A published in JAMA in 2022 for failed back, look at the Census study, 198 patients of a new stimulation paradigm that's paresthesia free, 10 kilohertz, published in Anesthesiology. For diabetic and neuropathy, look at the Peterson study, published in JAMA Neurology. There's durability study not mentioned in Dr. Chen's report or the AAI report that this data is robust to 24 months. Next slide, please.

The AAI report did not include SCS comparator studies in addition to the mechanistic and clinical reasons why we must do this, there are some additional reasons. Next slide. The first is that this presents the best highest quality evidence that we have for the modern day use of SCS. We talked about the publications, the size of the studies, the high impact journals. The ACCC has recognized in the past. Now there was some discussion about industry sponsorship. We must prioritize the highest quality science that has the least amount of biased. However, at times, the best clinical design studies, methodologically and technically, especially of new paradigms of treatment are found in industry-sponsored studies. The ACC has recognized this the past. In 2017, the committee approved the use of percutaneous coronary intervention based largely on the Courage study, which was this industry sponsored study for total disk replacement of the cervical spine. The committee in the past ruled in favor because of largely because of industry sponsored comparative studies. Next slide.

When we have patients that reach the point of needing a spinal cord stimulator, we are talking about end stage chronic pain. We have no more options for these patients. These patients are severely disabled have pain scores described as unmanageable or horrible. Sham, spinal cord surgery in this high-risk patient population when an alternative existing stimulation parameter exists, has some serious ethical concerns. Next slide. We mentioned this earlier, but the HTCC, HCA, and ACCC cares about the best available evidence. Back to the cervical disk replacement example, the committee was largely comparing surgery to surgery. Those comparative styles, those comparative studies were ACDF, cervical discectomy, infusion versus total disc replacement. There were different surgeries, therefore they were fair comparators. Similarly, SCS versus SCS is a fair study because these are mechanistically different types of modalities. Next, next slide. Next slide. For the interest of time, I want to go through these slides quickly.

We did our own clinical evidence review of the literature. Next slide. The red boxes highlight methodologically flawed studies. The green boxes highlight the studies we need to look at. Next slide. Next slide. And what we included in these studies were the literature update from the last HTCC review in 2018 to October of this year. Next slide. We found 33 publications that were RCTs, 9 of them we looked at have really good evidence and they stem from 4 primary RCTs they are listed on the slide here. Next slide. We chose these studies specifically for the following reasons. They are the largest studies we have. They reflect modern day use of SCS. There were no previous SCS experience these patients. They were compared to the standard of pain care. They're methodologically and technically sound and they had robust follow-up on multiple domains of pain measurement up 24 months and they were published in our best journals, JAMA, Lancet, Anesthesiology. Next slide. The first study to look at for failed back surgical syndrome is the EVOKE RCT. Looking at closed loop stimulation versus traditional stimulation. Look at this graph here. If we were to give a fixed output of spinal cord stimulation without understanding the physiology of the patient, we have a high risk of overstimulating or under stimulating the patient, which leads to poorer outcomes. On the right here, when we use closed-loop stimulation, we're able to measure the evoke count on action potentials and adjust the stimulation based upon the physiological needs of the patients. Next slide. Not surprisingly, the EVOKE

study at 12 months showed that with closed-loop stimulation, 83% of patients achieve the primary outcome of greater than 50% pain reduction compared to traditional stimulation which was 61%. We saw improvements in ODI, we saw improvements in disability and mood, general functioning and other health care outcomes, as well as a decrease in opioid use. Key here, we have durability publication in 24 months in JANA neurology that these results continue to persist beyond the 6 months mentioned in Dr. Chen's presentation. Next slide. The next study to look at is a 198 patient study published in anesthesiology of 10 kilohertz stimulation.

Val Hamann 5 minutes remaining.

Fang Xing This is a, this is a paresthesia free stimulation pattern that is upgrade from our traditional patterns. These graphs show a significant drop in our pain scores at the start of stimulation, tonic, traditional versus 10 hertz on the bottom one. Lower the number, the lower the pain score. Next slide. What was really impressive about the study is that we had patients with disability categorized as crippled to moderate to severely disabled and after 12 months of treatment these patients moved into more mild and moderate categories of disability. We also had an improvement in their opioid use, their general satisfaction, their health care quality of life, and there was an advantage to 10 kilohertz stimulation pattern. Next slide. The next study to look at is the JAMA neurology study on diabetic neuropathy. Again, this is the new 10 kilohertz technology randomized the conventional medical management. This plot says it all. The left-side conventional medical management, each line represents one patient. If you move to the right, that's percent improvement in pain. In the conventional medical management arm, 5% of patients reach the primary outcome of greater than 50% reduction. In fact, many of these patients got worse over time. In the 10 kilohertz plot on the right side, 85% of the patients reached the primary outcome a greater than 50% pain relief and this is again not highlighted the AI report or Dr. Chen's presentation, there is 24 month durability data published in the Journal of Diabetes. Research in Clinical Practice in 2022. Next slide. For the for the reasons of time, we're going to move over these slides quickly.

These are secondary outcomes. There was a line in Dr. Chen's report that there were no function outcomes. This is not true. Next slide. Next slide. This is the EQ-5D-5L 10 kilohertz versus conventional medical management. We see the separation here. Patients that increase capacity to exercise, less mood issues, more self-efficacy. Next slide. Next slide. Improved sleep. Next slide. And what's really interesting is that in the 10 kilohertz stimulation arm, the patients actually had a reversal of some of the neurological deficits, whether sensory motor or reflex and this is an active area of clinical research. Next slide. Next slide. Next slide. Spinal cord stimulation is a safe procedure with a low risk. You've seen a lot of different numbers as someone who educates and trains practitioners for this, procedure, it's only gotten better and we're getting better and better at this. Look at the most recent evidence published in JAMA and Lancet. 5% wound complication rate despite a high risk diabetes population. 2% complication rate of infection in the Lancet study. Most importantly, in these 2 studies, no deaths, disabilities or long-term neurological injuries. This is consistent with our practice at the pain clinic in the state of Washington. Next slide. So we want to

acknowledge here that hey look the evidence does show that in the hands of clinical expertise in thoughtful physicians, this can be applied skillfully and can lead to profound improvement in pain and suffering. But we also realize that like any medical treatment, there is a chance for overutilization. Therefore, we advocate for the use of spinal cord stimulation only in FDA approved indications. According to NCD guidelines from Medicare and Medicaid Services, and also we have we advocate for additional guardrails specifically for our state of Washington. Next slide. Next slide, please. The, this is a summary. Can you please go back one side, please? Thank you. This is a summary slide of key core recommendations for coverage. In our appendix, we have additional disease specific recommendations for how we can cover this technology in our state. Next slide. Next slide. In conclusion, the AAI report is in sufficient. We need to look at the best quality evidence.

Val Hamann 1 minute.

Fang Xing failed back. Please look at the EVOKE study published in Lancet neurology durability study at 24 months published in JAMA neurology. For failed back, please look at the census study. 198 patients publish in Anesthesiology with 12 months of robust data. For diabetic neuropathy, please look at the Peterson study published in JAMA Neurology, understand that these results are durable to 24 months with robust secondary outcomes published in second additional studies thereafter in the Journal of Pain of diabetes research.

Val Hamann 30 seconds.

Fang Xing And we advocate here that we deploy this technology with the understanding that we want to do this with evidence-based approach to reduce over utilization and we want to provide an efficacious treatment to some of the most vulnerable members of our community and give them equal access to high quality pain care. Thank you very much.

Josh Morse Thank you for your comments, Dr. Xing. I'd like to specifically thank Dr. Singh for, for the work we've done together in, coordinating your presentation for today. Thank you, Dr. Singh.

Val Hamann And the next presenter has been elevated and they will not have slides and have 2 minutes so I will let you know at the 30 second mark. So Cindy when you If you are ready, go ahead.

Cindy Steinberg Thank you. My name is Cindy Steinberg. I have no conflicts. I am the director of policy and advocacy for the US Pain Foundation and national nonprofit patient organization with 30,000 members nationwide who live with chronic pain from conditions that include diabetic neuropathy, failed back surgery, and complex regional pain syndrome. Our members are primarily people living with high impact chronic pain that destroys your ability to function on a daily basis, is a devastating condition that can best be compared to being locked in your own body and subjected to relentless torture, 24/ 7. It robs you of any quality of life and often leaves the depression, anxiety, and even suicide. Research has shown that the risk of death by suicide is double for those with chronic pain. In the 13 year period since the Health Care Authority has last reviewed

SCS, there have been vast improvements in the ability of the technology to block pain and provide durable relief. Not every patient with high impact chronic pain is a candidate for SCS. Careful selection of appropriate candidates that meet a list of criteria is required by all payers. When a large duke study failed back surgery, apply these standards, only 4.3% of patients were selected and these demonstrated superior efficacy and long term cost effectiveness. SCS has been in.

Val Hamann 30 seconds.

Cindy Steinberg an essential and treatment option in the toolbox of treatments and for certain patients, we've seen it make a difference between a life worth living or not. It's covered by as you've heard by Medicare, Tri-care and numerous commercial payers. It is unfortunate and inequitable that Washington State would deny this treatment to its state employees, injured workers, and impoverished citizens receiving Apple Care that is available to those with private health insurance and Medicare. We implore the Washington State Authority.

Val Hamann And that concludes the 2 minutes. We appreciate you. Coming this week today. Thank you.

Cindy Steinberg And store access. Thank you.

Val Hamann And the last individual that we had on our list, can you please raise your hand if you are here Farshad Afarard, as we have not seen you and you could be under a different name.

Sheila Rege Do we have that person's email to send a quick email asking and if they email we can make time. If they don't respond now.

Val Hamann It looks like they may not be in attendance today. We're not seeing any raised hands. We're not seeing anybody by the same name.

Sheila Rege Okay. Sounds good. Thank you and, I hope the committee members have, we appreciate all the comments about these studies that were not put on or discussed. But I hope the committee members, have looked at the, final evidence report appendices. It was 191 pages on the excluded studies and kind of the analysis. We had asked our vendors to go to that and we could pull it up as needed. If anybody has trouble, please, email Josh or Val on how to find that. I know we have several new committee members. And I haven't mentioned that before. Josh, what should we do next? And it has the other person responded.

Josh Morse Dr. Rege, we are at a break point. We're a few minutes behind, but we have 10 min. We had called for a 10 min break, which I think is probably really important to us all today to make sure we take care of ourselves. And again, I think we're not. Not too far behind, so.

Sheila Rege Now, let's, let's not come back. At 11:15, which you know plus minus 2 min will you give us the 10 min is that okay?

Josh Morse Sounds good to me. Thank you.

Sheila Rege Sorry, Sheila here, sorry about that.

Josh Morse No problem. I think I put the agenda back up. I think we are at the evidence reports for spinal cord stimulators from Aggregate Analytics. That'll be the next, on the agenda, Dr. Rege, unless you have, something else right now?

Sheila Rege No, and, if during the presentation we could talk about it later, if you can discuss us on the studies that will mention in public comment and kind of help give us your views as well to help during, you know, later during the discussion. Thank you.

Josh Morse So, Andrea or Erica, I don't know which one of you will be presenting. Are you ready to go?

Erika Brodt Yes, Andrea will be presenting, so. I think she's probably. Getting ready to go here.

Andrea Skelly Yes. And I'm going to share my PowerPoint. Can people see the PowerPoint?

Erika Brodt Perfect.

Josh Morse We can see it. Looks good. Thank you.

Andrea Skelly Okay, great. Thank you so much. Alright. I'd like to begin by thanking the team at AAI for their work on this report. And I would like to also acknowledge and thank our internal clinical and methods review, Roger Chou, as well as our clinical experts and peer reviewers, Carl Noe and Kim Mauer. Going on to the next slide. I'm going to make some of this brief because it's already been covered by Dr. Chen. This is an update to the 2010 report, the 2010 report did find that spinal cord stimulation was superior to conventional therapies in the shorter term for pain relief, but the benefits did decrease with time and there was no difference versus controls, with longer term but longer term data being very sparse. The evidence on function and quality of life was sparse at that time and inconsistent. One study did look at revision surgery and side effects and they were not uncommon through the five-year follow-up and there were no trials looking at placebo or sham stimulation. So as you all know, the rationale for the update for this report was to encompass and look at new evidence that may be available for spinal cord stimulation including high frequency or burst stimulation that are available since the last report. I would like to briefly comment that the topic refinement for this did include extensive look at the public comments to the topic nomination, the draft key questions and scope as well as a petition to the technology assessment program. And they were looked at and considered we did discuss them with the health technology assessment program and we did get clinical input prior to finalizing the key questions and, and PICOT scope. And so I would like to just indicate that all the comments that have been made during this present during this meeting

also reflect many of those same comments and it was the decision of the technology assessment program to help us finalize the scope. I would want to point out to that all the suggested citations were evaluated against the final PICOTS for possible inclusion. As Dr. Rege suggested there is an extensive appendix that describes the inclusion exclusion or the rationale for exclusion for some of the studies that were suggested. We did get clinical input on specific clinical questions throughout the process. And again, I'd like to thank our clinical experts.

By way of background, again, all of you know that chronic pain is a leading cause of disability. It's of an immense public health importance and it's a challenge, with a high rate, annual expenditure for its management. I don't think we need to dwell on that. We, we are very well aware of the problems with chronic pain. With regard to the conditions included, again, reinforcing the back pain, complex regional plain syndrome and neuropathy were included. I would like to point out that the included studies included different populations of patients with back pain, while most of them included failed back surgery syndrome when they looked at failed back pain. The definitions and the diagnostic criteria were not explicit in most of those studies. Another set of studies, another study looked at non-surgical refractory back pain. Which was chronic refractory back pain that did not respond to conventional medical management in a patients who did not have a history of spine surgery and or who were not candidates for spine surgery. With regards to the included conditions and the spinal cord stimulation as was mentioned by many of the presenters, it's generally considered a last or late resort and eligible patients would generally undergo a trial of spinal cord stimulation to assess whether or not there's a clinically meaningful pain reduction achieved before implanting a permanent device. The spinal cord stimulator as you know has been discussed in terms of the primary aspect of this using electrical energy. The mechanisms of spinal cord injury. Excuse me, the mechanisms for, there are 3 main components. Did I miss a slide? I'm sorry. The mechanisms of action have funny pain as was pointed out by one of the speakers is very complex and in the past decade or more there's been a greater understanding of chronic pain and what it may take to improve chronic pain and it continues to evolve. Similarly, the understanding of mechanisms for providing pain relief and managing relief have evolved in the last 2 decades, including mechanisms of actions related to how spinal cord stimulation may improve pain. However, the bottom line is that there are still a number of gaps in the understanding of some of these mechanisms and much work yet to be done. As was mentioned, there are a number of approved devices and the indications again were familiar with from the prior discussions. Contra indications include failed trial stimulation. In other words, the patient didn't experience effective pain relief. Some patients maybe poor surgical candidates, they may have other comorbidities or conditions that would preclude use of the spinal cord stimulator and as mentioned previously CMS and most payers require extensive screening both physical and psychological and that a diagnostic team that's multi-disciplinary is able to evaluate the patient's a suitability for, for a permanent, permanent placement.

Again, as you know, there are 3 primary components. There's an implantable pulse generator, the battery, there are leads, and then a control device. As you know, it's a 2 stage, a 2 stage procedure. One for the trial and then one for the permanent implant. The pulse generator is programmable for a variety of settings. And some are even able to sense a change in position to help adapt stimulation to a patient's activity and needs. Conventional stimulation involves delivery of a constant or tonic pulse at usually frequency between 40 and 80 hertz. High frequency stimulation is generally then anywhere between 200 and 10,000 hertz using a fixed pulse with. Burst stimulation involves the delivery of intermittent trains of stimulation. And the stimulation, patterns parameters may vary. So, the newer devices again, as has been mentioned, include, so conventional devices are the lower frequency devices that may have associated with them a while tingling sensation, paresthesia sensation, whereas the higher frequency and burst pulse devices do not have a tingling sensation or feeling associated with them. Input from our clinical experts suggests that there is some heterogeneity in the devices, modes of operations and parameters that are used across clinical practice. Some of the specific risks have already been covered and we will discuss some of the harms related to spinal cord stimulation as part of the evidence.

With regard to questions and scope again, this has been covered. We're looking at for the effectiveness compared with medical therapy, surgical treatment, or in some instances, sham or placebo, looking at efficacy, safety, differential efficacy or safety, and cost effectiveness. The scope again has been described in terms of patients who had not been previously treated with spinal cord stimulation with one of the following conditions. And again, FDA approved devices that were permanently implanted were considered for inclusion and again comparators of medical or surgical treatment or other comparators that did not involve direct comparison of devices, spinal cord stimulation methods or devices. And the prioritized outcomes for strings of evidence will function pain, opioid use, and adverse events or harms. We considered only cost-effectiveness studies that were considered full economic studies for inclusion. In terms of study design, best evidence does relate to methodological bias and we've focused primarily on RCTs, although we did include, as you will see, non-randomized studies with concurrent controls that controlled for confounding. We did look at non-randomized studies as well as RCTs for harm specifically. And for key question 3 for looking at, for looking at differential effectiveness or harm RCTs, we did look for those and then full of formal economic studies.

In terms of methods, we applied standard methodological review methods embraced by AHRQ, what used to be the Institute of Medicine, now NASA, and Cochrane in terms of methodologically strong objective systematic review. We did include a topic refinement as I discussed looking at key questions and scope obtaining public input as well as clinical input before finalizing the work plan and our clinical experts again did provide information at those stages. After finalizing the work plan and the scope, a formal structured search was conducted and there's a two-stage process by which we

dual reviewed both titles and abstracts of potentially includable studies. And those that were even remotely potentially includable, we did do a full-text review and applied the inclusion criteria at full text. So what you see in your appendices in terms of the description of studies that were excluded, those were at full text and the reasons are provided. So that's the process. Once identified, each study was just, was subjected to predefined criteria, criteria to assess individual study risk of bias based on methodological aspects of study design. And the good studies were considered to be low risk of bias and met most criteria for methodologic quality and we're generally considered valid. That included valid methods for selection, patients, inclusion, treatment allocation, report that some, reporting a similar baseline characteristics especially for prognostic factors that may be important between the 2 treatment group between treatment groups and they clearly described attrition and had low attrition and no differential attrition and had appropriate means for preventing bias and use of appropriate analytic methods. Most studies generally fall in the category of fair, which means there may be some study flaws. They may not meet all the criteria for good quality, but no single flaw is likely to cause major bias that would invalidate the results and many studies for this may be valid, some may not be valid. In contrast, poor quality studies are those that have significant flaws in implementation or design that really call into question the accuracy and the validity of the of the information presented. Criteria are listed in your in detail in your appendices and most of you are familiar with the parallel randomized control trials, which we look at the general aspects of randomization and concealment of allocation, intention to treat, evaluation, blinding of patients, especially when we're dealing with patient reported outcomes. That's an important thing to consider whether the groups are comparable a baseline or not and the extent to which follow-up is acceptable and did they report on specific outcomes, which is an attempt to look at is there selective reporting of outcomes. In contrast, parallel trials, what they do is they say we have the group of participants who randomize them to treatment A versus treatment B and then we follow them for a certain period of time.

Crossover trials are a different type of trial and there are some unique potentials for bias. In a crossover trial, patients will get treatment A during period one another group will get treatment B during a period and depending on the technology or the drug or the device, there needs to be a washout period so that the effects from treatment A don't carry over into whatever the patient may experience for treatment B. Similarly, those that receive treatment B, we need a washout period in most instances to make sure that carryover effects into treatment A don't influence or bias the results that we see during time period 2. And so some specific concerns in addition to randomization sequence concealment and blinding that are considered are looking at comp, comparability of studies at baseline between treatment A and treatment B at period one and then also the results of period one. Whether or not there was a washout period and whether that wash out period was substantially effective in preventing those carryover effects. There are statistical tests that one can do for that. They're not great, but what we look for is was there a washout period, was it sufficient or did they use other mitigation strategies to prevent that carryover effect. And again, completeness of data and is an important thing because patients are measured several times during the course of this type of trial, correlated data analysis is important to

prevent inappropriate interpretation. We also did include non-randomized trials, similar types of considerations in terms of patient sampling, hoping and, and looking for whether or not from the same underlying population is their comparability on prognostic factors at baseline. Again, assessment blinding is important. Follow-up and differential loss to follow-up are important looking at whether outcomes were pre-specified. And one of the important pieces is looking at potential for confounding and did they match, did they do propensity score matching, did they use multivariate analysis to control for confounding. So each of these criteria that I've got over are areas where studies may have been downgraded for risk of bias.

Once risk of bias is done in each individual study. We look at the overall strength of evidence. So as a reminder, it's not the same thing as a study risk of bias. And we look at the risk of bias and the things that we've talked about, for example, under risk of bias, but we also look at consistency, which is the degree to which estimates across studies that are reporting on a specific outcome are similar in terms of the direction for the effect, the magnitude of effect, and the range of effects. Obviously, if you only have one study, you cannot look across studies for consistency, so we called that consistency unknown. In terms of directness, we used what ARHQ does versus what pure GRADE does and looking at whether the evidence is directly related to patient health, health outcomes and we considered all of the health outcomes to be direct. Precision as its name implies looks at the variability around the effect estimates. And if it's a large variability, it calls into question the stability of the point estimate. Publication bias and report bias are difficult to assess. However, we did look at published protocols to get an attempt at assessing that but in general it's usually unclear. So in summary, we look at studies based on eligibility criteria, they're predefined and we assessed for risk of bias. And then we look at the overall strength of evidence across studies reporting on a specific outcome. So for different outcomes, the strength of evidence could be different depending on the all those factors that we just discussed for strength of evidence. We then consider how confident we are that the effect size of the effect is a true effect and our, our confidence could either be high, moderate, or low. Insufficient, we did distinguish between areas where there was no evidence versus areas where we did not have confidence in the effect. Important point to note throughout our report we have classified the magnitude of effect as a small or slight moderate or large or substantial a And this is based on many of our AHRQ reports where we have used for pain on a 5 to 10 point scale, 5 to 5 to 10 points on 0 to 100 point scale is small, greater than 20 greater than 10 to 20 points on a 0 to 100 scale as being a moderate and then a substantial or large effect size would be greater than 20 points on a 0 to 100 scale and then just moving the decimal point for, 0 to 10 scale. Most studies that the report on function looked at the ODI, Oswestry disability index and you can see that we've we followed a similar pattern. When relative risks or odd ratios were reported, a small effect was considered to be 1.2 to 1.4, 1.5 to 1.9 a moderate effect and then over 2 as a large effect. Again, the scale scores are based on mean differences between groups on continuous scores and a point to note is that we considered that small effects may be below published thresholds for published MCIDs. However in some patients a small improvement in pain or function may be important. And I would like to also note that effects below the threshold for a small were categorized as no effect or the effect being similar between groups.

So moving on to the results. Moving on to the results. We, our search identified, 1,551 studies and through hand searching of bibliographies as well as looking at those cited publications in public comment. There were 34 hand searched what we included for evaluation, title abstract review, many of them were excluded and we did report we did assess at full text 236 for eligibility that full text and we then were left with 65 citations and 57 unique studies, 13 of which were randomized control trials. 4 crossovers, 9 parallel studies across, 22 publications. Yeah, again, we dual abstract review, dual, dual full text review is part of the process for methodology, methodologic accuracy. You can see here how things broke out in terms of the different conditions, numbers of studies, the overall numbers of crossover trials versus parallel trials.
I would point out that we did include 5, studies that were nonrandomized studies of interventions, that's what NRSI stands for, that we're compared spinal cord stimulation to another comparator. And most of the non-randomized studies including case series were included for safety.

So moving on for key question one, looking at effectiveness. Again, our primary outcomes were pain, function and opioid use. And you can see that in terms of failed back surgery syndrome, we had 3 studies that were crossover trials. We have also 2 conventional spinal cord stimulators parallel trials. And one that looked at spinal cord versus stimulation versus re-operation. We did have one parallel trial looking at this non-surgical refractory back pain. So we have a total of 7 RCTs, 5 of which were industry funded. And we also did include 5 comparative non-randomized trials. Very brief overview of the trials in terms of some of the demographics. Mostly 50 year old individuals, range of female patients ranged from 14 to 54%. Patients had at least 6 months duration of pain reported. 2 of the trials required failure of conventional medical management. Most trials did not provide details on how multidisciplinary evaluation, including psychologic or physics, physiologic comorbidities were assessed, but all trials did exclude patients with psychological comorbidities or substance use disorder concerns. All of the implanted patients randomly assigned to phases, different phases, which we'll talk about for the crossover trials here in just a moment, including a sham or a placebo setting. I would like to note that there is a lot of heterogeneity across these 3 trials, both in terms of the population studies as well as the methods. And this is an example of one table that is in the appendices that provides you additional information about some of the parameters for the trials and the numbers of people who were subjected to a trial of spinal cord stimulation, the number who completed what those thresholds were, whether a permanent implant was made whether the same device or mode was used for the trial device versus the permanent implant. And I would like to point out that as many of the commenters have pointed out, that there is substantial heterogeneity across the studies and that the one trial, Hara did use a different threshold for implanting a spinal cord stimulator compared to the other 2 trials and compared to what the standard practice is for most payers. It's unclear, in some of these instances, whether the same device or mode was really used. Hara did not use the same mode or device and that has been pointed out. Again, they used a tonic device for looking at the trial and they were using burst as first technology as a, as the permanent implant. So there's a problem, problem there. Again, the ratings of good fair and poor relate to the methodological quality from a study design basis.

I would like to also note that here we have active treatments that are very different across the studies. The Al-Kaisey study used a variety of different frequencies and compared to sham, which they didn't have the implantable pulse generator on, on at that time for no stimulation. They used a proprietary programming situation to get at these to get at these. The Hara study used burst at 40 hertz, at, they said was 50 to 70% of procedure paresthesia threshold. And then the Socal study, they did include 78% of patients who failed back surgery syndrome and is generally practiced we did include state patients if at least 75% of the patient population did include the condition, we included it under that condition, but that is a caveat to that particular thing. None of them really clearly reported a washout period. Al-Kaisey was the only one that checked for period effects and none of them reported first phase data. Co-intervention medications, physical therapy, etc, were not well reported. And very little information was available across the 2 that did not, that did record some information about that. So this is the general again, the general point is that there's a lot of heterogeneity across these studies. All of them have flaws and problems associated with them as we have noted in many places in the report.

Terms of function only one study on a lot of these 3 studies reported function, ODI on a 0 to a 100 scale and that was Hara and again because of unknown consistency, only one study we don't know how consistent the results would be across other studies. We downgraded it and but we considered it moderate evidence of no or similar functional improvement between spinal cord stimulation and sham. Again, I point out that these patients, they did not classify them as persist as a failed back surgery syndrome. They did classify them as patients who had persistent radicular pain following low back surgery. In terms of low back pain, pain on a VAS or NRS scale. Again, the Hara study found similar back pain improvement between burst and spinal cords, burst spinal cord simulation and sham. Again, we thought that was moderate at moderate evidence again based on the criteria that we use. And then looking at Al-Kaisey, the authors do report that the highest frequency did show a statistically significant improvement in pain compared with sham, none of the others did show statistically significant improvement in sham. The authors in their study note that they used a MCID of 2 for improvement. So it didn't make me did not meet their MCID. It, we considered it a small improvement in pain based on the paradigm I shared with you previously. However, because of the potential for risk of bias, unknown consistency, and basically the very large confidence interval, which to us pointed to in precision, we considered the evidence to be insufficient from that study. Similarly for leg pain. Hara indicated that there was similar leg pain improvement between burst and sham. Modes of operation was not statistically significant, but there is some in precision, so the strength of evidence was low. ,Al-Kaisey did not give us information on variability, around their mean, means, and so we cannot really evaluate precision and again we felt the information was insufficient to draw conclusions. The Socal study reported pain, VAS pain, they didn't specify whether it was leg or back or or where. And this was a very poor quality trial. And I should have mentioned when we talked about strength of evidence, if the only evidence available is poor quality, we considered this insufficient evidence.

If we move on now to. I'm sorry. Yeah, if we move on to spinal cord stimulation in parallel trials. We find that there are 4 RCTs, 4 of which were industry funded across 6 publications. Relatively small number of patients 577 in these parallel trials. Most of them compared to, to conventional medical management. One did look at as an older study looked at spinal cord stimulation versus reoperation. Again, these are patients who had pain duration for many years. Mostly female, about 50 little over 50% female again around 50 years of age is a mean age. One trial used the 10 kilohertz high frequency spinal cord stimulation. The others used conventional spinal cord stimulation. And 2 other trials required failed conventional medical management. 2 trials used explicitly said that he used a multidisciplinary evaluation, 3 excluded patients with psychological comorbidities in 2 excluded patients with substance use disorder concerns as stated in their inclusion exclusion. Patients who had a successful trial were, were implanted. All trials were allowed all patients were allowed to cross over to spinal cord stimulation after 6 months. So as you probably remember from, from your studies, studies of studies that breaks the randomization so these results were no longer comparative. And we do have the results for longer term beyond 6 months as they were reported, but they do not, we do not do strength of evidence on them because they are no longer comparative. And again, I would note that there's substantial heterogeneity in the populations that we're studied as well as the devices that were used and the methods that were used. So one study, the one study that looked at patients with non-surgical refractory low back pain, employed 10 kilohertz spinal cord stimulation and found that and let me just make a point here that we separated the higher frequency devices from the conventional devices. And so that's because they are different technologies. But I'd also like to point out that the populations in this group of studies also had different, different conditions. So Kapural had this non-surgical refractory back pain, whereas the other 2 Rigoard and Kumar explicitly looked at patients with failed back surgery syndrome. As you can see, there was large improvement at 1, 3, and 6 months in terms of the likelihood of reducing the ODI score of at least 10 points meeting some sort of clinic meaning that as a clinically important difference. There was a large improvement in that likelihood at those time periods. However, we did that downgrade for risk of bias and you can see that the confidence intervals are very large so there's substantial imprecision calling into question the effect stability of that effect. If we look at the scores themselves, again, we see that there is a large improvement with the high frequency, but a smaller improvement with a conventional spinal cord stimulation. The strength of evidence was considered low. If we take a look at pain responders in terms of back pain specifically. Again, we see that the likelihood of a large improvement for both back pain and leg pain was, was large for both high frequency and conventional spinal cord stimulation. We don't show it here, but the same conclusions were drawn at 3 months across the studies. We considered the strength of evidence low again because of risk of bias and concerns about imprecision. If we take a look at the pain scores. Again, we see that there's large improvement with the high frequency. There's less improvement but still a moderate improvement with conventional spinal cord stimulation and this is at 6 months, again separating out the high frequency and the conventional, again, noting that these are different populations, as well in terms of the back pain for the conventional and the high frequency. For the leg pain, again we see that there is

improvement in the pain scores but there is substantial, substantial heterogeneity in the patient populations. This may be because one of the studies looked at patients, patients had to have more back pain than leg pain the other had to have more back, leg pain than back pain. And that may describe, that may partially account for the heterogeneity that we see here.

In terms of opioid use, substantially more patients receiving the high frequency spinal cord stimulation, experience decrease or stopping of opioid use. As you can see here, again, there is some precision related to that with regard to the proportion of using patients using opioids at the end of the 6 months before patients were allowed to cross over. We see that there is maybe a suggestion of a small increase in the likelihood of not being on opioids at that time frame, but the risk of bias and imprecision across these let us to a conclusion of low strength happens across these. Looking at the studies that reported, mean morphine equivalent dosages. We felt that the evidence was insufficient. When we looked at the conventional, conventional spinal cord stimulation. We felt the strength of evidence was low that there was a statistically significant reduction in the mean morphine equivalence dosage, but the clinical significance of this reduction was not described and is not clear. Let regards to the one study that looked at spinal cord stimulation versus reoperation, we felt that the evidence was insufficient from this this older study.

If we move now to painful diabetic neuropathy, again we see that we have a total of 3 studies that were parallel studies. One of which did look at high frequency spinal cord stimulation versus conventional medical management. All 3 were industry funded. There were 7 publications. Little older age group compared to some of the other to the back pain group and again about 50% women, 50% female with again a long duration of pain. 2 trials used conventional spinal cord stimulation, all required patients to have failed conventional medical management. One explicitly indicated use of multidisciplinary evaluation. And all trials excluded psychological comorbidities, substance use, abuse issues and then patients who, were successful were randomized to receive permanent, received a permanent implant. Again, I would note that all trials allowed patients to cross over to spinal cord stimulation after 6 months. So we focus again on the results that are comparative, which are up to the six-month point. Looking at the extent to which pay people experience the clinically important. Difference in pain response in terms of lower extremity pain We see that there was a large increase in the likelihood of achieving the pain response for, for both the high frequency as well as the conventional spinal cord stimulation and again number of the concerns that have related to risk of bias that have been presented in my previous speakers fall into this category, influenced our the risk bias influence our decision to downgrade for risk of bias and as you can see again there's a huge confidence interval for all of these estimates calling into question the stability of the estimates. So the strength of evidence was low for across all of those. Estimates. If we look at the parallel trials of spinal cord stimulation versus conventional medical management for PDN looking now at the scores. Again, we see that both types of spinal cord

stimulation were associated with a large improvement in lower extremity pain scores at 3 months. There was only one trial. At each time. At 6 months where we did have both a high frequency and the conventional, conventional spinal cord stimulation but again there's good bias concerns and in precision led to a conclusion of low strength of evidence for all. When we look at the opioid use, the one study that looked at this found that the proportion of patients taking opioids was similar between groups. At 6 months and the strength of evidence was low.

If we look the complex regional pain syndrome, we see that there was one crossover trial. And we have then, 3 other trials that looked at parallel, treat other parallel trials that looked at this as well. So 2 of the studies were RCTs, 2 studies, 2 RCTs, neither of which were industry funded were parallel trials and looked across 4 publications. There was one crossover trial that was industry funding with industry funded with a total across all these of 95 patients. Little younger age group than, than some of the other conditions again about 50% female but a large range. Duration of pain was 12 to 38 months. One trial used conventional spinal cord stimulation plus physical therapy and compared it to physical therapy alone. One trial loop looked at the low frequency or more traditional spinal cord stimulation versus conventional medical management and the crossover trial used a variety of high frequency and low frequency modes as well as burst their version of a burst spinal cord stimulation versus placebo. All of the trials required that patients fail conventional medical management. All used multidisciplinary evaluation to include patients. One trial excluded those with psychological comorbidities to excluded them if, if there was substance use disorders. Again, patients had to have had a successful trial for implantation. And the one trial that looked at PT allowed patients to cross over to PT if the trial failed. All the others allowed crossover at 6 months, 2 spinal cord. Looking then looking now, looking at the evidence. From the one poor quality study that was a parallel trial that that reported on function. The evidence from this trial was considered insufficient to draw conclusions. If we look Yeah. If we look at then the complex regional pain syndrome parallel trials. We see that at 6 months the one poor quality trial, we did see moderate improvement, but because of the risk a bias and being a poor quality trial we considered that insufficient. Across the conventional studies we found there was one fair quality and one poor quality study. The strength of evidence was considered low based on the fair quality study of a large improvement at 6 months and a moderate improvement at 12 to 24 months. In pain scores. The pain scores in another trial were similar at 16 at over 24 months and you can see that the pool does the pooled estimates or just across the 6 months for the conventional trial. If we look at the one crossover trial, again it was considered to be poor quality and so we considered the evidence to be insufficient to draw conclusions.

We look at safety. We felt that strength of evidence for safety was low for many types of safety concerns. Again, I would like to note that there was a lot of heterogeneity in how safety was reported, how it was categorized, the extent to which it was considered severe or not severe, and across the studies there's a wide range of frequency of various, various safety and adverse events which we'll talk through. I would like to also note that in some instances, particularly with the randomized

control trials here, that some of them had very small numbers and so the percentages may be somewhat misleading. But we looked at the randomized control trials separately and any spinal cord stimulation related adverse event ranged from 12.4% to 17.6% within 6 months and that was in 2 RCTs, the Ns noted there. Increased to 24 to 32% between 12 and 24 months across 3 RCTs and these are all parallel group RCTs. The one crossover trial reporting this, found a rate of spinal cord related spinal cord stimulation related adverse event in 18% in a population of 50. The spinal cord stimulate related adverse events requiring surgery again ranged a bit at 6 months there seemed to be more at 12 months. But here's where I would caution you that those higher percentages are in the patient population that included only 24 patients. Withdrawals do, yeah.

Josh Morse Andrea, I'm gonna, I'm gonna. just pause here and interrupt you for just a moment and ask for everybody involved here in the presentations and on the committee. If you would, please consider turning your cameras on. We've had a request from stakeholders that we use our cameras during this portion of the of the meeting.

Sheila Rege Thank you. That's, a bit unusual, but please do. And, if there's a bandwidth problem, staff, please let us know, okay? Like if you have issues.

Jose Morse Thanks. Really appreciate your help here. Thank you. Thank you, Andrea.

Andrea Skelly Okay. Yep, thank you. So again, looking at AEs requiring surgery considering the fact that the higher percentages are in patient populations that are very small. With regard to withdrawal due to adverse events, they were similar between spinal cord stimulation groups and conventional management groups within a 6 month timeframe. There were only 2 studies, 4 studies, 2 in chronic low back pain and 2 in peripheral neuropathy. And the range of withdrawals was similar between the 2 groups at those time frames. And again, the ends are very small for that. Taking a look then at device related events, this slide describes a summary of the events across different study designs. So it includes the RCTs as well as non-randomized studies. There is excruciating detail in the appendices in terms of specific studies and what the ranges of events were in those studies, what the time frames for those were and the like. My intent is to provide just sort of the biggest picture of possible on this. The most common were related to device exploitation, revision, or replacement including removal for inadequate pain relief or loss of efficacy, lack of efficacy, or an adequate benefit. Also lead or electro replacement or revision was fairly common. If you look at the upper end of the range and lead failure migration, which was not generally specified as requiring surgery also did have a range. and lead failure fracture again had arranged. That's the bottom line to almost all of these is that you can see that the frequency ranges from fairly low to a much higher percentage. And it's unclear to the extent why the range is so large other that we have a variety of studies using a variety of definitions and a variety of ways of looking at these. Less common adverse events were removal of the implanted pulse generator for infection or infection or dehisance of wound.

Unknown And. Did I? Okay.

Andrea Skelly

I'll go on. And serious infection, was, arrange for 1.4 to 6%. And, that was very low when reported within 30 days. Is, am I interrupting someone? Is someone trying to speak?

Okay, I'll move on. So again, these were less common. There are a number of, studies, a number of adverse events for which we felt evidence was insufficient or mortality was one and part of the reason for some of these being insufficient is that these may represent very rare or uncommon events and most studies were underpowered to detect some of these kinds of events. Especially over the longer term. and so you can see what the list is. For the studies that were not randomized. We tried to focus on studies that had at least 100 patients to summarize across those. But again these are the outcomes for which we felt the evidence was insufficient for harms. There were no randomized control trials that did explicit evaluation for differential efficacy or safety, so there was no evidence related to that.

With regard to cost effectiveness as a reminder, there is no strength of evidence across studies of economics for, for our report. As already mentioned, there are full economic studies that were reported, 8 of them since the new since based on our new search. 5 industry funded and 2, only 2 are US based. One of the US based studies was a cost-effectiveness studies and workers compensation population. I would like to clarify that we considered it good quality for the way that the economic evaluation was conducted. And we do realize that yes, it was based on a non-randomized trial, which was included in our report. Spinal cord stimulation was not considered to be effective at common willingness to pay thresholds compared with either usual care or pain clinic referral and that was over a 24 month time horizon. However, the author's note and we note in the report that the applicability of these findings to other populations may be unclear for a variety of reasons, which we do talk about in the report. The other US based studies with in patients with non-surgical refractory back pain.
And it was a cost utility analysis of high frequency spinal cord stimulation with conventional medical management versus conventional medical management alone. We considered it poor quality for a variety of reasons. The formal evaluation is in the appendix and in the full report. The base case scenario suggests that spinal cord stimulation is cost-effective versus conventional medical management at 6 months. However, the authors point out that they their modeling did not include the initial spinal cord stimulation cost or procedure cost and when they did include these costs, their graph indicates that the incremental cost effectiveness ratio, the ICER, was over $200,000 per QALY adjusted life here at 6 months. It did go down to 100,000 upper QALY at 12 months and they felt that it would be cost effective at 2.1 years. One, a couple of the things that are concerns about this study is the unclear modeling of adverse events and limited reporting of sensitivity analyses. There were other cost effectiveness studies not performed in US populations. Most of them were good quality. For failed back surgery syndrome and for complex reasonable pain syndrome studies indicated that spinal cord stimulation combined with conventional management was cost-effective compared with conventional management alone and one in the failed back surgery syndrome group also looked at re-operation and spinal

cord stimulation was considered to be cost-effective related to that. Almost all of these trials extrapolated beyond what was available for clinical data as they reported it. And so it's unclear how some of those modeling assumptions would hold up. With longer term data in terms of longer term benefits and complications as well. Not all of them included the initial spinal cord stimulation trial or the implantation procedural cost. And so it's unclear to what extent those would have impacted their conclusions. And in some respects the effectiveness assumptions are not well articulated and are not clear. The only group that was not considered cost effective in the short term was in patients with peripheral diabetic, painful diabetic neuropathy. One good quality cost utility analysis concluded that it was not cost effective due to the substantial cost of the spinal cord stimulation but they did consider spinal cord stimulation more effective and that the cost effectiveness was sensitive to the baseline cost and balances. As usual, the applicability of the non-US studies to the US system is unclear.

So moving on to our summary of findings which are in the executive summary. When we look at chronic back pain. We have 2 different populations. In the crossover trials one again not specifically calling it chronic failed back surgery syndrome but chronic radiculopathy after back surgery. We see that for function and pain, the results were similar between spinal cord stimulation and sham and this was a burst type of spinal cord stimulation. We considered the evidence moderate for back pain and function and low for leg pain. Again, this is based on methodological criteria. We have no evidence either in shorter term or in longer term. For failed back surgery syndrome, again, we felt that the studies were insufficient to provide data for conclusion and that included a variety of frequencies that were evaluated versus sham stimulation. Turning now to patients with failed back surgery syndrome parallel trials in comparison of the conventional spinal cord stimulation with conventional medical management. In terms of responding having clinically meaningful improvement in back pain or leg pain. You can see that at 3 months and 6 months spinal cord stimulation was associated with was favored. compared to conventional medical management but strength of evidence was low for risk of bias reasons, lack of unknown consistency reasons as well as in precision. Low back pain scores were small and moderate depending on the time frame. Again, limited number of patients below at the short term leg pain scores appeared to be had a larger effect for moderate for both blood pain and back pain at 6 months across 2 trials with regard pain at 6 months across 2 trials. With regard to function none of them recorded patients who had clinically meaningful reduction in ODI scores. When we look at the scores themselves there were small improvements in ODI function across 2 trials the strength of evidence was low and in terms of the proportion of patients using opioids after the end of the 6 months the strength of evidence was low that there was a small increase. A strength of evidence for looking at mean morphine equivalence was not was insufficient. When we look at the, non-surgical refractory back pain study the parallel trial of that we see together there's a large increase in the proportion of patients who met a clinically important change in pain as well as the pain, as well as scores and if you look at the function and response to function, again, a large improvement across that one study for both functional responders as well as scores and as well as the portion of patients who stop or decrease opioid use. Again, insufficient evidence to look at mean morphine

equivalence. When we look at the parallel trials with re-operation the strength of evidence was insufficient to draw conclusions. If we look at peripheral, painful diabetic neuropathy in the parallel trials again we see that spinal cord stimulation is favored with increasing the likelihood of being a pain responder and also having better pain scores. With regard to opioid use, the proportion of patients still taking opioid use was similar. We look at the high frequency study just if we look at the high frequency comparison for this study we again see that there's a large increase in both the likelihood of pain response as well as pain scores at 3 months in 6 months. I would like to again comment that when we say no evidence under the 12 months, we're looking at the comparative evidence where there is still evidence that's comparing the 2 treatment groups. We do have, for, as an aside, since I've stopped here we do have an appendix that does describe the long-term effects after 6 months in studies that continued to follow up patients. But again, it's not comparative so we don't include it for strength of evidence here. For complex regional pain syndrome, again, we see that spinal cord stimulation conventional is favored at various time frames in terms of both improvement and pain scores and function scores. With regard to the high frequency comparison to sham, high frequency comparison to either the sham or the, the conventional medical management, the strength of evidence was insufficient to draw conclusions. So in harms, again, I need to point out that there is so much heterogeneity in the way things were classified and reported. There was lack of consistency in definitions and the severity of the adverse event. And I think the bottom line is that a spinal cord stimulate, a spinal cord stimulation related AEs are common, but there is a substantial range of event frequencies. Again, just looking again at some of the RCT information, there is a fairly large range again, keeping in mind small sample sizes contributing to some of those higher ranges. Similar withdrawal for adverse events up to 6 months across the RCTs. And then again across study design some of the more common ones with the higher ranges related to explantation, revision or replacement and removal for inadequate relief of pain. Any lead or electrode, replacement or revision and lead fracture failure, again, noting that the range is quite large from, from small to, to larger, less common again. Failure of the leads or migration of the leads, removal for infection, serious infection, unintentional durotomy and the least common again were revision, removal, replacement, for displacement or migration of the of the pulse generator again, serious infection reported within 30 days is very, very uncommon. And again, CSF length and tear are possible, fairly uncommon, and neurologic deficit has a bit of a range but still fairly uncommon. Again, cost-effectiveness, the 2 US-based studies come to opposite conclusions. Both have strengths, both have weaknesses. And non-US based studies, mostly were good quality and indicate that it is cost-effective compared with conventional medical management. But again, the limitations across all of these studies is the absence of long-term data, limited sensitivity analyses and unclear modeling of adverse events. Some considerations. For any patient recorded outcome especially when patients are not blinded to treatment one needs to consider the extent to which a placebo effect may at least partially impact the reported effect. And the portion of placebo response is due to a variety of things in that we call nonspecific incidental effects that would occur whether or not you had a treatment at all. And just again as a reminder that what we see is a treatment response is a combination of factors, some of which are not necessarily attributed to a given treatment. They may

very well be, but then there are these other considerations that need to be made. A couple of points, other considerations. The magnitude of effect varied depending on what comparator was used. The sham or conventional medical management that may be partly related to the comparator, it may be related to problems within the studies. There are a variety of different potential considerations. Nonetheless, this is what this is what we've noted. Again, effects being partially be due to lack of patient blinding, maybe some expectation of benefit or the nonspecific effects as well as the effect of the intervention. Again, there's so much heterogeneity across all the included. Studies. In terms of the populations, the types of spinal cord stimulation used, the components of conventional medical management were not generally described. And concurrent medications are generally not known. They weren't generally noted. And our clinical experts suggest that it's unclear how comparable or applicable some of the parameters used in the RCTs are to clinical practice. That there is likely substantial heterogeneity in what is used clinically and it's basically also geared towards the patient. Again, I would note substantial lack of precision in the effect estimates, especially when the effect sizes were very large for some of the outcomes. And that again calls into question the stability of the effect sizes and the estimates and that decreases our confidence in them. And again, consistency across single studies, we can't know what that is. Other considerations.

For this for the crossover trials, it's unclear to what extent. The lack of an adequate washout period between the spinal cord stimulation modes and sham may have impacted the results that we're seeing. It could have biased them to the null. It may not have. The potential carryover effects from the phases is really unclear because we don't have information to assess that. And part of it may also relate to the potential for breaking patient blinding. As we noted early on, the conventional spinal cord stimulation has sort of a tingling effect to what the patients may perceive. And if there was changing from a mode that was produced paresthesia to a mode like burst or higher frequency that did not produce paresthesia patients may have been able to discern what type of treatment or frequency they were getting. So the blinding for some of the modes of operation may have been not optimal. In crossover studies. Again, the impact on these is unclear. Many of the studies were underpowered to detect benefits, but also underpowered to detect uncommon or rare adverse events or differences in effectiveness. And again, so much heterogeneity and classification, description of the adverse events is noted. Terms of applicability I think we can say that in enrolled populations included those that had failed conventional medical management and they were selected by multidisciplinary team that it included some form of psychological evaluation, although specific instruments, thresholds or standards were not described. And they had a positive response to the trial for spinal cord stimulation prior to permanent implantation. Again, definitions and criteria for some of the diagnosis for failed back surgery syndrome or the non-surgical refractory back pain are not well described. And the economic study limitations we've already discussed. So I will. I will stop there.

Josh Morse Thank you, Andrea.

Andrea Skelly You want me to stop sharing?

Josh Morse You're probably gonna wanna leave those up. Dr. Rege.

Sheila Rege I'm having trouble. Sorry, I'm having a trouble if I turn video on and stuff. I tried, I got booted off. I'm back. Can you hear me?

Andrea Skelly Yes.

Josh Morse Yes, we can hear you.

Sheila Rege Okay, good. Ready for, question. At this time.

Andrea, thank you for a excellent presentation.

Andrea Skelly Of course.

Janna Friedly And I can help facilitate since Sheila, I don't know if you can see, but Tony has his hand up.

Sheila Rege Yeah, I can’t see hands. So yeah, thank you.

Tony Yen Oh. Have a question for our vendor. On 57 of your presentation. Where would you see the Kapural study 2022 being? On that summary because it I'm trying to make sure I see everything.

Andrea Skelly Okay, slide 57, sorry. Okay, so this one.

Tony Yen Yeah. Well, sorry, yeah, sorry, that one. My number brings different from yours. Yeah, that one. With the Okay.

Andrea Skelly Okay, this one. This one is only the crossover trials. So it's the Kapural study is not represented on this slide.

Tony Yen Okay.

Andrea Skelly It is represented. The parallel trials.

Erika Brodt That slide right there, slide 60. Or maybe you're, yeah. The non-surgical refractory.

Tony Yen I apologize, can you point that out? To me is it this entire area or some more than that? Okay.

Andrea Skelly Yeah, so this is slide 60. And the only study in non-surgical refractory back pain is the Kapural study. High frequency versus conventional medical management.

Tony Yen Okay, thank you for pointing that out for me. I appreciate it.

Andrea Skelly Yeah, no problem. I know I tend to go kinda fast.

Janna Friedly Jonathan.

Sheila Rege Jonathan, you have your hand up? I can now see him finally.

Jonathan Sham Thanks so much. I had a question for our expert in the context of this data being presented. Could you give us a sense of what kind of the natural course of this treatment is over the long term? The reason why I ask is we have a lot of data, 3, 6, 3, 6, 12 months, even 24 months in some of the trials. I'm trying to put that into context for some of the data presented by the AMD, particularly the 2022 journal of patient safety article showing really high rates of removal of these devices is that part of just the standard path of to patients just at a certain time when get these removed, are they used for many many years. Can give us a sense so we can put that data into context.

Joe Strunk Yeah, so it's a good question. It is, there are patients that do have explanations as you can see from the, from the data, but from my clinical experience, patients especially early on when well selected at the very beginning those do not tend to go towards, towards explantation and often those that could be exploited might be someone who has had a lead migration that wasn't, wasn't able to be successfully remediated. And then there are even patients, that do have enough resolution of their pain that they no longer have pain in those also get explanted as well.

Jonathan Sham So I guess it's a follow up to that. Could you just. Maybe give us some insight. I'm trying to figure out the discordance between really good safety profiles reported in and some of the trials and most of the trials, 5.6% infection rate, you know, less sub 10% lead migration rate. I'm trying to kind of unified that with the nearly, you know, 50% rate of removal when you're in relative terms in that Australian paper can you give us any inside of why you think that might be.

Joe Strunk I guess, can you clarify the question just a little? I feel like I lost what the exact.

Jonathan Sham So in much of the data that's been reviewed again, there's a question about safety. And just understanding. Indications for removal. It seems like the data, is fairly positive as far as safety, when we talk about infection, lead migration, we're talking about sub 10% rates of, of those complications. However in the data that was presented earlier out of the Journal of Patient Safety, 2022 out of Australia essentially over the past 6 years. About 20,000 been put in and 10,000 have been taken out. Is that I'm just trying to be out is that part of just the natural flow of these is that some sort of unreported complication we're not seeing is that because these are older units that are, they don't work anymore and kind of an inflection point of the treatment. I'm just trying to get a sense of why. That data might be so starkly different.

Joe Strunk Yeah.

Jonathan Sham Then what's been presented.

Joe Strunk So, not every country does a percutaneous trial. So that's definitely something to consider selection is really important in these patient, in this patient population. If we implant every patient that just fails to get if we just offer spinal cord stimulation to from almost every patient that walks in our clinic doors, a huge chunk of those patients would fail. It's imperative that we select those very closely. And so, and appropriately, so I think that could reflect some of that difference in what we see in trials done here in the US. And the clinic practice that we have versus the data that you're seeing there.

Jonathan Sham Thanks.

Janna Friedly I think Conor was next.

Conor Kleweno Yeah, quick question for the expert on a similar note. You know, some of the complications, I was wondering if you could comment are those on from the removal. So from my standpoint, orthopedic surgeon putting stuff in sometimes easier than taking it out. And so like, durotomy and, a, a, a hematoma, are those, is your sense is that from the removal process or? You know, is there more of a risk of putting them in or more of a risk of taking them out when we think about these?

Joe Strunk So. So removal tends to be a fairly simple process, but again, we're dealing with the Naraxis, which is a very precious real estate. Durotomy that's most likely going to occur during placement because of the technique that requires placement for these devices. And so I think that it's most likely that these are complications around implantation or lead migration after implantation, not necessarily pulling, pulling these out and then having complications afterwards. I think it's fair to say though that there are some patients that aren't amenable to percutaneous placement. And do end up with paddle leads and so those require like laminatomy. And so that is a higher risk surgical population.

Janna Friedly And Kristoff?

Sheila Rege I saw, yeah, thank you.

Christoph Lee Yeah. Just a question for our, local expert again. How common is high frequency? SCS versus traditional SCS, in terms of practices in Washington right now. Is, is the field going towards high frequency therapy or is the majority of SCS still conventional?

Joe Strunk Well, I obviously can't pull the entire Washington state pain practice in this moment, but I know that our practice specifically is much more in line with high frequency stimulation at my institution and from those that I've worked with and trained in that have gone out into practice they're really the mainstream is high frequency stimulation that is what is predominantly being done.

Christoph Lee Thanks for the helpful as some of the data slightly differs between 2. Thank you.

Joe Strunk And that gets back again to this question of mechanisms and where we think about, we'll talk about wall and melzach, and the gate theory and what we're really trying to understand we're seeing such changes. rapidly within the field is that we're changing what we're actually stimulating instead of really stimulating the dorsal columns maybe we're moving over and actually evidence is showing maybe it's actually more like the dorsal horns and that's where we're getting in inhibition of those pain signals and that is partly why the field has moved in that direction because of those that successful, those successful results.

Sheila Rege Janna, go ahead. I can't remember who's next. I see 3 or 3 hands up.

Janna Friedly I think Laurie was next.

Laurie Mischley Yeah, my question is for the clinical expert also. I mean, it, and the distinction between risk of bias and bias? And there's been some downgrading for things that weren't included in some of these manuscripts and. my question has to do with how we screen for appropriate people for this procedure. I mean, and what are the things that we might find in that psych eval or what are those comorbidities that might shift these outcomes? I mean, I we talking about a neglected sentence in a paper or is that a real opportunity to skew that data in a particular direction? Like what would be the concern about not including some of the psych eval stuff or some of the screening procedures.

Joe Strunk So this is really good question. There's, there is good clinical guidance in from various societies but the one that I immediately think about is the what came out of Azra and that really looks at very comprehensive evaluation looking for like active psychosis, ongoing substance use disorder, poorly controlled depression, high risk, psychosocial factors, that would either impair the patient from follow-up and getting good care and, and even is the patient going to be able to use the device and make sure to charge it and things like that. We're looking at, how is this patient someone that is likely to succeed with this therapy because we have taken care of all of those other neural cognitive areas. And that's just part of it of standard practice in these multidisciplinary practices. Is that answer your question?

Laurie Mischley It does. So when you personally read a manuscript that does not make this statement, a psychological evaluation was done. Do that is that a red flag for you that you can't trust the data now?

Joe Strunk I would say that these patients, it's something I always want to make sure that that that occurs that the patients are evaluated and as far as my understanding is that is by far the, the, the standard of care throughout all of these if these trials though I can't speak with, with you know 100% clarity there's a lot of various trials here, but it would be something that, of course, you would want to consider heavily. If there was, if you were concerned that this kind of data was admitted and that they were not taken through that rigorous process.

Laurie Mischely But there's also a good chance that it was just a sentence that was left out and that is part of the routine protocol for.

Joe Strunk Yeah, and and again it's something that's required by all major all insurers across all the states except Washington.

Janna Friedly And Chris was next.

Chris Hearne I have a question for our evidence vendor. One of the public commenters presented some data from a couple of studies that at least as they were presented to us seemed to show some good outcomes. I think it was the EVOKE, the Senza and the Petersen in JAMA Neurology and I'm, I'm sorry if you addressed this in your presentation. I may have missed it, but I wonder if you could comment on why that those studies weren't included in the evidence report.

Andrea Skelly Yes, yes, I would be happy to. Those studies compared different types of spinal cord stimulation to another type of spinal cord stimulation. So they did not, did not meet our inclusion criteria. One of the studies that was brought up I think it actually may have been Dr. Strunk. El-Dabe 2021 it was in patients who were had previous experience with spinal cord stimulator so that was why it was excluded. But we did take a look very seriously at all of the studies suggested by the public commenters. And where we could find citations from the presentations today. We also tried to look very carefully to make sure that we had not missed anything that met our inclusion criteria. And that's one of the big, big a concern from the public commenters throughout the process has been lack of comparison of different types of spinal cord stimulation or modes of stimulation. And, and there's a lot in the appendix, you can look up any of the studies and we have that information. Erika, did you have something to add to that?

Erika Brodt Yeah, I just I just wanted to clarify that in the presentation that the Sorry, that the public commenters made. I think they cited 4 studies that had, you know, best evidence and some they said we didn't include. Andrea is correct in that 2 of them, you know, one being the EVOKE, I can't remember the other one. They compared things like closed loop versus open loop and different types of spinal cord stimulation, which As Andrea mentioned, you know, after figuring out what kind of scope the HTCC really wanted, those were not considered comparisons of interest. So they were excluded. However, we did include some that they said we did not include. For instance, the Petersen, Senza the, the one in peripheral or painful diabetic neural that that was included that is in there. We didn't include as Andrea said the data past 6 months as comparative data because it's not comparative so it didn't undergo the strength of evidence rating process, but it is. In the appendix and it is described in the report as well. So as far as those 4 go to did meet our inclusion and were included, 2 did not meet our inclusion and were excluded. Does that help?

Chris Hearne Yes, that's very helpful.

Sheila Rege We still have Jonathan and John, I don't know who was first.

Jonathan Sham I think John was first, but could I just ask a follow up? Cause it pertains to this exact point. Is that okay, John? Great. So just on the point about excluding, because I guess this is really central to our discussion here and perhaps Joe, you can comment on this. So for example, the McKale study looking at open versus closed loop was excluded because it was considered non comparative. Can you give us some perspective? I guess why, were those 2 arms chosen was it because you know, open or sorry, was closed or sorry which one was the, the not, let's see here. Yes. Was it because open was already viewed to be obsolete Like, is that why it was chosen to be the control or was it truly equipoise between the 2 in the field, I think it's really important when we're determining whether or not in our minds to exclude it from.

Joe Strunk So your question is looking at those 2 comparators. The open is kind of the standard of care and the novel treatment with closed loop is, it's new technology to technology that would allow for sensing of the actual action potentials as they're propagating and then a tailoring of that. So it was, it was designed as a, will take the standard and then we will see if this technology results in meaningful improvement. Is that?

Jonathan Sham Okay, thanks. That's helpful.

Sheila Rege John.

Josh Morse Gonna pause for a minute and just remind everybody. We cannot use the chat function in these meetings. If you have information that you would like us to share. with the group, it needs to be public and we can provide that on our websites. I apologize for the complications with the technology. It's very difficult to manage and I know how hard it is to do that. So I apologize for the interruption. Thank you.

Sheila Rege Thank you, Josh. Dr. Bramhall?

John Bramhall Yeah, so a couple of questions for Dr. Strunk. Thank you for being here. Okay, during the sort of public, testimony there was a comment made, which was testimony from people who are pretty evangelical about the technique and we're critical of some of the older techniques that we used in the older data and we're starting the, the current way of performing this procedure that's reported in the current literature, literature is it's the point of coverage and, and the second thing that was, was observed by one of the presenters was that you shouldn't trust the information you should trust medical judgment and I, I sounds very flat on the face of it and I sort of understand what he was saying. But what I want to get from you, Joe is if you wouldn't mind, I need a mental image. It seems to me like there's a population of patients in clinical practice in in your world. There's a group of patients who've, who've got chronic pain of one specific ideology of 3 that have failed you know conventional modalities and they're just having a miserable life and they come to you the thinking, therapy, SCS, to intervene to, save their life. And what's done, correct me if I'm wrong, is a trial, that, that, that I imagine consists of a basic epidural placement of a, of a lead to a particular defined anatomic position.

Joe Strunk That's correct.

John Bramhall The depth of insertion perhaps and then, there's, there's a, twiddling of dials there's, there's a, there's a sort of a optimization of the frequency of the of the stimulus and a frequency of the pulse you know, 4 4 hertz at 10 kilohertz or whatever it may be. And what I'm, what I'm trying to sort of understand is, so if you It if there's no effect at all those people don't go on and get a permanent implantation I would assume fine but if there is an effect do these people clinically do they get an immediate cessation of the pain that's plagued them for all those years. If the frequency and pulse interventions are the appropriate ones and, and, and if that's so that then That is then the decision sort of point at which you say, OK, let's go on implant an electro permanently at this depth or in this for a and, and we'll use these, these frequencies and away we go. ,Is that? I know it's a little colorful, but it's that that basically what, what is going on clinically?

Joe Strunk Yeah, so clinically when and a patient that may end up it in down this pathway comes to our clinic and they get evaluated and we get to the point where we've exhausted all other methodologies and we consider them for spinal cord simulation they will go through that trial period, which as you described would involve an epidural placement, a percutaneous placement under local anesthesia light sedation it to place those leads into that epidural space and then they undergo a trial somewhere between minimum of 3 days, but it's usually 5 to 10 days of trial. And in the cla, in the classic, what we'll call classic, in that the older model of conventional spun upward stim because it was paresthesia based patients would tend to get a benefit quite quickly. Nearly instantaneously. The technology has Changed and with now what we call sub perception or high frequency or burst, these ones that patients don't have that sensation that's almost from their perspective, it's almost like it's replacing the painful stimulus. They may take several days and that's probably reflective of the fact that we're dealing with a different mechanisms. And instead of that more classic gate control theory where we're trying to turn off those A deltas and those C fibers were by activating those A betas, we now are dealing with inner neurons that are now trying to downregulate that. We're looking at whatever, gene expression or other modality or other clinical mechanisms are occurring. And so that does take some time and there is some trial of moving through several different programs as you'd mentioned the, the fiddly bits, you know, making adjustments to try and optimize that patient and then if they do have that reduction the demonstrates good results and they do go on to placement. And then there's continued follow-up with those patients and sometimes future programming at time points beyond just that you know you you've had them plant see you later. They often come back and have relationships with the with the programmers and make adjustments to their stimulus because it or to their programs because it can change and adapt. Does that answer your question.

John Bramhall Yes, it does. It's very helpful. And so the, the, it's a little curious that the, the outdated paresthesia the, the SCS that generated paresthesia that were sensed by the patients seems to have distorted the data perhaps but I'm curious it's so historically let's say 5 6 years ago, systems that generated a paresthesic kind of response that the patient was aware of that that, that also led to a subject decrease in in quote pain for those patients see even though the mechanisms by which it would have been observed and documented is a little confusing because of the paresthesia. Nevertheless, is it true that that even with that technology the patients would assert that they had less pain. And now we have something that's a little bit more subtle. We have a high frequency stimulus which isn't perceived which then also leads in some cases to a subjective sense of decreased pain and, and that it's only those patients that go forward and get the implantation of, of a permanent, permanent device.

Joe Strunk Yes, they're, I mean, patients are unique and we still have, there are patients that have been responders to paresthesia based techniques and that continue to respond to it but we're finding that the, the, when we compare conventional or paresthesia base techniques to these higher frequencies those patients are responding even more robustly, the responder rate is higher. The, the pain control is better. And so it's likely That some patients have, the theory is that patients Get benefits from different technology because the pain, pain pathway is complex and we, we aren't able to lock down one specific mechanisms for everyone.

John Bramhall Okay. Thank you.

Joe Strunk And then there are modalities that even choose to use both. That we'll use alternating from conventional and and sub-perception as well.

Sheila Rege I think Janna had a hand up.

Janna Friedly Yeah, it was just in follow up. So that and I think you just. Sort of answered it. But I'm, I'm, trying to reconcile in my mind. There are some studies that show that high frequency is better than low frequency and then there were, you know, some that show that patients prefer the low frequency over the high frequency. And I've been really trying to reconcile. And, and then make sure that that I understand the differences between those different techniques because that seems to be at the heart of what, what the concerns are with the data that we're looking at is that you know, the age-old concern that the trials that are negative are using technology that we don't that's not appropriate or the procedure itself is not appropriate. And so I want to make sure I understand what you know, practically speaking, if you were to say what the appropriate technology is to be used. What would that range be? What, what would be an appropriate range of technologies that you think would be needed first final course stimulation in general? Does that make sense?

Joe Strunk Yeah. So. I wish that we had the crystal ball to predict what every patient would need, but the reality is that we have evidence that many patients respond to par, sub, sub, sub, paresthesia, our sub-perception and others respond to paresthesia And so we try to target with the therapy that seems that is most effective for each patient. And so. I think that everyone is, is unique and we have to use everything in our, our momentarium to try and, and address that. And as technology has changed, we are getting to the place where we can offer a variety of, of programming options while a delivering a range of with, with a single device so the hopefully we continue to evolve in the technology and that we can continue to offer unique therapies that are individualized to each patient. And I don't think I could say that paresthesia don't work for first for everyone and or high frequency doesn't work for everyone.
I think there's going to be a range.

Janna Friedly But so clarify then for me, because again, this came up earlier about the Hara study and, that that, intervention was deemed to be, you know, no difference than, than a placebo. Sham. So, so there's, and not, something that is used here in the United States. So I'm just trying to understand what, what, what are the parameters that, that are around this because certainly you wouldn't want people using an intervention that is not effective, right? So that's what I'm just trying to understand.

Joe Strunk Yeah, so what I would say is that the I would use the FDA approved waveforms that have evidence in patients. And rely on the, the clinical experts that are actually. I'm treating those patients to help work through that therapy with them. I think that beyond just thinking Hara, not providing an effective treatment the unfortunate situation with Hara is that those patients, well, in order to enable that complete blinding they weren't allowed to do any sort of therapy adjustments and so we also have a, a non-individualized therapy for that patient as well. So not only was it a waveform from that we don't use, it was not even allowing that patient to make any adjustments to the therapy and so that's what's partly key to delivering SCS to patients is working with them to find programs that do work.

Janna Friedly Thanks. I think Clint was next. Sorry.

Clint Daniels Yeah, thank you.

Josh Morse Yeah, can I, today interrupt for just a sec. We are overdue for a break. We did start an hour later today than we normally start, so it does feel a little later than typical because of that, but I, this may not be a great break point because we have 2 hands up now, but I do think we need to move to that soon. But I'll leave that to the chair vice chair to decide. Thank you.

Janna Friedly What if it's okay, why don't we, just handle the last 2 questions and then we'll move to break. Clint.

Clint Daniels Yes, thank you. So, I'm hearing that the newer devices do have the ability to tailor toward it to the patient's needs. Do the new devices have the ability to do both the conventional and the high frequency? Or those separate devices that you would consider.

Joe Strunk There are some devices that do have that capability, not every, not every device can offer every therapy.

Janna Friedly And Jonathan.

Jonathan Sham Yeah, just one last question for, Andrea and team. I was hoping you just comment on the Peterson JAMA Neurology paper 2021. That you guys looked at which at least on the face of it has you know, really strong signal as far as efficacy, but was deemed to be of low quality. It's on page 161 of the final report. I was just wondering if you could take us through that. Cause it is one that both, both was mentioned in the report was also mentioned by several of the speakers previously.

Andrea Skelly So you're wanting to know about the risk of bias for Peterson? Is that what you're asking?

Jonathan Sham Well, that's part of it, I suppose, but the quality of evidence was team to be low. And so I'm sure bias was, a large component of that.

Andrea Skelly Yeah, so we can do 2 things and I will have Erika also jump in. She was key to working with this section. I need to pull up my report which is challenge for sharing my screen here.

Jonathan Sham It's section 5.1.6 if that's helpful.

Andrea Skelly Yeah, Got my little tiny laptop screen up here. I'm having trouble moving.

Erika Brodt Yeah, so this study was deemed to be modern at moderate risk a bias, so fair quality. So it wasn't a bad study as far as risk of bias goes, which you know, Andrea talked, there's often confusion about, you know, the risk of bias for an individual study versus how we rate overall strength of evidence. And that's just one component that we consider. So for this one, it looks like, you know, one of the problems with a lot of these studies is that you had this imprecision. So when you look at the confidence intervals, it's pretty wide which calls into question the effect estimate cause if it if it varies between a small and a large effect. It's hard to know how much you can trust that that point estimate. So that's part of why we downgrade it, one for risk of bias, one for imprecision. And you know it was the only study in the high frequency compared with conventional management. Unfortunately, so there weren't a lot out there that compared the high frequency to conventional medical management. That was not a common comparator.

Jonathan Sham So then perhaps the most important follow up question is for Joe. You know, the 9, 5% comps interval was 6 to 25 on the, you know, VSNRS scale. Is a reduction of 6, clinically significant?

Joe Strunk On the scale, sorry, I wanna make sure I've got the scale. Are you talking about a scale of 0, 0 to 10? Are you? You're talking about a 0 to 100, correct?

Jonathan Sham So I'm just looking at the evidence report, section 5.1.6. Looking at the Peterson trial. I don't know if you have the ability to bring that up, Andrea.

Joe Strunk Give me 1 second.

Jonathan Sham But essentially it's essentially lower street pain responders, reduction low quality pain on the VAS, NRS, 0 to 10 scales what it says and essentially shows a strong effect with the 95% confidence interval being from 6 to 25. And so what's what we were just told was, well, that's that imprecision is decreasing the quality of evidence, the strength of evidence. And so I guess my question is even at the lowest end of that confidence interval 6 is that clinically significant?

Janna Friedly 6 out of a hundred is under the VAS.

Jonathan Sham Six.

Erika Brody Well. Are you?

Jonathan Sham Right.

Andrea Skelly Are you looking at the pain responders? Are you looking at the?

Erika Brodt Yeah, I think you're looking at the pain responders. It's a risk ratio.

Jonathan Sham Yes.

Erika Brodt Not a mean difference.

Andrea Skelly So the first part of table.

Jonathan Sham So I'm just reading. I'm happy to share the report. I'm looking at the page.

Joe Strunk Yeah.

Jonathan Sham Is page 161. I don't know if you ever going to bring that up. I'm happy to share as well. I guess what I'm getting in is. You know, when I see, when I see a wide range, at least to me, it's not necessarily a knock on the trial. I mean, yeah, like it just it It's be we're downgrading the study or the study has been downgraded because of that and so I'm trying to say under the worst case scenario should we, should we be discounting this data given the wide range? That's the point I'm getting at. And so again, I'm happy to share what I'm looking at, but.

Andrea Skelly Yeah, I see which tape I see what you're looking at, at page 161 and there's a risk ratio of 12.1.6 with a confidence interval of 5.93 to 24.9. So both the low end and the high end are consistent with a large.

Jonathan Sham Okay. Yeah.

Andrea Skelly Effect, a substantial effect. The thing is that in in general when you have that large confidence interval even though your conclusion about whether it's large or extra large, is not going to change. That's still a very large confidence interval and suggests imprecision.

Jonathan Sham Okay.

Conor Kleweno But I think Jonathan your point is if we're throwing hand grenades, if you're pretty close, it still is a big deal.

Jonathan Sham I mean, to me a risk ratio of 6. I mean.

Andrea Skelly That's huge.

Jonathan Sham Relative risk of 6, and anything that I do in my work is that's like bigger than anything I, you know, ever studies. So I'm showing you a sense of in this field is relative risk of 6 on the scale. Something that we need to look at is it kind of be significant. Would that be within the MCID? I mean, that's really what we care about.

Joe Strunk And I think the answer to your question is yes, it is clinically significant. I'm struggling to make sure that I'm looking at the right data cause I wanna make sure I answer your question correctly. So you're looking at.

Jonathan Sham It is possible to share the evidence report directly. I'm happy to do so if we're not out if one of the.

Andrea Skelly Yeah, I think I have to stop sharing my presentation. And try to figure out how to present.

Jonathan Sham Would you be okay if I just shared this?

Andrea Skelly There we go. Yeah.

Jonathan Sham So, so again, this is what I'm looking at relative risk 12, you know, confidence interval of 6 to 25. I mean, yeah. So I guess I'm trying to put that into context into other things that are treated in this field. Again, I'm used to much smaller.

Joe Strunk Confidence intervals?

Jonathan Sham Well, no, no, I, well, kind of, intervals aside, the relative risks. I'm saying like this is, you know.

Conor Kleweno Massive effect.

Jonathan Sham It's a massive effect.

Joe Strunk Yeah. Yes.

Jonathan Sham But the reason why what we just explained was the reason for this being low was again, I think, and please correct me wrong, Andrea There's 1 point for bias and 1 point for in precision, is that right?

Andrea Skelly And we don't know what the consistency across similar trials would be. So all of those go into the concern that our confidence is low. So in other words, if there was another trial.

Jonathan Sham Got it.

Andrea Skelly Of the same technology in the same type of patient population, we don't know whether it would consistently show that relative risk of 6 or 12 or whatever it is.

Jonathan Sham Got it. To the.

Andrea Skelly And so it's a combination of things that the judgment into low goes into.

Jonathan Sham Got it. I think it's just important for me to understand. So it's just because this is the only trial. Just looking at the specific question, is that right? That that goes into

Andrea Skelly Well, okay, randomized control trials start out at high. We downgrade one for risk a bias. We downgrade one for the imprecision. So that's already from high down to moderate to low. Then if you add in the lack of lack of we don't know whether or not another trial would show the same thing. We're just saying we're not really confident that when we get more trials that it's going to be so it's not just the risk of bias or just the imprecision. It's, It's the whole shebang.

Jonathan Sham Perfect. Very helpful. Thank you.

Erika Brodt Yeah. Cause, cause again, if I can clarify strength of evidence is, you know, if we were to have more evidence would this stay the same? Like how confident are we this no matter how much more evidence we get you know, this is the effect we're going to see. And with one study, it's just, we can't. It's low. We don't, you know, we can't know that.

Joe Strunk This. Alright.

Laurie Mischley On this, oh sorry, go ahead. On this exact point though, can I just clarify Andrea that when you call something wide confidence interval or narrow that's subjective, not objective. Right, is there a criteria by which you start calling something wide?

Andrea Skelly We've wrestled with that for many, many years and larger minds than mine have as well. There is no strict cutoff. Part of it is gestalt. Part of it is looking at what the range is. You know, across things. You know, as an epidemiologist, when we see a relative risk of over 2. We always are curious because most things don't give us that higher risk ratio. And looking at the confidence in, while it's not an exact, you know, you must be 3 points in one way or the other of the point in one way or the other of the point estimate. But if you're going from 5 to 3 times that, twice that that's, that's kind of a gestalt.

Janna Friedly I think we are overdue for a break. So we, we should, stop the conversation now and take a break. Right, Josh?

Josh Morse Yeah, we're gonna break for 15. Per Dr. Rege, we'll call that lunch. Does that work for you, Dr. Friedly?

Janna Friedly Okay. Yeah. So back at.

Josh Morse 1:25.

Janna Friedly 1:25. Yup.

Josh Morse Great. Thank you. Andrea, your camera still on if you wanna turn that off for the break, your call. Thank you.

Andrea Skelly Oh, oh, okay, thank you. Yeah, thank you. Sorry.

Sheila Rege I think this is time. Is everybody here? If you are here, turn your video on just so we can see you and Val and us will try and figure out if we have committee members here. John, Laurie?

Laurie Mischley Back.

Sheila Rege Hi Laurie, thank you. Chris. Oh no, I'm sorry, I'm nothing good here. So just John is who I'm not seeing. Are you seeing everybody else, Val?

Val Hamann Right. Yes.

Sheila Rege Yeah, let's get started. I think, sorry about my computer problems. I see a question from Tony.

Tony Yen I was hoping to carry on the discussion about the Peterson study. I thought that Cochrane comments that were pointed out by the agency medical directors were kind of compelling to me in terms of how I actually view that study as well. So on a page 13 of the agencies report. The agency medical director's report if you guys want to look at that for yourself.

Sheila Rege Can we try and pull those up? Just have the whole PDF available.

Josh Morse Is that from Dr. Chen's presentation?

Tony Yen From Dr. Chen's presentation. It was page 13 of his presentation. I thought that, those comments about the Peterson, 2021 study was. I found that to be very useful.

Josh Morse Yeah, I should be able to get that here in just a moment.

Christopher Chen Thank you, Tony. I just want to also just clarify this. The quote was from the, from analysis from the evidence vendors rather than the Cochrane review.

Tony Yen Oh, I apologize. I misspoke I interpreted that and correctly.

Christpher Chen It's one to clarify. Yeah, sorry, I didn't, I didn't type that reference on there. So my fault.

Josh Morse Thank you, John.

Janna Friedly This was taken from the study itself and in the disclosures, I believe, right? Those, this quote?

Erika Brodt That's correct.

Janna Friedly Yeah, and so Tony to your point, I think this is where I struggle the most, I think, with this particular study and some of the other studies, but typically when we think about, industry sponsored studies it's there are many industry sponsored studies and they are high quality and, you know, very, very well conducted. One of the challenges is when there's no separation whatsoever between the study the funding for the study and the, the conduct of the study and the analysis and the data interpretation and results. So it introduces to me another level of bias that I makes it a little bit challenging on this side of things to understand what the impact of that is on the results. So there's a less transparency and some concern, especially when you see results that are so far on, one side compared to all the others and, and really thinking about any trial for any painful condition, this, the results suggest that this is wildly effective. And combining that with the design of the study where the control group has you know a really a 0, very little chance of any improvement given that they're getting the treatment that they have already proven doesn't work. It adds, adds to it. So it is it's very challenging to know how to interpret this data. For me.

Tony Yen Yeah.

Janna Friedly Conor.

Conor Kleweno Yeah, just to follow up with, that come from Janna, you know, it does, it is always a difficult thing. So I guess I have a question for the expert. You know, it seems like there's the camp of, you know, we have a lot of data it doesn't it's not clear there's some issues with some of the data and then we heard a lot of compelling public comments about well you know we figured out how to modulate this better and it's much better and it's gonna have much more efficacy. And you know, from the literature that we have, we have some that's comparing one version versus the other and in this Peterson study that seems like the only one that had the intervention versus medical management. And part of my impression of what the discussion is that this, technology is still in sort of its, you know, high, slope of learning curve.
And so they're learning how to modulate a better, you're learning how to interact with patients and make some adjustments, etc. And so I guess my first question for you is, is that true? Is this still a technology on a steep learning curve and investigation curve and then 2 would we expect to see some additional studies like the Peterson study that maybe decoupled from the industry sponsor because sometimes the first studies in a new technology are by the industry because they have the money and they have the incentive to do it. But after that, once it becomes available, it's much more easy from a clinical researcher standpoint to reproduce something once it's more readily available.

Joe Strunk So I think, it's hard for me to answer that again with that with complete clarity, but what our hope is and what we would like to see is that that future trials do continue to to come out that are, you know, not industry sponsored that we could teach to show that but that's, that's something that I can't know the future of. But if history is bears any indication of what you know the future might hold often as you mentioned once something can be used more widely and then there is an opportunity for, for others to spend money on it then then that can happen and I do think that when we just look at what, what we used to have being paresthesia based techniques and that was pretty much it and then that really rapid change in the last. 8 years or so. I would agree that that this is it we're in a very rapid period of change where different therapies, modalities that are targeting different mechanisms are being trialed.

Conor Kleweno Yeah, I mean, my concerns are less about the bias. I think we've, with that at all, it's more about, you know, where we are in that curve. Have you figured it out? But can you reproduce the Peterson study easily or you know, is that gonna happen or is it? Or is it still needs some more learning more technology, just more research before we can more reproducibly recreate that?

Joe Strunk Well, I think we have the data from the Peterson study and then the follow-up data from there that does show the durability. I can't speak to what data doesn't exist. But, based on the effect size and how impactful this has been. I would say that it would we would, we're likely to continue to see this field continue to study this more to understand are there other ways that we can improve on what we already have. So I do think research will continue to come out and it will continue to support that. At least that's the hope.

Sheila Rege: Hi, I had my hand up and accidentally brought it down. Sorry, John. And Tony, I hope everybody's found the appendices on kind of the analysis from our vendor on kind of conflicts and stuff. And I really struggle because there's some that are so positive. And then there's some that just are not and just trying to, trying to wrap my head around it. And, and also, how popular this is, how much we've not had a meeting with so much public testimony. So there is, you know, pain is a horrible thing. But looking at what on page 45, 191, it says on Peterson, research support which most academics get from the companies consultant for Abbott, Medtronic, you know, a bunch of them and stock options for others. So that and I don't know how to figure that out and then the other thing I'm trying to wrap my head around is the, the risk. If you put this in and it doesn't charge and it has to be replaced, I mean, how often that happens, how often these things need to be changed out and the risk of that, I mean, is it every 2 or 3 years? Is it? Does it last for 10 years? I mean, that's something that I'd be interested, Dr. Strunk and you, you helping me out with. When you look at the literature, do you kind of look and say, oh, it's Peterson because he's, you know. We've heard of talk in meetings and we talk for those companies. Or, if he really respected in the field and, you know, kind of that, you've got other research that, that's really believable. And second, how often are you thinking to replace them? Is it is it hard for the patient to constantly go in and replace it and the cost. Thanks.

Joe Strunk: So in regards to Peterson, well I would just let their body of work stand for them and you know Lancet Neurology and you know, like that's the best way I can, you know, they're peer reviewed publications, that's the best way I can speak to their, their status within, within the, the medical community and what work they're able to produce. In terms of like replacements, the, the rechargeable devices do have quite lengthy life expectancies 10 to 25 years whereas the more conventional last for more along lines of 5 to like 3 to 7 something like that so they're more replacements for the non-rechargeable than for the rechargeable systems. But my experience has not been that we are replacing devices for anything really with the exception of end of, end of life for the battery.

Sheila Rege: Is that every 2 years?

Joe Strunk: No.

Sheila Rege: For a replacement?

Joe Strunk: For a for a rechargeable device that's somewhere over, over a decade usually and for a non-rechargeable device that's more on the terms of under a decade something like 5.

Sheila Rege: Thank you. Next question. I think it was John, but was this Chris to Christoph?

John Bramhall Yeah, I just want you to, I just wanted to sort of add by then actually on what Conor was saying about the Where are we on the the curve of development of this technology? And the reason the reason that and you know I have the same question is that Hara paper which, which we heard about at the beginning of the presentations was fairly convincing. It's a 1920. It's a, it's a 2022 paper government sponsored data that showed no benefit. And then, we have to make our own minds up about the benefits or non-benefits of the data that's in that paper but we were invited to just reject that because oh, that's not what we do anymore. We no one does that. And so it's, to me, it's a bit of a problem. You know, 19, sorry, 19, a 2022 paper. It's only 2 years old. It's in reputable journal and it's sponsored by a government agency and yet we're sort of being invited to just dismiss that as being medieval. That's not what we do. So it's the same question that Conor asked, well, we do what we do now today. What are we going to be doing next year? What are we going to be doing the year after that? And is there a trajectory and you know, why is the, why is this so much variability in the response? I don't want to ask a naive question. I understand that if the frequency modulation is set just right, you're going to get the benefit of that frequency modulation. But it does seem that there's been a paradigm shift. In the technology, so we've gone from a paresthesia based sort of system where you do low frequency and the patient's aware of it and they get a response subjectively which is then recorded. Because it's difficult to get really objective measurements that are not subjecting in their basis with, with, with pain right and, and, and, and then the technology shifts oh it's not a mechanism that involves gate theory and paresthesia. It's a it's a different mechanism and we're doing it in a different fibers and a different frequency domain. I get that and I don't, I don't dispute that, that may in fact be what's happening but it just seems that we're on rather unsettled ground at the moment over the last, say, 5 to 10 year period. So I don't I don't want to assert that as being a major obstacle to funding of this or approval or anything like that. I just I just represent it as a problem that we're on, on a trajectory somewhere, we're not quite sure where that that's going to lead and where we are on it.

Janna Friedly Christoph?

Christoph Lee Yeah, yeah, I just wanted to point out when we're talking about Peterson, that, that at least specific to diabetic neuropathy so I don't know if some of their ability has to do with the patient populations because we were looking at different clinical indications and pain syndromes. But that was specific to diabetic peripheral neuropathy patients. Beyond that, I, you know, I still have this question in my mind as, as John and others have alluded to about. How much is spinal cord stimulation as, as a whole standard of care or considered standard care for refractory pain syndromes. Is it in your toolbox? As a pain specialist, Joe, to offer it as a potential standard care for refractory pain that has not responded to anything else?

Joe Strunk So the answer to that is, is yes, it is in my toolbox and it is something that is pretty much this is the standard of care across the US. And in supported by all major societies that that are involved in pain management. So it's definitely something that used but it's something that it is used as a last resort. It's not something that most of my

patients when they walk into my clinic, I'm like, can I get you signed up for a spinal cord stim trial. It is it is a thorough evaluation about and looking at what pain generators they have and making sure that we've maximized medications and physical therapy and what other interventions and evaluation to with surgical colleagues is their surgical intervention, having our pain psychologists see them. So it is not something that we go to just because they graced us with their presence, but it's because they are truly in a bad spot and we have we have exhausted everything and that is the standard by which all folks that offer this when they adhere to those guidelines which are what Medicaid, requires and all my other major insurers. That is the standard.

Christoph Lee Thank you. That's super helpful. And I think that's something that we haven't discussed as much the standard of care and the coverage under CMS and, and other most private insurers. And everything that you just mentioned, Joe is my understanding as well for Medicare coverage you have to basically go down this checklist of all these exclusion criteria. It seems like it is the last resort. So along those lines, I guess my follow question for Chris and if he's on Chris Chen, Is what other what other Medicaid programs are doing across the different states in terms of coverage? If we know that or not.

Christopher Chen Yeah, thank you. I'm not aware of, other medications that don't cover spinal cord stimulators. I think I will, if I might just comment, a little bit further the Peterson data does seem to kind of imply a very significant effect on pain, almost I might conjecture, almost curative. I don't know, they're pretty significant orders in magnitude there. And I, do think that's a little bit at odds with the last resort narrative. And if something is truly last resort and then all of a sudden someone gets the therapy and miracles happen. I think that kind of raises questions, and those are kind of inconsistent. And I think I'll, just highlight another narrative that I'm hearing today which is that traditional spinal cord stimulators are better than placebo. And the modern spinal cord stimulators are better than traditional spinal cord stimulators. Just want to highlight there's not a trial that we discussed for or reviewed that captures that. There's not a single trial that demonstrates that modern spinal cord stimulators that are better than traditional spinal cord stimulators that are better than placebo. And so I think, just kind of our recommendations are coming based in what the evidence center was able to produce in that in the report. So thank you.

Christoph Lee Thank you.

Sheila Rege Tony? I think you were next.

Tony Yen So, oh, am I next? Okay, great. So there's one piece of, one another author of the literature is Kapural 2022 that I thought was actually fairly compelling. It really showed, I think, probably what would be considered high frequency or more modern spinal cord stimulation against placebo and that that to be that actually displayed to me that this is what we really should be looking at. But then, and Chris, I apologize, that this is actually the slide I was trying to indicate, before, but your presentation slide 11. I don't Josh. I don't know. You can bring that up. Show us the Cochrane quotation about the criticisms behind their Kapural study as well. And so I guess, you know, what I'm trying to tease out is. First of all, this spinal cord stimulation, even effective or not

even if it is standard for care about our community, it could be standard care in our community, but I'm trying to really understand via the data. Is this even effective or not? Bottom line. And so the Kapural study to me at least was super compelling at first when I was trying to read through it. But it's through these comments of the Cochrane review that you can see on screen right now that made me Let me to question the validity of the study as probably the, the most modern interpretation of what's really going on. So I, I just wanted to just cancel that out there in terms of like, about the studies that we're looking at, how valid are they? And did they really show a difference at all, whether that be with traditional spinal cord stimulation or the high frequency spinal cord stimulation. What I'm trying to get at, really to the core of it is that is a truly effective? That we can see within the literature, the literature really tells us to be a randomized control trials.

Sheila Rege Who are you addressing that question to, telling the vendor?

Tony Yen No, it's just a comment. Sorry. Yeah. So.

Sheila Rege Yes, and while Jonathan's going to bring it up, can we bring up page 15 kinda so we can think about start thinking about what's in scope as we start. Go ahead, Jonathan.

Jonathan Sham Sorry. So maybe I just, I just ask a question to the group. And based on what Tony just said in this slide. The, I mean is enrichment of the trial design a bad thing here? Like isn't that exactly what clinical practice is doing by using it as a last resort? But you're enriching for patients that you think it's gonna work in and highly selecting them. I mean, to me, I don't see that as a critique. I think that is.

John Bramhall Hmm.

Jonathan Sham Just good trial design and good clinical practice. I guess that's how I would respond to that just if looking at it. I guess my question for Joe, it is, it's kind of along the, get how we select these trials to, and again, we don't, we don't select non comparative trials for the, the data report but Like, is the field past that? Like, can you imagine a trial in 2023 that is placebo versus some type of SCS or is the, is there not equipoise anymore amongst the field? Like has that time passed and now every trial we're going to have moving forward is you know, version 2.0 SCS version 3.0 SCS so on and so forth.
I guess I'm just trying to get a sense of are we kind of looking too far back.
Are, are we trying to planning for a, a time that's never gonna come because all of these professionals societies you know at the end of the of the report they sent out, you know, whatever, dozen or so professional societies or and Medicare and as Dr. Chen said most Medicaid programs are covering it. Like I said, do you think it's gonna be impossible to do that trial or does that ship sailed?

Joe Strunk I think the points you've raised are really valid. We have over 10 societies labeling this as the standard of care and so I know that as physicians and health care providers, we have a hard time offering therapies that we feel like are the standard of care to some and then withholding those therapies from another patient from an ethics standpoint. And so it may be something where we struggle to even recruit patients or design that trial moving forward because of that change and that that perception.

Sheila Rega I think Andrea wanted to say something.

Andrea Skelly Yeah, I just wanted to also I don't remember whether I mentioned this during the presentation or not but most of what Kapural presented was a per protocol analysis, not an intention to treat analysis. And so just wanted to throw that out there in general we try to, when we synthesize evidence in for, for these things try to focus on intention to treat. And, you know, given the lack, loss to follow-up, etc, so I just think that it'd be important to consider that this is a per protocol and advances and I don't know to what extent that may have impacted the, the results that we see.

Sheila Rege Okay. That's a good point. If we could, project page, I think it is 15 to just get us started on getting us off. So in scope is chronic back pain and specifically failed back surgery syndromes when we start thinking about this, do we wanna call out failed back surgery syndrome or just chronic back pain? Complex regional pain syndrome which is, you know, kind of trauma possibly cancer and then painful diabetic neuropathy. Is it this group's feeling that you know, and I will, kind of maybe do it, I'm gonna make an executive decision to do it separately for all 3. And, because the study's kind of like, I was Tony who said one was only diabetic. And maybe kind of do the straw poll and that was I believe going to page 227 or 228. Let's go. Based on our strategic retreat, we talked about kind of going, let's go to 228. And if I have trouble, I'm gonna turn off video again if I start getting unstable internet. Here we go. This was something for safety and we should go back and list the safety what we would mean by this. But we had come up with, kind of that grid based on thing. So the safety is listed here. Do we have any more things to add? Anybody? I have seen so I'm looking back on what I've written, just give me a minute. Anybody else? Question. Do cardiac pacemakers and defibrillators, are those an issue anymore? For our experts.

Joe Stunk Placement adjacent. Is that the question?

Sheila Rege Yeah, so if a patient has a cardiac pacemaker or a defibrillator, should that, is that in your decision tree consideration or it's not it's a non-event doesn't matter.

Joe Strunk Due to the differences in location, they patients. Can you have a spinal course to be replaced as long as they're remote.

Sheila Rege Those locations. And then I saw, lead migration, breakage and some of the studies. I don't know where we put that.

Janna Friedly Yeah.

Sheila Rege Because some of them really, we could clearly correct and help me out. Who had raised your hand? Oh, I should unraise my hand. I'm sorry.

Janna Friedly Yeah, so Sheila let just along the, you know, there's, AEs requiring surgery, but, but I don't think that that necessarily captures the you know having to replace, replace them you know repeat surgeries or procedures or migrating leads and things like that. Maybe that falls within that, but. Seems like.

Sheila Rege Yeah. Yeah, maybe we could just let the hyphen there and say, lead migration, breakage or fail connection.

Janna Friedly But I think also, you know, thinking about. You know, the battery replacement. Although it sounds like some of the newer devices have, you know, the rechargeable, may be longer lasting. It's still, you know, for the, for someone with the trajectory of chronic pain, which is, which is considered long term you know you this is not a short term treatment this is something that's going to have to you know for the most part, be, be continued. So that I think that has to weigh in there, there somewhere. And it's still, still not.

Sheila Rege And then. Right. Is there anything?

Josh Morse Am I capturing what you want on here, Janna or Sheila?

Sheila Rege Yeah, revision and failed connection, which is the same thing.

Janna Friedly Yeah, I mean, I guess I'm just saying that it, you know, replacement of the of the device due to battery issues is not necessarily an unexpected adverse event. I guess, I guess it would be, we would still fall under that. But. It's just part of the expected trajectory for someone who's, who is getting one.

Sheila Rege And then.

Joe Strunk And the magnitude of, sorry.

Sheila Rege Go ahead.

Joe Strunk I was just gonna clarify that the magnitude of lead migration is also that will depend on whether it needs to actually be revised or not because small amounts of magnitude, small distance in lead migration can be reprogrammed. But there are times when that lead has migrated such that it is no longer possible to get correct positioning for a stimulation. So it just depends. And I don't have the data to tell you what that percentage is other than the whatever data we've been able to review in terms of revision surgeries.

Sheila Rege And then remember the FDA in 2020 sent scared me, the letter saying there's been 420 spinal cords stimulated patient deaths. Talk about testing and stuff. Have the newer ones, I mean, are they significantly changed and I don't know what they I can't remember. I just remember that letter. I guess I could pull it. Let's just, put in there FDA cautionary just so we remember that if we have to come back to it. FDA 2020 caution letter. Just so everybody knows we talked about it. Does anybody who has no experience in this or Strunk. I mean, do you wanna say something about that? I see a hand raised. Conor?

Conor Kleweno Oh, I mean, I'm a proceduralist, so I have a somewhat bias, but just wanna remember that the safety outcome should be put into context if it's a procedure versus Non-procedure, right? We're not comparing 2 procedures. So if you say some of these things are just part of doing a procedure and so, you know, there's high risk procedures and low risk procedures, but even that is within the context of that field or even in the field of doing procedures. So remember it's hard to say, oh, something's not safe because you might get a durotomy versus doing physical therapy or something. But again, we want to, in my mind as a committee, highlight things that have very high risk within the context of doing procedures in that part of the body or the similar amount of invasiveness or something like that. So is something higher risk like a disc cervical displacement versus, you know, placing a percutaneous lead somewhere. So just, if we recognize safety with respect to procedures in the context of a risk profile that that incurs by definition of doing a procedure.

Sheila Rege Right, and I actually just pulled something on that letter and it did say they did not, it just did death within 30 days and they did not have enough data is see a causal relationship between the device and reported event. I just wanted to make sure, I went back to that. Anything else we need to add in safety? Let's move on to efficacy when we start thinking about our grid. Is there anything else in terms of effective outcomes. I mean, pain getting better is the biggest in function, opioid use, anything else that we've missed?

Janna Friedly I think the other, you know, sort of things that I think about when I'm thinking about these kinds of procedures is you know sort of downstream utilization of surgeries and other procedures for pain so in addition to opioid use there are other interventions that people are seeking after. Don't think that the data is refined enough to be able to, to report on that though to be able to tease that out.

Sheila Rege Laurie, you've been very quiet so has Clint. I'm gonna call on you guys to help us with this.

Laurie Mischley I don't have any efficacy outcome issues to add.

Sheila Rege Clint? Anything you, you always help guide.

Clint Daniels Sorry, I was having trouble unmuting there. I don't see any others either as I’m looking through again.

Sheila Rege Okay, moving on to cost when we start talking about this. And I had my question answered which was how often do these have to be replaced? You know, it's not just one procedure. It's, a lot of my patients have to have go back and have it and actually in mind that's a win because they actually lived enough years. So. But it sounds like they've, they've solved that for the most part. It's not every 2 or 3 years, maybe 5 or 10 years. So in cost effectiveness, I would just, I would say need for repeat procedure. I don't know how to phrase that. Help me out. John, you're good at helping with things like that.

John Bramhall So are you struggling with, with.

Sheila Rege That fact that this is not just one procedure, multiple, so multiple risk, you know, cube a little risk of.

John Bramhall Right. Right, but I so. Yeah, but I mean, I to me a parallel here is, you know, an implantable cardiac pacemaker or something of that sort that seems to be a comparable kind of device. And you know as Janna said you know if you have an old style implantable pacemaker that needed a battery re replacement It's, it's not trivial, trivial. It's a cut, but it's a relatively trivial thing to replace it every 5 years. And it was it was predicated and predicted. So I'm not sure that that that replacement is a big cost-effectiveness issue. To be honest, it's an upfront. We said we've seen it in the data in the papers, right? So the first year cost is you know, 38,000 and the second year cost is 1,000. It's one of those things that comes with, that Conor says, the nature of the procedure you do the surgical intervention you implant the battery and the pacemaker driver and then you forget about it for a period of time and then come back and the expectation is that currently place devices are likely to be lasting a very long period of time. The cost effectiveness, I'm not, you know, I'm not very good at that. So I'm not very good at the, so I'm not very good at the cost effectiveness of removing pain for a patient. I understand the statistical way that sometimes we look at these things in quality life years and what have you, but I personally struggle with cost-effectiveness of, let's say, eliminating a life of pain. If this device eliminates, pain from diabetic neuropathy that's going to persist for 20 years and is life altering then it cost effectiveness of that is, It's difficult for me to process personally.

Sheila Rege Yeah, are we good? I mean, anything else we need to add in the cost outcome?

Conor Kleweno Not I, I would motion to go ahead Sheila.

Sheila Rege Let's go, and special populations I think is fine. Obviously not, so let's move to, kind of this is the straw poll. Is there sufficient evidence of the technology is safe for the indications considered? And again, we, know what's in scope the 3 conditions, the diabetic, failed back surgery, and complex regional pain system. How do you want to do this, Val?

Val Hamann So Josh will display it like he is and. My thought would be to go through each syndrome first and give safety, efficacy, cost-effectiveness. But if you would like to do safety for each of the 3 and then we can transition to efficacy, we can definitely do that. And so how this will work for any of these is when I call your name, if you do feel there is some type of risk or efficacy less equivocal more you won't give me you will say less and then the confidence you will let me know of low, medium, or high, unless you feel there are no relevant studies. Does anybody have any questions about that?

Sheila Rege No, I'm good with them.

Val Hamann Okay, so, let's just start with failed back surgery. And so we'll start with Bramhall. So if you wanna let me know. Low, medium, high risk, no relevant studies, and then you're confident it you do feel there is a risk.

John Bramhall Well, send me some studies and the number that sticks in my mind is 40% a complication rate if we included complications like having to you know, remove the leads and remove the, the stimulator and what have you and that same data set seemed to include a very significant number of quote deaths though I think was 460 deaths out of the pattern but it wasn't clear to me at the time of looking at that study that these deaths for example were indicative of a real risk of the study that these deaths, for example, were indicative of a real risk of the procedure. They're indicative of a real risk of the procedure, the coincident deaths really. The coincident deaths really, people who die with this pacemaker in place. So I, I think, and I have to say that it's a moderate risk procedure, it's a moderate risk procedure. It's an your axial intervention that's an your axial intervention that persists for many years, the implantation of the pacemaker, which I don't think is risky. I think there's lots of models for that. But again, the actual penetration of the epidural space and leaving a anitis there foreign body for a long period of time is I think associated with a moderate risk and that's reflected I suspect in some of the complication rates in the literature that we were presented with. So I'm going to say a moderate risk and I would have a pretty high Confidence in saying that there was a moderate risk to this procedure.

Val Hamann Okay. Daniels.

Clint Daniels I may say moderate and high confidence. And do we want discussion or do we just want the vote Or sort of where we're at on it?

Sheila Rege Just a vote.

Clint Daniels Okay, thank you.

Val Hamann Friedly.

Janna Friedly Moderate and high. I'm sorry, moderate and medium.

Val Hamann Hearne.

Chris Hearne Moderate risk with medium confidence.

Val Hamann Kleweno.

Conor Kleweno Yeah, moderate risk with high confidence. I think of risk as anatomic and intervention and we know the anatomy know what placement is and because like John said we're next to moderate risk as opposed to low risk.

Val Hamann Lee.

Christoph Lee Moderate and medium.

Val Hamann Mischley.

Laurie Mischley Moderate in medium.

Val Hamann	Rege.
Sheila Rege	Moderate medium.
Val Hamann	Sham.
Jonathan Sham	Moderate medium.
Val Hamann	Yen.
Tony Yen	Moderate and high.
Val Hamann	And then we can, are you okay moving down to efficacy now? For this? For failed back surgery.
Sheila Rege	Yes, please. Yes.
Val Hamann	Okay. We'll start with Yen.
Tony Yen	I would say for me that would be equivocal and low.
Val Hamann	Sham.
Jonathan Sham	And are we where this is for all indications?
Val Hamann	This is just for failed back surgery, and efficacy.
Jonathan Sham	More low.
Val Hamann	Rege.
Sheila Rege	Okay, equivocal and low.
Val Hamann	Mischley.
Laurie Mischley	I would say more and medium.
Val Hamann	Lee.
Christoph Lee	More and low.
Val Hamann	Kleweno.
Conor Kleweno	More and low.
Val Hamann	Hearne.

Chris Hearne	Equivocal and low.
Val Hamann	Friedly.
Janna Friedly	Equivocal and low.
Val Hamann	Daniels.
Clint Daniels	More and low.
Val Hamann	Bramhall.
John Bramhall	Equivocal and low.
Val Hamann	And then we'll move down to cost effectiveness if you want to scroll down, Josh. And we'll start with Kleweno.
Conor Kleweno	Equivocal and low.
Val Hamann	Hearne.
Chris Hearne	Equivocal and low.
Val Hamann	Okay, Friedly.
Janna Friedly	Equivocal low.
Val Hamann	Daniels.
Clint Daniels	Equivocal and low.
Val Hamann	Bramhall.
John Bramhall	Same, equivocal and low.
Val Hamann	Lee.
Christoph Lee	Equivocal and low.
Val Hamann	Mischley
Laurie Mischley	Equivocal and low.
Val Hamann	Rege.
Sheila Rege	Equivocal and low.
Val Hamann	Sham.

Jonathan Sham	Equivocal low.
Val Hamann	And Yen.
Tony Yen	Less and low.
Val Hamann	Okay, and then we'll move on. We'll start from the top and we'll go on to diabetic neuropathy. And we'll start with Rege.
Sheila Rege	And we are doing safety?
Val Hamann	Yes, safety for neuropathy, diabetic.
Sheila Rege	Moderate and low.
Val Hamann	Sham.
Sheila Rege	Do you want me to do all of it or you want to safety?
Val Hamann	Just safety for now.
Sheila Rege	Okay.
Jonathan Sham	Moderate, moderate medium.
Val Hamann	Yen.
Tony Yen	Moderate and high.
Val Hamann	Mischley.
Laurie Mischley	Moderate and medium.
Val Hamann	Lee.
Christoph Lee	Moderate and medium.
Val Hamann	Kleweno.
Conor Kleweno	Moderate and medium.
Val Hamann	Hearne.
Chris Hearne	Moderate and medium.
Val Hamann	Friedly.

Janna Friedly	Moderate and medium.
Val Hamann	Daniels.
Clint Daniels	Moderate medium.
Val Hamann	Bramhall.
John Bramhall	Yeah, moderate and it's the same risk as the, failed back surgery. So moderate and medium.
Val Hamann	And then we'll go down to efficacy again for diabetic neuropathy and we'll start with Lee.
Christoph Lee	More and low.
Val Hamann	Kleweno.
Conor Kleweno	More and low.
Val Hamann	Hearne.
Chris Hearne	More and low.
Val Hamann	Friedly.
Janna Friedly	More and low.
Val Hamann	Daniels.
Clint Daniels	More and low.
Val Hamann	Bramhall.
John Bramhall	Yeah, more and low.
Val Hamann	Mischley.
Laurie Mischley	I'm gonna say more and medium.
Val Hamann	Rege.
Sheila Rege	More and low
Val Hamann	Sham.
Jonathan Sham	More and low.

Val Hamann	Yen.
Tony Yen	Equivocal low.
Val Hamann	Okay, and we'll go down to cost-effectiveness and we'll start with Friedly.
Janna Friedly	Equivocal low.
Val Hamann	Hearne.
Chris Hearne	Equivocal low.
Val Hamann	Kleweno.
Conor Kleweno	Equivocal low.
Val Hamann	Lee.
Christoph Lee	Equivocal and low.
Val Hamann	Mischley.
Laurie Mischley	Equivocal low.
Val Hamann	Rege.
Sheila Rege	Equivocal low.
Val Hamann	Sham.
Jonathan Sham	Equivocal low.
Val Hamann	Yen.
Tony Yen	Less and low.
Val Hamann	Daniels.
Clint Daniels	Equivocal low.
Val Hamann	Bramhall.
John Bramhall	I apologize. I'm gonna say more and low. This is for the diabetic neuropathy, correct? So I'm the same one though.
Val Hamann	Correct. Okay, and we're going to move on to complex regional pain syndrome. Back up to safety for this one and we will start with Sham.

Jonathan Sham	Moderate medium.
Val Hamann	Yen.
Tony Yen	Moderate and high.
Val Hamann	Rege.
Sheila Rege	Moderate medium.
Val Hamann	Mischley.
Laurie Mischley	Moderate medium.
Val Hamann	Lee.
Christoph Lee	Moderate medium.
Val Hamann	Kleweno.
Conor Kleweno	Moderate medium.
Val Hamann	Hearne.
Chris Hearne	Moderate medium.
Val Hamann	Friedly.
Joanna Friedly	Moderate medium.
Val Hamann	Daniels.
Clint Daniels	Moderate high.
Val Hamann	Bramhall.
John Bramhall	Moderate medium.
Val Hamann	And now we'll go down to effectiveness. Again, for CRPS, we'll start with Daniels.
Clint Daniels	Equivocal low.
Val Hamann	Bramhall.
John Bramhall	Equivocal low.
Val Hamann	Yen.

Tony Yen	Equivocal low.
Val Hamann	Sham.
Jonathan Sham	More low.
Val Hamann	Rege.
Sheila Rege	Equivocal low.
Val Hamann	Mischley.
Laurie Mischley	More low.
Val Hamann	Lee.
Christoph Lee	More low.
Val Hamann	Kleweno.
Conor Kleweno	Equivocal low.
Val Hamann	Hearne.
Chris Hearne	Equivocal low.
Val Hamann	Friedly.
Janna Friedly	Equivocal.
Val Hamann	Okay. And then we'll go down to cost-effectiveness for CRPS. And we'll start with Mischley.
Laurie Mischley	Equivocal low.
Val Hamann	Rege.
Sheila Rege	Same, equivocal low.
Val Hamann	Sham.
Jonathan Sham	Equivocal low.
Val Hamann	Yen.
Tony Yen	Less and low.
Val Hamann	Bramhall.

John Bramhall	Equivocal medium.
Val Hamann	Daniels.
Clint Daniels	Equivocal low.
Val Hamann	Friedly.
Janna Friedly	Equivocal low.
Val Hamann	Hearne.
Chris Hearne	Equivocal low.
Val Hamann	Kleweno.
Conor Kleweno	Equivocal low.
Val Hamann	Lee.
Christoph Lee	Equivocal low.
Val Hamann	So that concludes that piece and I can share that information so you all can see how you did this.
Sheila Rege	That was helpful because we have no, we understood you know, kind of what we were voting on. So this is on safety on the top.
Val Hamann	Yes, for failed back surgery, everything and this is all for failed back surgery.
Conor Kleweno	For Val, for mine and I meant on the top one, moderate medium. I'm sorry. Thank you.
Sheila Rege	Everybody pretty much all of us thought they was moderate risk. In terms of efficacy. We thought eco versus more. And go down, I can't see the bottom. And in terms of cost effectiveness we were low mostly. You know, I think I'm gonna go down to less on cost effectiveness, just on cost effectiveness.
Val Hamann	And do you want that for low as well?
Sheila Rege	Yeah, low. Does everybody else happy with where we are? And so let's look at this for.
Val Hamann	The next is diabetic neuropathy.
Sheila Rege	Okay. Moderate risk, more effective. Except for one with equivocal and then equivocal on cost effectiveness. Everybody happy with that? Next time, well, it just, you know, where your cursor is or your highlighted sellers will put in what this thing is diabetic now obviously everybody knows that looking at it.

Val Hamann Okay, and then CRP.

Sheila Rege But you can type that in. So, and then let's go to the next one.

Val Hamann So this is CRPS.

Sheila Rege that's, that's chronic, regional pain syndrome, you already, one address equivocal versus more and equivocal in terms of cost effectiveness. So based on that let's start with failed back surgery syndrome. I can't remember how we decided to do this. If we had to kind of do a straw poll vote, let's go back to go back to the FBSS. If we had to do a straw poll vote would anybody, would there be any takers on? Not to cover, just jumping ahead.

Janna Friedly Sorry, Sheila for which. Or failed back or for.

Sheila Rege For this, yeah, this is the, FDA as the failed back. Would anybody go to not to cover?

Val Hamann We can. Sorry, go ahead.

Tony Yen Oh, Yeah. I would probably vote to not to cover.

Sheila Rege Okay, so that so. I'm just trying to see if there’s anyway we would vote not to cover. Let's go to the second one, diabetic retinopathy. Based on looking at how our thoughts are, would anybody say not to cover?

Tony Yen Again, that would be me.

Sheila Rege There, oh yeah, little Tony. Okay, and tell us why because that's I you know, I kind of like to hear from. the person who on whether we missed anything or not. If you want.

Tony Yen No, it's simply I think, the way that I would interpret, least the literature at hand. And this is my own personal interpretation. That I think there's issues with demonstrated efficacy ith the literature that we're presented with. And then there's also the risk of you know, accessing their actual space. So I think it's with that questionable efficacy if there's any efficacy at all and weighing that against the risk of actually doing this type of procedure and having this space access, potentially for the very long term that concerns me.

Janna Friedly And.

Sheila Rege I vacillated Tony between the, you know, making any equivocal or more. I really was struggling out on that fence. Anybody else?

Janna Friedly Yeah, Sheila. Go ahead, John.

John Bramhall Well, I. Sorry, Janna. Oh, okay. Well, I would just comment. Yeah. So the data that we're presented from the from the, the data experts is, is not convincing to me, that, that would persuade me to cover this, right? I would, I wouldn't vote on the basis of to cover on the basis of the information presented in an ordered, logical, academic way. And I'm feeling that this particular session I'm feeling influenced, unduly perhaps by the clinical experience of our expert, and a pretty evangelical testimony from the from the public commentary period. Where what's it's not it's not the vigor of the argument it's, it's the, the suggestion that we've been reviewing old data, data from 2022 and we should be reviewing data from 2024 and, and that's sort of weighing on me a little bit because, because I, I say I sense and sense isn't a good word when we're dealing with data I sense that there's something here. I sense that there's a modality here that will help some patients, but the data that we be presented with in its entirety isn't convincing that there's a benefit. So, so I'm still struggling. I'm sorry, I haven't come, I haven't come to a decision and I'm probably going to be swayed by my colleagues here, but that's my struggle is the dissonance between the absolutely new technology that is asserted to be effective and the data that comes from, you know, technology that's 5 or 10 years old.

Janna Friedly I can add, I also am struggling quite a bit with this and I think what I, what I am struggling with is that for you know we, we have discussed the limited number of trials against sham placebo which, which would be the idea to be able to determine effectiveness, but we have, we've discounted the trials for one reason or another in that category and there's very few. So we're left with clinical trials that are comparing you know, medical conventional medical management to the, to the intervention, most of which are, have a very high risk of bias in my opinion from, from industry involvement and, and unblinding, which essentially, and then crossover, which essentially becomes an observational study, one arm study because you're, you know. that's really how it ends up you know falling because you don't have the benefits of that randomization and blinding and to be able to use that. So, so then I compare that data that shows that the trials that show these really spectacular results you know, at least the Peterson trial with some of the other well done observational studies including an older one that was discounted because it was an older one that was discounted because there was in workers compensation patients, although that is part of the population that we are addressing today and a more recent study, which was, which was a large, observational study using Optum data I think it Druca was, was the, the primary that we didn't really discuss today, but that, or Druvas, sorry, that, study was an observational study and showed fairly high rates of complications and, that, study was an observational study and showed fairly high rates of complications and you know, 20% removals and not, great outcomes so again, that's observational data. So I'm really struggling with this. you know, the disconnect and then you, piece that with the safety data and I'm struggling even more. So I think about a coverage, you know, a cover with conditions and then we've heard repeatedly that this needs to be done that we, wanna have access for people to have equitable. But yet the criteria for covering that has been recommended and that we've talked about today includes you know access to multidisciplinary programs and psychological you know evaluations and other things that and even criteria about what a positive trial of a spinal cord stimulator is, 50% improvement, 30% improvement, 3 days, that 5 days, 7 days. But I don't think that the data is very clear that I've seen that, that the data is very clear, that I've seen that suggests that 30% improvement is worse than 50% improvement or 80% improvement site. I'm left with in my mind thinking, you know, what's the evidence behind those, particular conditions and those guardrails that we would put up for this because if there are no guardrails, these are populations of the very large populations of patients that have diabetic neuropathy and, and chronic back pain. So those are the things that I'm struggling with and, and, and going back and forth about what's the right decision here.

Sheila Rege Janna, are you struggling more with this, with peripheral, or, than you are with the others?

Janna Friedly I am because I, I think the Peterson, study that we've been presented has, you know, very, very, you know, strong, you know, some of the other trials that we looked at had relatively small magnitudes of affect the magnitude of effect in the Petersen trial, which is the one, you know, key one, I think, that is, is so much higher that it's, it's pulling me, you know, a little bit more on that side.

Sheila Rege Anybody else? Conor?

Conor Kleweno Yeah, I was just gonna echo what Janna said, not only the study, but just mechanistically, you know, we, you know, we have a model of diabetic neuropathy where there's some sort of damage to nerves and now we're intervening on the nerves. The low back pain and failed low back, syndrome. I don't really know what those mean mechanistically. I don't understand what those mean. I think the heterogeneity in those and the variance in those is going to be quite broad. Obviously we don't have all of diabetic neuropathy figured out, but it just I can wrap my head around the mechanisms there a little bit better and then when I see the data, albeit biased it makes a little bit more sense to me, I think, in terms of being able to capture us more a population with perhaps a little bit less variance inherent within them.

Sheila Rege So we had to vote not to cover today would most of us, would any of us vote except for Tony would. Would we vote not to cover?

Jonathan Sham You're talking about diabetic neuropathy, correct, Sheila?

Sheila Rege Just, this is the one I struggle the most with because I I could go either way and I worry that I'd be swayed by my federal committee members.

Chris Hearne I'm sympathetic to a cover with conditions, but. I really agree with one of the concerns that Janna brought up, which was that, I'm not sure what conditions we would use that are going to be deeply rooted in the evidence.

Sheila Rege And I don't think the, just like Janna said, I don't think the evidence is strong enough for us to say cover with conditions. We're being swayed a little bit by realizing stories or examples.

John Bramhall It just, just for a clarity, so just for clarification, so the, the proceed, are we, are we going to treat the procedure as, as an, as an entity, as a, as an, in dishonorable entity. In other words, are we going to look at the trial, the percutaneous placement that precedes the permanent implant. Is that is it reasonable to combine those 2 together in a decision or would we each be comfortable making a condition the condition is the percutaneous test trial frequency determination and, and depth of placement or what have you. The that a group of patients who respond to that then go on to permanent placement. It can, can we split this up in that way? Is it rational to do that, do you think? Because it does, it does seem that there must be a group of people somewhere who fail the percutaneous the test they, they fail the test they've got the problem and we here have a solution here but first of all we're going to test it the solution will work. And we do that by pretty, pretty, I mean, it's invasive, but it's no different from, you know, epidural steroid injection or something like that. You place the electrode and set the frequencies and then wait for a day or 2 days or 5 days apparently and then make a decision and I I'm, I'm ignorant as to how what proportion of patients who present as viable candidates for spinal cord stimulation fail to use the wrong word but don't go on to implant because they fail the test phase. Is it 50% is it 1% is it no one what kind of number is that? And would that, that test be an appropriate filter for people who could then go on to to get the permanent placement which is the expensive surgical procedure.

Sheila Rege That's a good that's an interesting thing. I think I think most of these people do have responses right away. So the question is, you know, mean, I said right away within days question is whether that should be something for everyone be an interesting question. So if I.

John Bramhall Actually, maybe Joe, sorry, Joe, can you, can you answer that question to in people in your practice what, what proportion of people who undertake the test, let's just call it the test, go on to get the permanent placement. Is it a large proportion? Or is it is this test preliminary test pretty selected?

Joe Strunk So again, echoing what the committee has said. I don't wanna bias with anecdotes. So I guess I would. And maybe the concern continues to be with the data that is available. I don't have the numbers exactly in front of me of how many enrolled in in the Petersen trial, but that's what I would look to in terms of how many went on to success there and, and give that as a as a surrogate for what we could expect. Does that, is that a justifiable answer?

Sheila Rege Yeah. We have 3.

John Bramhall It sure is.

Sheila Rege We have 3 hands right and we have a break and we are gonna lose the committee member within 20 min. So I'm, my thought is to answer the questions now. I'd like to move on to, I just want to see if there's any of them we would not cover, in which case after the break we would come back and try and work out conditions and have it really think about conditions during the break or cover unconditionally each other we come up with. But is it okay with the committee if we go through the 3 questions first and just think about whether you would not cover any of these. While people are talking. Because I'm gonna take a straw poll. Go ahead. It's, I don't know who was first with the Janna or Kristoff or Plant, whoever it was.

Janna Friedly I think it was, I think it was Clint.

Clint Daniels Sure, I just wanted to comment on Dr. Bramall's question about the whether an appropriate condition would be a successful trial and I just wanted to point out that for Medicare and Astna which do cover it is one of their conditions for coverage having the successful trial. Just wanted to highlight that.

Janna Friedly Yeah. I think that is clinically what is done.

Joe Strunk Yeah, and I would echo that.

Janna Friedly I think the question is what duration of trial that you requires that if you do cover. Can I just, create quickly and I already know the answer to this, but it might be able it comes up a fair amount where we've mentioned it before but it might be able it comes up a fair amount where we've mentioned it before but one of the options that would be ideal that comes up a fair amount, or we've mentioned it before, but, one of the options that would be ideal that I think is not an option is, a cover with, evidence, development. Josh, do, do you wanna just speak to that? And, how, it, the, in probability of that.

Josh Morse I'll do my best, Janna. The committee. In past formations of this group has talked about that and at one point attempted to come up with criteria for when, when that would be a consideration, but. Unfortunately, it's not really an option. What it does happen, what is an option and we've talked about this I think before with largely with most of the people in this group is that if you were to say something is not covered the programs could still cover it in the context of a clinical trial. So if a trial was. It was available, the agencies and certainly for Medicaid are required to consider coverage when it's an appropriate trial. So I think I'm answering your question, but if I'm not, I'm happy to try again.

Janna Friedly Yep, no, that's perfect. Thank you.

Josh Morse I do, I do think with this new format, I just add this comment, I like what you developed in our in rethinking how to vote on these different aspects for each condition that it's 2 dimensional here you have where you think whether it's more efficacious and how confident you are, I think that gives it better Something better to grab onto in a case like that because you seem to be saying you think it's more effective, but you're not very confident in that is how what I take away from this in this data, which I think is very interesting. So. I like the development here. Thanks.

Sheila Rege Go ahead, Christoph.

Christoph Lee Yeah, I was just gonna say that, for coverage with conditions. We could look to the language used by Medicare and other party sharers that specify a lot of the things we talked about. And we could also look at the inclusion of the RCTs in our evidence report. And you'll see that there's a lot of overlap, psychological, comorbidities, substance abuse disorders and I think Medicare did have a 50% threshold for the trial effect on us, the one to 2 week trial period before implantation. So if we do go down that road, I think rather than reinventing the wheel, we should look at language already used by other bodies.

Sheila Rege On break, our homework will be to look at that somebody asked a question on Medicaid, and I looked at California just because they're very close to Washington State and they have language as well. So we can look and then be prepared to give suggestions on which language we would like to project if because of the conditions when we vote, but it doesn't sound like, it sounds like we're not going to not cover correct? Anybody want to speak to not cover itself at Tony? We've already done that for a diabetic. Let's move before break to complex regional pain syndrome. Look at how we voted. And again, I think everybody go down if you don't mind. Who said low Tony? So. Same thing I don't think is there anybody any takers on not covering so we, no, I don't and see any based on that data.

Val Hamann We can also do a straw poll and I can replicate this over and over and over. However, many times you guys.

Sheila Rege Let's do that. Let's do a straw poll before break. So let's just keep it. Let's go back to failed back surgery syndrome, the first one we looked at, failed back surgery syndrome.

Val Hamann Yeah, we'll start with Bramhall.

Sheila Rege This is, is this failed back? Oh, okay.

Val Hamann Yes.

John Bramhall And, this is a question about coverage already on, on failed back.

Val Hamann Yeah, it would just be a.

Sheila Rege Yeah, Would you go cover, and, cover with conditions?

John Bramhall Alright, okay. Okay, yeah, covered with conditions.

Sheila Rege Do you want to do all 3 at once?

John Bramhall Well, I can do that. Yeah, you can do it because the screens up there. I think the same comment for diabetic neuropathy. I complex regional pain, I honestly. I'll straw poll. I'll put cover with conditions and we'll see how it shakes out. So cover with conditions for all 3.

Val Hamann Okay, then we'll do Tony Yen.

Tony Yen Not covered for all 3.

Val Hamann Okay. And do Daniels?

Clint Daniels I'm gonna do conditions all 3.

Val Hamann Okay. And Sham.

Jonathan Sham	Cover with conditions for all 3.
Val Hamann	Okay, Rege.
Sheila Rege	I'm not cover for the diabetic and code conditions for the other 2.
Val Hamann	I will go to Friedly.
Janna Friedly	I am going to say to covered for, for, back, and, complex regional pain and covered with conditions neuropathy.
Sheila Rege	So we can change this.
Val Hamann	Okay. Yeah. Yep. Hearne.
Janna Friedly	Then I'm going to change mine, sorry, change mine in that case if we are still going to discuss, I'm going to change mine to not covered for all three.
Val Hamann	Okay, Hearne.
Chris Hearne	I will say for the purpose of the straw poll covered with conditions for all 3.
Val Hamann	And then we'll do, Mischley.
Laurie Mischley	Cover with conditions for all 3.
Val Hamann	Kleweno.
Clint Daniels	He put something in the chat that he needed to leave.
Val Hamann	Okay.
Sheila Rege	Oh no, I hope you.
Val Hamann	Lee.
Christoph Lee	Cover with conditions all 3.
Val Hamann	So as long as Dr. Kleweno is still gone then. We'd heard from everybody.
Sheila Rege	Can you, hold on for Kleweno for the straw poll? I thought we had until 3, so call him on the straw poll and see if he had 3. So call him on the straw poll and see if he'd be willing to give you what he thinks.
Val Hamann	Are you you able to do that Josh?
Josh Morse	I can try to reach Dr. Kleweno. Yeah.

Sheila Rege Okay, during the break, how long we were scheduled, I think, on our schedule for a 10 min break. Is that still okay with everybody and in the break? Please look up, you know, anything that you would suggest we start using as a template instead of reinventing the wheel. And I think we'll take the easy one. Which is, the, not the diabetic, whether it's last. Just in case people start rethinking things. Is that okay? And we'll come back. Alright, 10 min break till 5 to the hour.

Andrea, you have your hand raised, is that, were you trying to say something to get us going?

Andrea Skelly Yeah, I had 2 points. One is about two paragraphs behind, and that is that the appendices do describe the percentage of patients who did have implants after a trial of spinal cord stimulation. So that was one thing. But the other thing is, and I don't know, if this affects your decision making or not, but the Kapurall study was not in patients with failed back surgery syndrome. It was in, non-surgical refractory back pain. And so I, I don't know whether a question would come up whether your coverage decision would be strictly failed back surgery syndrome or any back pain. Just wanted to point that out if it matters.

Sheila Rege Oh, that, that matters.

John Bramhall Andrea, what, on that first point, what would the, Sorry, what was the number then? And of the, in that study of the proportion of patients that, that quote failed the trial. Do you remember?

Andrea Skelly I would, I have to look at the, look at the appendices and, and Erika may have it at the ready. But we did it for all of the studies.

Erika Brodt Yeah, is this for Peterson? For Peterson, Andrea, is that the question? Or.

Andrea Skelly Yeah, Dr. Bramhall was for Peterson or did you want all of them?

John Bramhall Oh, I, no, just, just a guesstimate, well, what that number is.

Erika Brodt Yeah, so across the 3, trials. In painful diabetic neuropathy for example, it ranged from 82% to 94%.

John Bramhall Okay, alright.

Erika Brodt Who ended up getting had a successful trial and were eligible for permanent plan. So that's 94% in the Petersen since we've talked a lot about, Peterson. And then let me see for complex regional pain syndrome a bit more variable one was 67% The other about 90%.

John Bramhall Okay, alright. Well, thank you. That's useful to me just personally. It's so it sounds like there's, I mean, I don't mean to be factitious, there is discrimination, you know, 10% of the patients just fail and also at the point of the test is presumably to, to refine the position of the electrodes and what have you are ready for permanent implementation. So that's useful to me. Thank you. Thanks for checking on that.

Andrea Skelly Thank you.

Sheila Rege I wouldn't like go back to that first comment. We have been I've been treating it as fail back surgery syndrome but if you look at our scope it was chronic back pain. And there's a lot of chronic back pain. And that's, that I'd kind of be interested in comments, from the committee members
on that based on the data.

John Bramhall Well, so there's a difference obviously between quote, failed back, which is what we were sort of discussing a little bit earlier on, failed back syndrome and, and chronic back pain, it's a world of difference there and, and not being an expert in either, it would opine that when we look at the specific situation of failed back you're gonna look at what the trajectory for that patient is going to be if they didn't have an option like SCS and my lay experience is that a lot of them go for further surgery. Now they're getting to get another surgery and another one then the higher level and a lower level and, and so whether that fact whether that should factor into our objective decision about SCS it's maybe a bit debatable, but in that specific instance of failed back, if the alternative is that the patient is going to go and get Medicaid or Regence or LNI coverage for further back surgery which is probably likely to be relatively ineffective to be honest. That that might weigh on our decision. It's not that's not true for quote lower back pain though. I don't think.

Sheila Rege But, correct me, John, but we, in our scope did say chronic back pain and a subtitle was failed by surgery. So did all the studies for back pain, were they all failed back or what were the other conditions included?

Andrea Skelly So the parallel trial, the Kapural trial, was in a group of patients with quote non-surgical refractory back pain. So these are patients that either were not good surgical candidates, my understanding, or they did not have back surgery, but they still had chronic, chronic back pain. The Hara study, the crossover trial did not specify failed back surgery syndrome but that patients did have back surgery in that study with continued or new radiculopathy. So they might fit more neatly in the failed back surgery, somebody who's an expert and that would be better. But the criteria for diagnosing either failed back surgery or this chronic non specific, non-surgical refractory, low back pain were not well specified.

Sheila Rege Would the second one fit into complex regional pain syndrome or not? But could that? I would not really.

Andrea Skelly No.

Sheila Rege That would not.

Andrea Skelly Yeah, no, no.

Sheila Rege When I was voting, I thought about pretty much failed back surgery syndrome. How about the others? Were you, was everybody thinking like me or were people thinking, I'm sorry, chronic back pain like what was in our scope?

Jonathan Sham I would just.

Sheila Rege Can, can we project out a on the on the poll on the straw poll, that page.

Jonathan Sham I just point out that the.

Sheila Rege And. Go ahead.

Jonathan Sham Yeah, the EVOKE trial published in the Lancet Neurology was also just chronic intractable back pain. It was not specifically FPSS. So just point out there's additional data for that that group as well.

Sheila Rege So Tony, were you voting for back pain when you said not cover over you voting for? Or, did a made a difference to you failed back surgery because I been voting failed back surgery and chronic pain.

Tony Yen I was voting for both.

Sheila Rege You voted for both, okay.

Tony Yen Yeah, I kind of love them to put together.

Sheila Rege Would anybody else change their vote if this became chronic back pain?

Laurie Mischley This is Laurie. I just say that you know when we're saying chronic back pain we're talking non-surgical refractory or chronic intractable it sounds more benign when you just say chronic low back pain but.

Sheila Rege Intractable chronic pain. Because we're gonna, we're looking at covering with conditions not unconditionally, so nobody else would change.

Joe Strunk And. Most of the, the EVOKE trial, majority of patients in the oak trial were for failed back syndrome not for back pain, not for chronic, intractable back pain.

Sheila Rege They were on back surgery, is what you're saying?

Joe Strunk Failed back surgery. Yeah, syndrome.

Sheila Rege Yeah, that's, I voted for back surgery, if it was just chronic back pain, I may lean towards not covered. This is gonna complicate here,

Jonathan Sham Sure. Joe, can you

Sheila Rege But, Tony.

Tony Yen Yeah, the EVOKE trial really compares 2 methodologies of spinal cord stimulation. One is open loop and one is closed loop. So those are the 2 comparators. There's no comparison against placebo. So just to be clear.

Sheila Rege And Jonathan?

Jonathan Sham Yeah, no, thanks. I can, bring that up just as far as the definition of what we're talking about kind of like what we said before, about what, what chronic intractable back pain really means and so maybe I ask Joe, I've seen greater than 50 on the VAS and, and EVOKE has greater than 60 is there kind of an agreed upon level.

Joe Strunk Yes. Greater than 50% is the standard of care across got all guidelines including the nationals recover national covers determinants by Medicaid or Medicare sorry. I mean for relief.

Sheila Rege Oh, I will have your hands up. Sorry, Andrea, you still have you hand up.

Andrea Skelly I guess I'm a little confused because I, are you talking about the threshold for implanting a device which should be, sounds like 50% or are you looking at I guess the Tony or Jonathan's question are you looking at what is a threshold for determining what is non-surgical refractory back pain. Those are 2 different questions.

Sheila Rege Okay. They are. I'm looking more as you know, I look at failed back surgery syndrome. Meaning now this is the last resort, so in which case I would take cover with conditions. But if somebody has chronic back pain in my mind, I'd want them evaluated for surgery first. So that's why I'm struggling because I don't think the data, the way I interpret the data, it was more last resort thinking so that's that's why I'm struggling with that now.

Joe Strunk Would that be?

Sheila Rege Josh, as a matter of protocol, we cannot keep it, we cannot as a committee change the scope because the scope was chronic back pain.

Josh Morse Okay.

Sheila Rege Is that is I'm asking a question as a process.

Josh Morse Well, I do think you could, I'm looking at the scope, you know, and I think the, these various conditions were included, chronic low back pain, failed back surgery syndrome and then parenthetically low back pain and persistent significant regular pain following surgery. So I think you they're separated by commas here. So I think you could choose to vote on both. You could lump them. I think it's important that you do figure this out though because I think they're different sized populations.

Sheila Rege Or we could just say consideration for surgery or not a surgical candidate. You know, kind of if for the others. Help me out somebody. I'm getting, deep down in the weeds and I need to be pulled out.

Joe Strunk I think it would be something that would be standard of care to include in that multidisciplinary process, the evaluation and in that candidacy for is there a surgery is there a surgical intervention that would be appropriate.

Sheila Rege So your practice also surgery. This is this is last resort for your, your consideration of surgery first. It's more, more narrative there.

Joe Strunk Yeah, well, it's critical that we have that we make sure that we are aren't.
We aren't, taking someone who would that we read to consensus about what therapies would be offered to this patient and so that multidisciplinary evaluation does include discussion with our surgical colleagues. If that is.

Sheila Rege I would make a motion. I would make a motion to have the support stand for failed back surgery syndrome which is kind of how I sold it or thought about it and I everybody I think thought about it. And then can we redo it, redo another box if we go to chronic back pain if people would stay the same on covered, non-covered and see everybody else is having the same problem I am or is everybody else fine? So I would actually move that to not covered. Yeah. How about others? Oh, you know, you're gonna take it all out. You can just ask.

Val Hamann Yeah, let's just go down the list real quick for chronic back pain. So Bramhall.

Sheila Rege Yeah

Laurie Mischley Can I just clarify, 2 things before we make this vote? And when we say chronic back pain, are we saying like I, I read several of them as non-surgical refractory these were people who hadn't necessarily failed back pain, but for some reason they were chosen deemed to be not good surgical candidates. Is that the cohort that we're voting on? And that was the Kapural study also.

Sheila Rege Does that?

Andrea Skelly Yeah, that was Kapural was the non-surgical refractory back pain and they could be they may not have been surgical, good surgical candidates. So it, it is a different population than the failed back surgery group, it seems.

Sheila Rege And, and was that the scope was non-surgical chronic back pain? So we can maybe.

Andrea Skelly Was that within our scope? Yes. And we have the Kapural study.

Sheila Rege So when you looked at it, you looked in non-surgical chronic back pain. And Laurie, I like that leaving that as a non-surgical chronic back pain. Well, you had a second point, Laurie?

Laurie Mischley Oh, I was just confirming that this Kapural study with the very strong. Effect size was in fact referring to the population we were voting on right now which was the non-surgical refractory and the answer is yes.

Erika Brodt Yeah.

Sheila Rege I would like that to be added, non-surgical refractory chronic back pain.

John Bramhall I mean, I think that's totally appropriate because there's a population of patients who are surgical candidates for their back pain, they have stenotic lesions for example and it just seems even as other lay person it wouldn't seem appropriate to obliterate the signals coming up from a stenotic lesion. That just it doesn't make sense.
So I personally I like that, that the, the perseveration about the patient being a non-surgical candidate.

Sheila Rege And how would you vote?

Josh Morse And if I may ask the contractor, Andrea your specific slide on this is it was slide 25 I believe where you break out the trials for failed back versus non-surgical refractory. Is that correct?

Erika Brodt Are you on mute Andrea, by chance?

Andrea Skelly Yes, I was also looking at my slide. So you said it was slide which?

Josh Morse I believe it's side 25 is that right? Maybe 26. You know, I think.

Andrea Skelly Oh. Yeah, slide 26 is just is the overview of studies of the back pain studies and yeah, what are you looking for, Josh?

Josh Morse I just I just wanna make sure that for my own understanding of this, there it looks like you summarize this, there were 3, 4, 5, 6. If I'm reading it correctly, 6 studies for failed back surgery syndrome and one study addressing non-surgical refractory back pain, is that right?

Andrea Skelly Yes, that's correct.

Josh Morse Okay.

Andrea Skelly That's correct.

Josh Morse	Thank you.
Andrea Skelly	Yeah, thank you.
Val Hamann	So would you like to take a straw vote on this then?
Sheila Rege	Please to see if anybody if it changes anybody.
Val Hamann	Okay, so Bramhall. We move on to Daniels.
Clint Daniels	Covered with conditions.
Val Hamann	Friedly.
Janna Friedly	Not covered.
Val Hamann	Hearne
Chris Hearne	Covered with conditions.
Val Hamann	It's Dr. Kleweno on? Okay, we'll move on to Lee.
Sheila Rege	No.
Christoph Lee	Cover with conditions.
Val Hamann	Mischley.
Laurie Mischley	Cover with conditions.
Val Hamann	Rege.
Sheila Rege	I would not cover.
Val Hamann	Sham.
Jonathan Sham	Cover with conditions.
Val Hamann	Yen.
Tony Yen	Not covered.
Val Hamann	Yeah. And then we can go back up to Bramhall. And I'm not hearing anything for Dr. Bramhall.
John Bramhall	That’s because I’m still muted.
Sheila Rege	Oh, there he is.

Sheila Rege Oh, I know I had video problems. Oh, there is.

John Bramhall Yeah, no, I think it came through. I'm in London actually, sorry. So it's a bit hazy.

Sheila Rege Would you cover with conditions?

John Bramhall I covered with conditions. Yeah, correct. Correct.

Sheila Rege Okay. But so I think it's still covered with conditions. So then when we do it, we can say you know, the Or's. So I like that what Laurie said, not surgical refractory chronic back pain and parentheses including or we can just say or failed back surgery syndrome. So we can do that. Right, because everybody's thinking cover with conditions. Does everybody, anybody want to? Speak strongly against cover with conditions and we have a hand raised by Erika.

Janna Friedly Erika has her hand up, is that?

Erika Brodt Yeah, at the risk of beating a dead horse. I, I just want to verify so for, for Kapural, the inclusion criteria, what they included kind of had 3 parts. So it was people who failed conventional management had not had previous spine surgery and who were not candidates for spine surgery. So it was all 3 of those. So it's not just people with chronic back pain who had and had surgery. It was people who hadn't had surgery and also were not surgical candidates. So I just wanted to make sure that when you're, if you're being specific about this population, you're clear on that, that all patients, surgical candidates.

Sheila Rege Do they have people that could have been surgical candidates? What's that, that you know, are we correct when we say non-surgical refractory chronic back pain.

Erika Brodt Yeah, so that's kind of the term that Kapural uses and so we used it and the way they define it is, is patients with chronic refractory back pain. That does not respond to conventional medical management and who have no history of spine surgery and are not acceptable candidates for surgery after evaluation by a spine surgeon. So that was their definition and that is the population they included. And this is again the one in the high kind of new or high frequency.

Laurie Mischley Can you keep that verbiage handy?

Erika Brodt Mmhmm.

Sheila Rege So would everybody be comfortable saying cover with conditions, there was a lot of conditions and we say, failed back surgery syndrome or non-surgical refractory chronic back pain or complex regional pain syndrome or diabetic retina, diabetic neuropathy. Is that language okay when we start talking about it covered with conditions?

Jonathan Sham So this might be more of a process issue, but I think it might be easier to break them up and not just have them all in one because each are gonna have very different standards for defining them whether it be, you know, a pain score or certain particular it is about their surgical candidacy. So I guess I would be in favor just to keep things clean to break them up by indication.

Christoph Lee Is that?

Sheila Rege Okay, anybody else for that because I've seen the other insurance policies when I was looking for things, they were actually lumped them together once they decided cover with conditions.

Christoph Lee Yeah, it might be helpful to pull up an example. I sent Josh the Medicare language and if we could share that on screen and see how that will look in terms.

Sheila Rege Yeah, and if you would pull that up Josh. Let's do that and let's also look at the California Medicaid. That also kind of

Josh Morse Yeah, I have, I also have an Oregon Medicaid.

Sheila Rege Okay, Oregon Medicaid is good too. Is that concrete? Is that something that's looked at? That would be good. I haven't seen the audience, let's pull that up.

Jose Morse Yeah, let me share that one and, and then we can go on the Medicare one is a local coverage determination. It's not a national from what I can tell though that though it may be. Yeah, hang on just a second.

Sheila Rege And just the one I'm looking at did say, that they, you had to have pain relief with the short term trial, the trial one.

Jonathan Sham Could I just ask Joe, as the expert so are, are there any differences in thresholds for like VAS scores for PDN versus FPSS or they all Is it all 50? Is it all the same?

Joe Strunk Yeah, it is all the same for the the pain threshold. I'm just gonna try and pull up the, the Medicare. To, as a reference for what it's worth. The I don't know if it's worth just looking for the at the FDA indications for spinal cord stimulation.

Sheila Rege No, we have to, we're looking more, we're just gonna. Is, is everybody okay with looking at this?

John Bramhall Well, I'm okay looking at it, but it troubles me, because it relates to what I was alluding to before about stenotic spine. So it is, is the spinal cord stimulator really an intervention that you would, would prescribe for a acordacidra syndrome in for a neurogenic platter. Is that really something that would be clinically appropriate?

Sheila Rege No, we're not, we're only looking at our scope, so we would only do diabetic neuropathy, failed back.

John Bramhall Well, no, but I'm looking, I'm looking, I'm looking at the, the, the guideline note here that is feeding, you know, feeding into that. So I don't need to worry about about patients who've got accorderacina getting in a spinal cord stimulator. I don't need to worry about that is that. Is that right?

Sheila Rege No, because that wasn't our scope, but we have a very narrow school. We have this calling. We're just pulling something.

John Bramhall Okay, all right, all right. All right. But still, but still this this document exists, it's being shown to us and I find that really troublesome can, Joe, can you comment on that? You have a patient with accordocina and the intervention is a spinal cord stimulated to suppress this pain symptoms is that Does that sound right, right?

Joe Stunk I can't say that that's anything that I have personally treated. I can't speak for everyone and it isn't listed under the, again, the scope of what we were looking at and the data that we have presented before us, but from a clinical context in my personal experience, that's not something I have treated. We would have to do a more in-depth literature review to, to really, to be able to enter that with more clarity.

Sheila Rege We can.

John Bramhall Okay. Alright.

Josh Morse And I'm sharing this strictly obviously this is their current policy, this is not maybe the scope as you've just identified of what you're considering today.

John Bramhall Well, sorry.

Sheila Rege Right, so we are. We are just looking at, I would suggest we take out everything to neurologic impairment to like the numbers that are long tracked abnormalities and erase all that starting in neurologic impairment. Somebody has their hand up. Who is that?

Gary Franklin This is Gary Franklin. I just wanted to mention that the Kapural study. Even though it doesn't say it's one of the criteria does say that the patients all had neuropathic components.

Sheila Rege Oh, they did. Okay.

Janna Friedly Yeah.

Gary Franklin So they're not just talking about chronic low back pain. But they don't define that anymore than that.

Sheila Rege So, do any of the other studies include neurologic impairment?

Andrea Skelly You mean as an inclusion criteria or?

Sheila Rege Correct.

Andrea Skelly Did we look at studies with neurologic impairment? I'm unclear the question. I'm sorry.

Sheila Rege Okay. No, no, no, did the studies require that patients had a neurologic impairment?

Andrea Skelly No.

Sheila Rege For a solution criteria.

Andrea Skelly No. I mean.

Erika Brodt No. There is one other study. Low back that did say that there was a neuropathic nature of pain in some but didn't really go into more. I can look a little more at the inclusion, exclusion criteria and let you know.

Sheila Rege I would, I would make a suggestion. But gosh, I wish I could write it somewhere. Okay, so. Let's do what Dr. Sinanan and used to do. He used to come up with things that really helped me. So let us start with. What is it called? God, my brain's fried. Don't take it all out. Oh, you can. Take it up. Here's, here's what we're gonna come up with.

Josh Morse Take, you want me to edit this or do you wanna move on to a different?

Sheila Rege No, you can, you, you can just add it on the top so we may be able to get things.

Josh Morse Okay.

Sheila Rege So just create some a white space on top of that.

Josh Morse Okay.

Sheila Rege Covered with conditions.

Josh Morse Okay.

Sheila Rege And then you're going to say, kinda like we always do. A short term file, off file cord stimulator. Now, do we specify lumbar or thoracic that's up to the committee as medically necessary or these conditions. One failed back surgery syndrome or whether we call it, Laurie, help me non-surgical intractable.

Laurie Mischley Non-surgical refractory neuropathic pain.

Sheila Rege Okay, or complex regional pain syndrome or diabetic neuropathy. And then I'm not, I'm not gonna work when number 2 all of the following conservative therapy criteria are met and we can decide a lot of things, say 6 months, some say 12 months. We can decide what to add there later. Or medical records, documents. At least one of the following, we can do exceptions if you want and what I've seen is one is modern pain with significant functional loss. The functional loss and I don't know if it's significant function loss definition. Two inability to tolerate non-surgy, inability to tolerate due to the co-existing medical conditions. And then we come to the VAS. The number 3 is the VAS thing and I'm looking now where this is I had it. I was looking at another policy and I probably should just send it to you. Where is Dr. Sinanan, he was good at this. Give me a minute. Okay. I will tell you and we can decide as committee whether we want to add this or not, give me a minute to look at something.

Laurie Mischley I'm not.

Sheila Rege I was looking at this on my iPad. Go ahead.

Laurie Mischley But I'm just seeing an old version of Josh's screen and not what's been typed and I don't know if I'm the one having the issue or if.

Josh Morse Oh. Let me correct that. Thank you, Laurie.

Sheila Rege Josh, can I email you something? So you can just paste it in.

Josh Morse You can do that, yeah.

Sheila Rege Okay.

Josh Morse Hopefully that fixed it. Thank you for pointing that out. Dr. Mischley.

Janna Friedly We have a couple of hands raised as well. Yeah.

Sheila Rege Go ahead, if you wanna do that, yeah, Janna, while we're, I'm looking at something.

Janna Friedly Yeah, Jonathan.

Jonathan Sham Yeah, I just wonder if it would be helpful as Christoph had had brought up before to look at the Medicare language. I think just seeing how different people's structure the language.

Sheila Rege And I'm looking at the Medicaid language. That's what I'm pulling all this from. It's the California Medicaid.

Jonathan Sham Yeah, yeah, I just, multiple languages, it might be helpful to help a structure in a way that everyone's comfortable with.

Sheila Rege Humor me by looking at this once and then we can we can look at the Medicare and then add it, if you don't mind. Because I looked at Medicare and I thought this was a little clearer. Just because it's an LCD and not a MCD. And I'm gonna, why you ask a second, I'll tell you what this has. And then please walk me down. This actually has a definition of the 10 point VAS scale. It, also says all of the following criteria, multi-disciplinary discussion. No untreated existing drug addiction problems. And they need at least one of the following active conservative therapy 6 months within the last 12 months. And, psychiatry, psychological kind of evaluation. Members obtain clearance from a psychiatrist or psychologist. They had all of that which was in a lot of the studies. Which I didn't remember Medicare having as much because I think it was the local coverage decision.

Janna Friedly Joe, you've had your hand up.

Joe Strunk I do have some language that we could, I could submit to you for possible inclusion. could define, need to fail back syndrome or the non-surgical refractory back pain as persistent neuropathic limb pain plus or minus back pain following spine surgery. For which additional surgical treatment would not be appropriate. And then.

Sheila Rege So you can submit that to Josh.

Josh Morse Can you say that again, Dr. Strunk?

Joe Strunk Persistent, neuropathic limb pain with or without or plus or minus. Back pain following spinal surgery for which additional surgical treatment would not be appropriate. And then from there, it would say recommend interdisciplinary collaboration with surgical expertise. We would recommend only considering patients 18 years in a older. That's where our data is and for other reasons. Quantitative pain scale. Indicating moderate to severe pain, intractable pain despite conservative treatment. This could include a combination of physical therapy, medications.

Josh Morse Yeah, it's going too fast for me to keep up. This point.

Joe Strunk Oh yeah. Could include

Sheila Rege Why don't we do this? Should we have Joe get on our line and with, It's unusual. Well, we did it at a strategic and it worked fabulous. And we can create a document to come back in. I mean, I'm sure we could take over 5 min. Is that okay, Josh?

Josh Morse We can do that. You wanna pause? Is that what you're saying? And you're gonna send me information?

Sheila Rege I wanna pause for 5 min. Let's get a, a submitting call kinda like we were done if we were in a room. Let's get Joe. Let's get Janna, me and anybody else who wants you all in here to get on a little call with Josh? We can type this up.

Josh Morse I think we can do it here. I think that's the better part of valor is just to stay in this room and do that.

Sheila Rege Okay, go ahead.

Joe Stunk Let me see. Physical therapy, medication, trials for greater than 6 months. And then, would be. Appropriate medical evaluation to determine and optimize procedural safety. These would be things like making sure that it's appropriate to proceed from a intellectual safety standpoint, infection, diabetes management all those things. And then multidisciplinary evaluation including psychological to evaluate readiness for procedure. And then, We, I would recommend we do a spinal cord system trial of 5 to 14 days. that would be.

Janna Friedly Joe, can you explain why the large range and how?

Joe Strunk So. The reason for a longer period of time just because of the sub-perception models that can take several days to start becoming effective. And that's consistent with what the evidence has been for the different trials that have been done, have fallen within that range. If folks feel that is. Too long of a period, we could discuss that obviously.

Janna Friedly No, I just, I'm curious why, you know, 5, 5 days seems very different to me than.

Joe Strunk Yeah.

Janna Friedly 2 weeks potentially. So that's, that's why, and, so I'm curious where the data drives, drives that and what the you know, if there's if there are people that have a response at the in the first week that then stop having a response after that or you know what the rationale is for a large range of time.

Joe Strunk Usually to allow enough programming variation to to make sure that we've like if there's gonna be a benefit, we've identified that and if not, then We, we can conclude that as a negative trial.

Sheila Rege I like, I thought we had thought about the shorter trial period just with the what do you call it, the, initial trial. They don't respond to the trial then why do the whole procedure, right?

Joe Strunk Absolutely. It wouldn't be appropriate.

Janna Friedly Oh, no, that's definitely having the trial. I'm just, I'm curious for the 5 to 14 days. Yeah, that's that was what I was.

Sheila Rege Everything I saw was left. 14 days seems a little out of the ordinary. Did a study have 14 days?

Joe Strunk I don't have a name in the study, but I, that is within the realm of what has been done I can't tell you the study off top my head, but we could find one. I'm sure.

Sheila Rege If all vendors will look at that. Dr.

Josh Morse Sheila, I'm gonna. You have a couple of hands up, but I'm also going to. Okay. I just want to remind you of, of an option here. Because we're coming up on rapidly coming up on 4 o'clock and I don't want this to be a rushed process. You know, this is an opportunity to form a subcommittee outside of this group that could come back at a future meeting with more information for the committee to consider including a draft. There's a very structured way to do that. So that is an option because.

Sheila Rege Yeah, we're gonna rush through this and I don't think that's good. And I think that maybe one of Dr. Chen raised his hands to tell us. Dr. Chen?

Christopher Chen Yeah. Thank you. I, I was gonna, I guess just offer that some of these suggestions from our clinical expert are they are decision points. There's a number of other elements that the committee could choose to consider in the crafting of a decision language such as what is the definition of conservative medical management? What are the options that have been tried and for how long? So 6 months is a starting place. There are policies out there that use 12 months. How long has the diagnosis been present for? Is there a documented pathology as a basis for that? To what degree of function has been demonstrated with that diagnosis like does someone have and, and also a tree disability index of a certain threshold. And you know other comorbidities such as the substance use diagnosis and keeping with some of the definitions for some of the clinical trials. I just want to share that there are a number of additional factors in addition to what's been suggested so far for consideration.

Sheila Rege I agree and the policies I'm seeing have, you know, just a lot more guardrails. I mean, even the license medical health provider has a license here and not have a financial relationship with the device manufacturer or a corporation affiliated of a device manufacturer. So there's a lot more guardrails in the policies I'm seeing. And I think it's gonna take us a long time to develop this. So if if this is a possibility for the committee and we have done this before with these asked for, Josh to kind of, you know, kind of get a get a committee together or with a medical director and give us a language that we can then evaluate. Is that something that the committee would be interested in? How many of this committee? I'll do a raise hands as I can see this. How many in this committee would like to go that path? Please raise your hand. Okay, and how many? Well, members of the committee, I'm seeing actually all of them. I don't see and how many would like to. No, your hands please. And how many would like to word smith and you know kind of here today. Can you raise your hand? I'm not seeing any. I just, yeah, I think. Josh, if we go that way, what's the process, the timeline be so anybody who wants to give you input could.

Josh Morse No, that is not the case. So let's, talk about how we want to do this. So we have in statute in our rules, we have the ability to form an advisory group to do this work. That's a very formal process. That is one route that you can go as the chair you can call for a vote to form established an ad hoc temporary advisory group. This would involve the committee chair or designee may appoint or remove advisory members and it calls for a certain structure to that group. We can do that.

Sheila Rege No, no, that's not what I was looking at. I was looking at what we've done in the past.

Josh Morse Okay, great. Yeah, if there's something specific that program staff can bring back to the committee, we can do that between now and, as I said, we were trying to schedule a meeting for January to close this meeting out, but that meeting time can be used to extend this meeting.

Sheila Rege Okay. How do we, vote on that, Val? How would you like us to vote on that? Because the poll right.

Val Hamann I just made, I just, yeah, I just made another sheet. So I, we can just go down the list and you can let me know, yes, no, for subcommittee.

Josh Morse Well, I think we heard, I heard we're not doing a subcommittee.

Val Hamann Oh, sorry.

Sheila Rege Oh no, no.

Josh Morse I think what I heard we're doing is we're going to come up with some instructions here on what the committee would like to see at a reconvening in January. I don't know that we need to vote on this Unless you, feel like you.

Sheila Rege Okay.

Josh Morse Need a vote from the group to agree that we're gonna stop here and do that. I do think it would be. Helpful to get some written instructions as far as what to bring back that will be helpful from the program staff, from our contractor and possibly from the agency medical directors.

Sheila Rege We have done this before. I think based on our discussion, you know that we're looking at cover with conditions for those for those conditions. I'm sorry, for the 4 things we talked about but from what I was hearing it was failure of conservative therapy definition you know pain and if you could bring something back like we have for the genetics we brought something back for this committee to look at.

Josh Morse We can do that.

Sheila Rebe The question I had, so the timeline is, and you put it on based on what our regulations is, when it will be circulated as well for us to look at. You know, it would be posted that we can see it before the meeting, right?

Josh Morse Yeah, we can definitely post meeting materials and meet with you about that prior to the meeting and then make and then publish that.

Sheila Rege Okay, is that and is that does any committee member have an objection to that?

John Bramhall No, and so Josh, you're the expert on this. It sounds, it sounds like there will be material generated in the interim meeting perhaps in January and we'll consider this in in depth with that information the information that's generated becomes part of the

public record contemporaneous with its formation is put up on the website is that. Like the, like the literature review?

Josh Morse Prior to prior to the meeting. Correct?

Sheila Rege Okay. That being said then did they have any other? Any other issues or any other discussion on the data or something we want to convey to Josh as he's, kind of, going to come back to us with.

Josh Morse Kristoff has his hand up.

Sheila Rege Okay. Okay.

Christoph Lee Yeah, just procedural. I just want to understand, are we okay to stop at a Strava? I don't think we actually formally voted. So rather than going to the links of creating language about coverage with conditions. Should we do we get the formerly vote? Before we branch off and, and create new language.

Josh Morse It's a good question.

John Bramhall I guess my, I don't think we do. I mean, I think that we're having difficulty. This is a, this is a topic that's closely watched and we're having difficulty just sort of sorting out our ideas so to be honest, I mean typically the straw vote is not changed a lot when it comes to the real vote because when we do our strove, we process the data as best we can. So, so I'm not, I'm not sure, I don't know, it, but I think we're, we're a bit stuck and we need. I think the idea of having a clarification of the language that we might use and the clarification of the language that is used in other states and a clarification of the definitions which we're still struggling with would be really helpful. And it and then we get to a straw vote and we discussed in January and then and then make a determination.

Sheila Rege Okay. Joe, you brought up a procedure question that is very valid. We only took a struggle and we started working a language. Maybe we do as a procedure, Josh. Need to take a, the final vote and then the final vote we would then start working on conditions or is the way John proposed that we have you work on it now after the straw vote and then we do the final vote later, which would be better with our rules.

Josh Morse I don't think the rules impact this decision. I do feel like voting now, making a formal vote now will make things more complicated.

Sheila Rege Okay.

Josh Morse I think what you would normally be doing now had you had we got to criteria is you would then look at that and you would vote to cover or not cover. You'd be voting to not cover or you'd be voting to cover with those drafted conditions or some may be voting to cover without any conditions. And I think absent those conditions, that vote doesn't make sense unless you have a sense that the group is going to vote to not cover or to cover without conditions. I don't have that sense, you may have a difference sense. I think we will just know we will need to develop conditions for conversation and voting. Yeah, and we've given everybody enough chance to say, you know, not cover. And I don't see anybody saying go with conditions. I'm sorry, cover unconditionally. I, so I think we're good the way it is. John, thank you for clarifying what we'll have to do when it comes when it comes back. Anybody else with any other comments? Okay. Our committee member Conor just messaging me that he is coming back on in a minute. We may be done by the time he comes back on. Yeah. And just to let you know, the, the January date may, may change, so just, be aware of that. And, look at your email especially now that we may need more time. My vice chair, Janna, anything else that we've missed?

Janna Friedly Nope, I think that sounds good. Sounds like a good plan.

Josh Morse So we will come back to this group and we will consult the chair and the vice chair about drafts developed drafts of potential language for the 4 areas that have been discussed.

Sheila Rege I do have a request, Josh. Can you get an easier topic?

Josh Morse Yeah, I've got a bunch of easy topics right here. And we just decided to give you this one today. So.

Sheila Rege Oh no, I'm just kidding. I mean, if it was easy.

Josh Morse We'll put that on your list for the holiday season.

Sheila Rege You wouldn't. Hey, everybody happy Thanksgiving. Thank you. I know we, have really, you know, it's rare we go this late, I apologize. It was a tough topic and we had to give it. The amount of time and you could see the interest level of it from everybody. Thank you. Bye bye.

Josh Morse Thank you all. Yeah, really appreciate everybody's work and attendance today. Thank you so much.