Washington State Health Care Authority

# Washington State Health Technology Clinical Committee Meeting

Spinal cord stimulation

February 16, 2024

DISCLAIMER

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| Josh Morse | And Erika, next up I think will be your presentation debrief. So, if you're hopefully ready for that when Val has confirmation of what we do, we'll jump into that. |
| Andrea Skelly | Sure, no problem. Just let me know when you want me to share. |
| Josh Morse | Thank you. |
| Sheila Rege | While we're waiting, and is everybody, any of the committee members having trouble accessing HTCC materials? Does anybody need help in accessing the past materials because we're gonna do a recap just making sure everybody. Otherwise, you know, to look through while we're waiting. |
| Josh Morse | And as, that's a good point, Sheila, as everybody on the committee knows the previous meeting information is available in the meeting materials. It includes all the presentations that were given at the last meeting, the public comment period, etc, the agency medical director's original presentation. |
| Sheila Rege | And you let Josh know if you're having trouble finding it, but maybe while we're waiting for this we could I'm just rearranging myself for all the studies and kind of the past discussion. |
| Josh Morse | So. Yeah, there we go. |
| Val Hamann | Okay, Josh, we, we have a workaround. And have some recording in place. I am going to be unable to do a lot of stuff though, however, so I don't know if Melanie is able to open the voting record document. My screen is recording so everything is being captured, but. |
| Josh Morse | And I think we have transcription on already? |

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| Val Hamann | Correct. |
| Melanie Golob | Yeah. |
| Josh Morse | Okay. So that's fine. If we have the transcription working and if you have a backup, we can work around that. We've had the transcription it sounds like on since the beginning so we're good there. I think this is the more complete recording part that switch wasn't thrown or something so why don't we get back to it and Melanie and I can work around the voting document, which I certainly have access to. It might take me a second and I'll work on that. All the presentations going on. |
| Sheila Rege | Okay. |
| Josh Morse | Apologies. |
| Sheila Rege | Oh, this happens. Let's go ahead. |
| Andrea Skelly | Okay, I'll go ahead and whare my presentation and are you able to see my presentation? |
| Josh Morse | We're seeing your screen now, yes. |
| Andrea Skelly | Okay, so let me. So you can see what you need to see. Are you seeing presenter mode? Are you seeing? |
| Josh Morse | We're seeing presenter mode. |
| Andrea Skelly | Okay, so we're in good shape then. |
| Josh Morse | Yeah, gotta switch it around. Sorry. Yeah, the link goes. Same thing, I had, I did the same thing. |
| Andrea Skelly | Oh, okay, so you see my notes. So I am grateful and thank all of my, my coworkers on this. |
| Josh Morse | Yeah. |
| Andrea Skelly | Let me. Is that better? |
| Josh Morse | That is correct. Thank you. |
| Sheila Rege | That is much better. |
| Andrea Skelly | Okay, super. All right, we'll get this down. So again, thank you for the opportunity to provide a little bit of an update but a recap of the previous presentation. Erika and I |

are here, here to answer any additional questions that you may have. I just wanted to give a brief overview of the question scope and methods as a refresher. Everything I have for you is either in the prior presentation and, or the report. So nothing new here. You're all familiar probably with the key questions that we are looking at adult patients who may have had either chronic low back pain, failed back surgery syndrome, complex regional pain syndrome or peripheral diabetic neuropathy and looking at spinal cord stimulation. As with regards to effectiveness, safety, differential effectiveness or safety and cost effectiveness. As a reminder, our scope included patients who had not been previously treated with spinal cord stimulators. And the comparator was to either medical and, or surgical treatment that was appropriate to the condition. And the scope did not include comparisons with spinal cord stimulation methods or devices or other neuromodulation devices. By way of reminder Appendix C lists all of the articles that were excluded at full text. There was some discussion with that at the prior meeting about studies that made that were not included and the reason they were not included is that they were comparisons of 2 different types of spinal cord stimulation or methods. So from our perspective, from the PICOTS there was not a control group. And that's just, as a reminder, to find some of those studies.

As you know, there were 2 different types of randomized control trials presented. In this review one is a parallel group which most of us think of as the quote usual type of RCT where groups are randomized and followed across time. And in all of these studies, most, well, all of the studies that were parallel group or usual RCTs in this report. there was an intentional crossover at 6 months and that really breaks randomization. And so as a reminder, that's why some of the follow-up is only up to 6 months. The studies that were included here in crossover trials, there's an intentional crossover to another treatment. All of them included a random sequence and there are additional risk of bias considerations in crossover trials. And just by way of review, we looked at eligibility criteria that were established our priority for efficacy, harms, and safety studies. All were appraised for risk of bias and classified as good, fair, poor in that regard and then across studies reporting on specific outcomes, there was a determination of the overall strength of evidence. And our confidence then in that evidence is based on, is related to high moderate or low confidence. For that outcome as a reminder across outcomes you may find that there is a different strength of evidence based on the types of studies and the numbers of studies that are available and the findings.

So with that in mind, I'm gonna give a brief summary of the findings. First of all, as a reminder, we classified the magnitude of effects as you see here for pain on a 5 to 10 point scale or 0 to 100 scale which is what most of the groups did so a slight improvement on a ten-point scale was point 5 to 10 points. And you can see then moderate one to 2 points and then over 2 is a large substantial for function most studies reported ODI and you can see what small moderate or large effects size risk of relative risk or odds ratios a small effect was considered to be 1.2 to 1.4 and a large over 2 as a note that was I made during our presentation is that large effects over to are not common. And small effects that were below the pump, these thresholds may

still be clinically meaningful, small effects. That are below published specials for MCID may so have clinical importance to patients as a small improvement may be important to them. If there were effects below the threshold for a small in this categorization, they were classified as no effect. So with that in mind, these are the same studies that are in the report and the prior, prior presentation. We've only added some color coding and the names of the studies for clarity. As you can see for back pain, chronic back pain we had one study that looked at back pain after surgery with chronic radiculopathy after surgery. And the strength of evidence, the studies were the study was confined to the 3 to 12 month period. We found that there were similar effects between burst and conventional spinal cord stimulation and the strength of evidence was moderate for that. It was a small study called small crossover study, but for leg pain, the effect was considered low strength of evidence. Study there was one study that looked at failed back surgery syndrome and look at a variety of different frequencies. We considered the strength of evidence was insufficient for that small crossover study for leg pain and back pain. There was another study where 78% of the patients had failed back surgery syndrome. And the pain was not specified in terms of leg or back pain. And again, we considered that the strength of evidence was insufficient. And there was no evidence that other timeframes as listed on this slide.

Erika Brodt — Andrea. Sorry, real quickly on that other slide one to clarify. I think you misspoke and said it was first conventional.

Andrea Skelly — Yes
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Erika Brodt — Spinal cord stimulation, it's sham.

Andrea Skelly — Oh, thank you so much. Yes.

Erika Brodt — Oh yeah, just to clarify all that was versus. Okay.

Andrea Skelly — Thank you so much. Apologies for those. I'll try to get through quickly. Thank you. So here we are looking at conventional spinal cord stimulation with conventional medical management in parallel tracks. And in the parallel trials, we had a couple of studies that looked at conventional spinal cord stimulation. And these are patients with failed back surgery syndrome with radiculopathy with a note that one of the studies enrolled patients with leg pain that was greater than back pain and the other enrolled patients with back pain greater than leg pain. And with regards to leg pain in terms of the individuals who met minimum clinical thresholds of at least 50% pain reduction on either of VAS or a similar scale, there was a large improvement in, or large, larger likelihood of pain, having being a pain responder. In the studies at 3 months and at 6 months, there's one study at 3 months, 2 studies at 6 months and the low back pain score is just looking at the mean differences in back pain scores. There was a small improvement in one study in 3 months, large moderate improvement at 6 months. And then leg pain scores, large improvement. Short-term in one study and then across 2 studies, a moderate improvement. And again, these would be mean differences. The

strength of evidence was considered low. There was no evidence at 12 months again as a reminder these studies had patients who crossed over to spinal cord stimulation after 6 months. With regards to function, at 6 months there were 2 studies and both showed as the pooled estimates that there was a small improvement in ODI. The proportion of patients was still using opioids. At 6 months, there was a small decrease across 2 studies. The strength of evidence was low for each of those outcomes. And in terms of opioid use, we felt that the evidence was insufficient to drop conclusions. And then moving on then to, we had one study, Kapural, who looked at, it wasn't failed back surgery syndrome, but it was non-surgical refractory low back pain. And in this particular study the percentage of responders there was a higher, much higher, higher likelihood of pain response with spinal cord stimulation and this was a high frequency spinal cord stimulation. At both 3 months at 6 months, there was no evidence with regard to leg pain responders. If we look at mean scores, there was again a large improvement, in the main difference, favoring spinal cord stimulation at 3 months and 6 months. And then if we look at responders with regard to at least a 10 point decrease in ODI from baseline. There's a large improvement both at 3 months and 6 months. And then the strength of evidence for all of this is low. And if you look at functional scores, ODI, again, mean difference there was a large improvement with spinal cord stimulation, but the strength of evidence was low. The proportion of patients who stopped or decreased opioid use, again, there was a large increase, higher likelihood of, of stopping or decreasing opioids within 6 months with regard to mean morphine equivalent dosage for opioids however the risk. The strength of evidence was insufficient.

Conor Kleweno Can I interrupt? Can you just remind us why you rated it as a low strength of evidence just as part of the review?

Andrea Skelly Most of these and, and the strength of evidence is in section 5 I believe of the report. But in general, they were downgraded for risk of bias.

Conor Kleweno I understand.

Andrea Skelly So that's one part of the strength of, parts of, there are 5 general parts of strength of evidence.

Conor Kleweno I understand that. I'm sorry. I'm just saying you're reviewing all of the parameters on this particular study which was quoted often so I just thought it would be helpful to review, you gave this particular study low strength of evidence just as part of our review.

Andrea Skelly I see.

Conor Kleweno Just because there was a lot of emphatic discussion amongst the public during our last session.

Andrea Skelly — Thank you, yes. And I would need to go back. I can't with the screen, go back to the strength of evidence tables, but both of them and this particular one, it was downgraded because of risk of bias. It was considered to be a moderate risk a bias. We, with a single study, are unclear what the consistency would be across studies because this is a single study. And then the, the strength of evidence downgrade for precision. We only downgraded one. And because the confidence intervals were so large across the, across the evidence estimates, those are the 3 primary reasons for downgrading. Does that answer your question?

Conor Kleweno — Yeah, and you're discussing the Kapural 2022 with those 3? Okay.

Andrea Skelly — Correct. Correct. Erika, you have the strength of evidence up, right? So, and that's.

Erika Brodt — I do. I do. So like for instance for low back pain responders. Just. Yeah. The confidence interval went from 8 percent up to 400. So very large. Yes.

Andrea Skelly — So that's, that's very large. Yeah, lot of imprecision.

Erika Brodt — One example. Yeah, so. Okay. But yes, if there are other questions.

Andrea Skelly — Okay. So we did have one study that was in the prior report that looked at spinal cord stimulation versus re-operation. We felt that the evidence was insufficient to draw conclusions. From this particular study with regard to either treatment success or opioid use, I created this summary slide again. It's nothing new here, but there was some discussion in the prior meeting regarding how heterogeneity, that there was heterogeneity across the studies looking at back pain with regard to the populations that were enrolled. The study design, the types of spinal cord stimulation that were used risk of bias and the numbers of patients available. And you can see that there were a total of 4 or 5 studies that looked at failed back surgery syndrome. 2 crossover trials and 2 parallel trials that looked at different comparators, but only one that we just discussed north that looked at re-operation. With regard to the crossover trials, we felt that the evidence was insufficient. For failed back surgery syndrome when comparing different frequencies of spinal cord stimulation with sham, the 2 other studies that looked at conventional spinal cord stimulation versus conventional medical management. Again, there were improvements in function that were small. There were large improvements for pain, back pain, modern improvement for leg pain. And again, estimates across these studies were imprecise and that was a reason for downgrading to strength of evidence being low. There was one study that looked at radiculopathy after back pain surgery and again, the results for function and back pain were similar, the moderate strength of evidence. There was low strength of evidence for leg pain. And then we had one study, the Kapural study that looked at chronic refractory, axial, no back pain in patients who are not surgical candidates. So these are different patient populations. As a reminder of the Kapural study also was a per protocol analysis not an intention to treat analysis and for the reasons we just discussed. The estimates were imprecise and there was a risk of bias concerns as well

as unknown consistency leading to a low strength of evidence. So that was low back pain. If we turn our attention now to neuropathy. We had, 2 studies that looked at conventional spinal cord stimulation. And then one study that looked at high frequency spinal cord stimulation. And across the studies that looked at conventional spinal cord stimulation versus conventional medical management. We see that the responders at 6 months across 2 studies, there was a large increase in the proportion of patients who had spinal cord stimulation, higher likelihood of being a responder. The strength of evidence was low with regard to low back pain scores. One study was available at 3 months, 2 were available at 6 months. And again, a large difference between spinal cord stimulation and conventional medical management. We're seeing again, strength of evidence was low and one study did look at proportion of patients still taking opioid opioids at 6 months. And there were no differences or the results were similar between spinal cord stimulation and conventional medical management. I'm seeing the evidence was low. So that was for conventional spinal cord stimulation for high frequency, one study by Peterson, a recent study. Again, found a higher likelihood and a substantially higher likelihood of being a responder with spinal cord stimulation versus conventional medical management. And a large improvement in being scores mean difference between spinal cord stimulation and conventional medical management. But again, the strength of evidence was low.

Josh Morse — Doctor, if I could interrupt Andrea, I think a hand to me have gone up and come down. Jonathan, did you have a question?

Jonathan Sham — Yeah, it just pertains to the, the imprecision question that was addressed before and for those of us who are statisticians on the line, I personally get much more worried when I see a common interval kind of approaching one or almost touching one and not when I see a relative risk, like in the double digits. And, you know, in this case, ranging from, in the Kapural, from 8 to 400. So I wonder if you just tell us a little bit about how you review precision in that context, given kind of what's being measured, understanding the variability in what's being measured. And I guess why such a positive result would be viewed as, I guess, decreasing the strength of evidence?

Andrea Skelly — Okay, so there are 2 different concepts here. The first concept is the point estimate itself and what goes into the point estimate. And the point estimate, is looking at the, the difference you know in in either meme scores or the relative likelihood of being successful. And a large a large effect size is generally not common in most studies. We don't downgrade for that. And that's a separate issue though from looking at the precision. The precision has to do with how much variability there are in the data. So if you have a room of basketball players and then you have those of us that are less than 5’ 5” there's gonna be a lot more variability depending on the number of patients who number of people who are like me, 5’ 5” versus those that are at 6’ 6”, 6’ 7”. If you have a lot of patients who are dissimilar, in other words, you will have much more variability. And the estimates, and that's what we're talking about when we're looking at precision. It's not how close it is to one or 0.

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| Jonathan Sham | Yeah, maybe I'll specify. I'm sorry, I wasn't clear with my question. So I understand what imprecision is here. I'm asking why conceptually is this imprecision factored into the strength of evidence in this way? I guess that's more specifically, in particular when we have a large effect size, I'm just thinking, we have an outcome that is highly variable given how it's measured in pain scores, etc. And I'm just conceptually trying to figure out my mind how much I should downgrade the evidence, and my confidence of the evidence, even though you have kind of a wide, or it's gonna go imprecise effect. |
| Andrea Skelly | Well, the domain, the downgrade comes from the application of grade. And looking at again, the variability around the point estimate itself and that is separate from considering the size of the effect estimate. And what we have done is consistent with application of grade not only here but across other projects. And if there is a difference between it's a large effect. Yes, it is a large effect. The downgrade does not have to do with the large effect. But if you look at the effect size of I think the confidence interval that Erika coded was for up to 400. That's a large variability. And I assume that what your. |
| Jonathan Sham | Yeah, you're gonna, I'll just follow question. Is it a true statement to say with the larger the effect size, it's harder to be precise? Like, if you had effect size in the fifties, sixties, it would be much more difficult statistically without a huge sample size to have a very narrow common interval relative to a much lower effect size? |
| Andrea Skelly | I mean, your effect size and the confidence interval has to do with the variability and the data and the sample size. So I think it would be difficult to make a sweeping statement. That large effect size will always have a large confidence interval because it's going to depend on the variability within that patient population. I think it's hard to explain a large effect size that is so, so, so large. And again, what would be necessary here from a scientific standpoint is to see to what extent do other studies provide the same level of confidence and consistency across that set of outcomes or that outcome. So we don't know what that consistency would be. And I see several hands up. I think Dr. Kleweno was the first one I saw. |
| Conor Kleweno | Yeah, I'll go a second because I talked too much. So I'll defer to Janna and Laurie and maybe talk after them. |
| Andrea Skelly | Okay. |
| Janna Friedly | You don't talk too much, Conor so your impact is critical. So I think I just want you to know that. But I will go ahead at your request. I think one thing I, Jonathan, I totally, understand your, where your concern is usually when I think of the you know the confidence interval of the low end of the confidence interval is still well above, you know, one that reassures me that if you were to repeat the study that you would get within that same range, I think where I'm, what I have to consider when I'm looking at this data in particular is the comparator of conventional management which these patients have already failed. So you're so the true effect size is going to be much lower |

than what is reported here because these are you're comparing against a group that you already, you have 0% improvement and we know that when you look at placebo or you look at sham control trials, trials you know a sham versus the intervention that the true effect is much, much smaller so that to me is where I have a hard time interpreting these point estimates, in these, in these trials because I think, that that, you know, really clouds what that, what that low end of the confidence interval is. So you combine that imprecision with that for me the, the lack of confidence in the actual point estimate is how I'm looking at it.

Andrea Skelly — Yes, and, later on we, as far as some of the considerations there was much smaller effect sizes with the studies versus sham which was the crossover studies. Then they're just conventional medical management. Laurie, were you gonna?

Laurie Mischley — Yeah, I was just gonna say I mean, I think this is not the time to get into a big philosophical conversation about downgrading, which we've done before and I have lots to say about. But I think my point of clarification here or question has to do with the rules being followed. Like what is the definition of too wide of a confidence interval? Right, like if it cross 0, I'd be okay with that, that's clear. I just, I'm uncomfortable downgrading something because of the, you know, that's a little too wide for my liking. So my question is, is there a rule that guides your thinking in terms of where do you slice it as too wide for your liking?

Andrea Skelly — Grade has a number of publications related to looking at precision. One of the finding points would be, would your, would your clinical judgment be different? At one end of the confidence interval versus the other. So your point regarding is it close to one or is it a small effect versus a large effect? That's one of the criteria that are consistently applied. We don't have that situation here. We have a large effect versus a larger and larger and larger effect. And to your point, no, there is no is it within 5% or 10% or 20%? I think the conventional wisdom is that if It is swinging as high as 400 that's pretty wide. That's pretty wide. The other aspect is considering again looking at the sample size, which gives you information about the variability across. The individuals that are in there. And when you look at a wide confidence interval, it seems that logical that the variability is much more substantial. The consistency in order to make a firm commitment of where, of how, how small that confidence interval should be. And you know, I can, you know, after I finish the presentation, look up much more information and send to people if they're interested. What GRADE says about downgrading, for, for precision and that is separate from consistency. And part of the downgrade is we don't know what the consistency across studies would be. If under the same conditions, we would be able to replicate that estimate. And the same or maybe lower, hopefully lower variability, but you're dealing with a study that also dispersed 1 one of the studies, the Kapural study looks at per protocol versus intention to treat. And that may be part of why we're seeing a larger effect size compared with a study that would have looked at intention to treat as well. So there are a number of unknowns. It's not just the precision. But there are a number of unknowns that go into

the overall strength of evidence. And our low confidence even though the effect size is high.

Laurie Mischley Thank you.

Andrea Skelly Conor, did you?

Conor Kleweno Yeah, I think you may have answered. I think there was a, you know, general discomfort by several of us to just chalk up a high variance or imprecision, even though it's, you know, clustered in a high effect size realm to just immediately go to low confidence. You know, if you're saying there's a summation of some bias as well as the methodology. It's just that you know, we have a study with that's, you know, randomized control, supposedly. And we see a large effect size and you know the imprecision I understand the concept, I'm not a biostatistician but I understand the you know precision accuracy consistency I think what you're trying to get across but you know I would not really expect a tight confidence interval in this type of patient population anyway. Given my clinical background, you know, if you look at other interventions that we do in medicine that have a high effect size and in my life you know a total hip replacement you know very high effect size. But even within that, we do see quite a range of imprecision, but it's all almost always clustered in positive effect size. So you know, when we get down to what we as clinicians, as care providers, how we interpret these studies, you know, I think that there were several of us that like we see a large effect size and we sort of expect some imprecision and I think that's where part of our hesitation was so thank you for you know expanding upon you know, your, report and why that's downgraded. I think if, several us just paused at that.

Andrea Skelly Yeah, no, I understand that and appreciate that. And again, the low confidence is not related to the effect size. And the low confidence is not solely based on the imprecision. But the fact that there are some methodological issues that go into the consideration of overall strength of evidence, unknown consistency. Those are 2 parts that also go into the overall strength of evidence. So it's not a single, a single thing.

Conor Kleweno But. But this so that's just a surprising that you know like let's say this was the first study ever done you would immediately downgrade it because you don't know if it's consistent, if it's generalizable. And I get that in concept. I just surprised that it's such a strong thing to do like somebody per you know reports a study and let's say it has good methodology and you say well we don't know if it can be repeated yet. So we may have some hesitation, but I would be surprised at that immediately sort of downgrade it and maybe the answer that I'm stuck on is that you're saying there's a summation of issues that have led to this downgrading, but you know, high, high imprecision with a positive effect size and the fact that we don't know a prior if it's. If it's generalizable for sure It would be unexpected that that would get such a downgrade from.

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Sheila Rege — No, in the interest of time, I see a lot of raised hands. Let's try and keep our comments, maybe to 2 min, and just trying to move along. I hear, I mean, all of us are struggling with this. Is that okay?

Jonathan Sham — Sheila, can I, can I, just one clarifying question I think could help solve this perhaps.

Sheila Rege — Yeah.

Jonathan Sham — So, Andrea, I just wanna make sure that I hear what you're saying clearly. Would it be true to say that this high well I guess as a background I think we're looking at it we wanna know is there an effect or not kind of at the end of the day, that's kind of the baseline question. Is the downgrade for imprecision? Is that just saying that you're really can't be confident that the relative risk is exactly 56. But like cause that I could agree with yeah, we're not really sure whether it's 56 or 70 or 30 like you know we're not sure But again, we're asking a little bit of a different question. We don't really care whether it's exactly 56 or not and that's certainly imprecise. I agree with that. Give them the wide confidence interval. We're really asking is there is a positive or negative kind of at the end of the day and so is the comment on imprecision regarding the exact number? Or is it whether or not there's an effect at all? Cause I think those are 2 questions, 2 very different questions.

Andrea Skelly — I understand, yes, and yes, there is an effect. We said that there was a large. That's a separate question from the precision. So to your point, yes, the question is, is it that 7? Is it 56? Is it 400? That's kind of a large continuum to consider where does the effect really land. And so your point is well taken. So yes, we've said that there is an effect. There's a large increase. Or a moderate increase. And then separate from that, you know, where does it land? So we're not, there's nothing in here that says that there isn't an effect. And yeah. You know, one of the things to looking at risk applying grade.

Jonathan Sham — That's very helpful. Thank you.

Andrea Skelly — Is risk of risk of bias is part of the consideration. And if randomized control trials start out as high. And you downgrade one or risk of bias or moderate. You know risk of bias. That already takes it down to moderate. If you downgrade for unknown consistency some people do some people don't we did not hear other than taking it into account overall. Then that brings it down to low. And that's without even getting to the precision piece. And in most instances, the effect size does not play into that confidence. If that helps at all. So are, are we ready to move on?

Sheila Rege — Yes.

Andrea Skelly — Okay, so when we last left our heroes and We were looking at peripheral neuropathy. And again, conventional spinal cord stimulation. Yes, there was a large increase in the proportion of responders related to spinal cord stimulation versus conventional medical management as well as pain scores, opioid use was similar at 6 months. The

high frequency study of high frequency spinal cord stimulation versus conventional medical management. Again, we saw a larger proportion of patients responding at both 3 months and 6 months timeframes as well as a large improvement in pain scores. But the strength of evidence was considered to be low. There was no evidence related to opioid use or at longer term. And these were again parallel trials.

If we look at complex original pain syndrome. Again, we see that across the board. At all time frames up to 24 months across 2 studies, pain scores, there was a large improvement at 3 and 6 months, moderate improvement across those 2 studies. At 12 to 24 months, one study we felt was insufficient to provide information at 60, 60 months. It was one smaller, the smaller of the studies and had some risk of bias issues associated with it. Looking at functional scores, moderate improvement at 3 months, small improvement at 6 to 12, 6 months in the 12 to 24 months as well. So improvement again that effect size yes there was an effect our strength of evidence was low. One study of high frequency versus final versus conventional medical management. We thought the evidence was insufficient. And that was the, the one study, the from 2021. If we looked at the crossover trials, there was one study, very poor quality study that we looked at and we felt that the evidence was insufficient.

In terms of harms and safety there was a lot of heterogeneity as you might remember and how the different harms were classified. Of the severity of implications for some of the events were really not specified for things like infection or lead migration and they weren't consistently reported or categorized. And most studies it was not clear to what extent patients might have experienced more than one event. And based on our clinical expert input, we attempted to prioritize and synthesize across common important categories of both device related and biological events as well as some utilization related things as well across the board spinal cord stimulator related. And first events were common, but there was a substantial range in the frequency of those events across study types. If you look at the randomized control trials, rated strength of evidence being low or any spinal cord stimulated related adverse event. And you can see that the range at 6 months was different than the range at 12 to 24 months. With regard to events, requiring surgery in these studies. Again, you can see that there were fewer, slower percentage at 6 months, a greater percentage at 12 to 24 months. I would remind us that the overall sample sizes for these studies were generally small. So keeping that in mind when you consider the percentages of the withdrawal due to adverse events in the RCTs was similar at 6 months. We also looked across study designs, so not randomized studies, including case series. And the most common, the ones were listed here and again the strength of evidence was low. And again you see a very wide range. In terms of explantation, revision and replacement of the devices and that includes a wide range of removal for inadequate pain relief, loss of efficacy, or inadequate benefit. Need migration or lead or lead replacement or revision, again, a wide range up to 21%. With lead fraction or failure being again a wide range of to 15.8% so a wide range that goes those higher. From higher to lower. If we take a look then at some of the less common adverse events that were reported. Again, this is across study designs. Lead failure or migration, again, was not necessarily specified as

being surgically needing surgery. And again, up to up to almost 10%. Removal for infection was less common. Serious infection was less common. And across that you signs the least common were revision or removal or for displacement or migration. Serious infection, radial tear, and neurologic deficit, those were the least common. There is excruciating detail in the report appendices, summarizing across study designs for these particular adverse events

Cost-effectiveness, there were only 2 US based full economic studies. One was good quality, one was poor quality study and workers compensation population, again may or may not be generalizable to a broader population. They did not find evidence of cost effectiveness and willingness to pay thresholds that are common. One more quality cost utility analysis in the non-surgical back pain population found that it was cost-effective versus conditional management alone, but that did not include the costs for the procedure to initiate the trial for spinal cord stimulation. And they concluded that within 2.1 years, spinal cord stimulation would be cost effective. Once those costs were considered, there were a number of non-US studies, mostly were good quality and among patients with failed back surgery syndrome, they reported that spinal cord stimulation was cost-effective versus conventional management or re-operation. Same thing with CRPS. 3 studies reported that it was more cost-effective to have spinal cord stimulation. Spinal cord simulation was not cost-effective in the one study looking at patients with peripheral neuropathy. There are a number of limitations across these studies that include extrapolation of data that were relatively short-term to longer term time horizons. Limited sensitivity analyses were done and the assumptions regarding the effectiveness were not always clear in these studies. As was modeling of adverse events was, was not often clearly delineated. As a reminder, the effects size that we see is not only related potentially to the difference in treatments, but also additive effect related to these other contributing factors. And also making a case that we look only at case series effectiveness is, not comparative and therefore difficult to truly assess. These are the same considerations brought forth at the in the prior presentation. Again, there's heterogeneity in the patient populations. In the types of spinal cord stimulators that were used and the parameters, the components of conventional medical management were not often well-defined or described. And concurrent medication use is noted across all studies. Again, may not be well specified. It's unclear based on consultation with our clinical experts how comparable and applicable some of the parameters used in the randomized control trials are to usual clinical practice and the bottom line is in clinical practice the delivery parameters are tailored to the patient.

Well, we already mentioned that the magnitude of effect was different when you looked at comparisons. Oh, spinal cord stimulation with sham versus conventional medical management. And some of the effects may at least be due to a lack of patient blinding. Yeah, expectations of benefit and other nonspecific effects. As well as the effect of the intervention. There is a lack of precision in the effect estimates. And we discussed about that, but the effects size and the confidence interval around that do call into question the stability of the exact estimate. The impact of a number of things

is unclear with regards to the crossover trials. It's unclear whether there was an adequate washout period that may have impacted the effects that are seen at subsequent. Subsequent methods used in the next sequence for patients. There was a potential for breaking, patient blinding for some of the loads of operation. In the crossover trials with regard to, adverse effects, the randomized control trials in particular may have been underpowered to detect uncommon or rare adverse events. And again, there was a lot of heterogeneity and how things were described and classified. Oh, with regard to applicability, the patients who are enrolled and followed were patients who had positive response to a trial of spinal cord stimulation and most reported failed conventional management. And they were selected using a multidisciplinary assessment, but that was not well described in the studies that were included. The criteria for diagnosing fail back surgery syndrome and non, non-surgically amenable refractory back pain were not well described. So we don't know what specific criteria we're used. And again, economic studies there were a number of concerns related to how those were conducted. So I will stop there. I do have the full presentation from the Fall appended to this if there are specific slides or things that you want to go back to. So thank you so much for your questions and your attention. Janna, you had your hand up.

Janna Friedly — I do. Can I just clarify, you know, one of the studies that you mentioned, here and that came up quite a bit, that I just want to review for a moment, is the, the Canos, Bridget, the CRPS study that was that you would rated as a poor quality study. I just wanna go back on and I'm trying to I think it's on page 196 of the of the report or the materials from, from the last meeting if that helps but you have a slide that shows the that there were significant baseline differences between the groups in terms of their baseline differences between the groups in terms of their baseline function and presumably pain where the where they, baseline ODI, in the treated groups. Was 65 58.5 and conventional was 32.4 so about half of what that was and then there was no improvement in the conventional medical management but the but there was improvement in, in the spinal cord stimulation that, really stood out to me. And I'm curious if that if that played into some of this discussion or how you consider. Those, you know, huge baseline differences in the groups. And how to interpret that.

Andrea Skelly — Is there a specific slide that you?

Janna Friedly — This one right here. Am I interpreting that correctly? This baseline you have here, baseline ODI scores, 65. 58.5 and then 32 in the conventional?

Andrea Skelly — This one. Okay, great, great. That is, go ahead, Erika. Okay.

Erika Brodt — Yeah. Oh no, I was just saying yes, yes you are. Yeah, this one, this one head a number. I mean, not only was it a very small sample size, as you can see. Yeah, there were differences in pain and function at baseline such that the spinal cord stimulator group you know, was worse at baseline so they could improve more obviously than the conventional. And there was also a difference in, I believe there were more females in.

Let's see, I had I had it up. There were, there were a number of differences. So there were more females in the conventional group by about 20%. Age, the conventional group was young, younger or sorry, older, more than the spinal cord. So they're just like a number of baseline differences and this comes into play with risk of bias.

Janna Friedly — Yeah, okay, I just wanted, I wanted to clarify that because that was a study that was highlighted multiple times in the in the comments and the presentations as that we discounted this this trial or the you know that that it there wasn't included in the report or that we discounted it and I just wanted to highlight that because that really stood out to me.

Erika Brodt — Yeah.

Janna Friedly — And so sometimes when we're talking about the summaries of risk of bias, some of these details like this don't, don't come out, necessarily in the, when, we're talking about reasons for risk of bias or potential and how to interpret the results for risk of bias or potential and how to interpret the results. So I just wanted to highlight that.

Erika Brodt — Thank you. Yeah.

Sheila Rege — Okay.

Andrea Skelly — And we can look up the rest of the risk of bias if, if you would like but part of baseline differences do go into our algorithm for overall risk of bias for a given study.

Sheila Rege — Dr. Bramhall, John has a question.

John Bramhall — Oh yeah, thank you. So this may not be the right time to raise this, but, but Andrea, I just want to get, an impression there were, there were other papers you didn't include in the report for good reason. In particular, I was interested in 2 papers that look at the variation in response to closed loop and open loop and I think we're familiar with these McHale papers and the point is that I understand that they were excluded initially on the basis of the, and we've continued to, I think, exclude those papers. And what I want to, I think, exclude those papers and what I want to ask is relatively informally the rationale for excluding these recent papers that are were commented on extensively in the public discussion at our last meeting. The, the reason that they've been excluded is because they don't have an objective control group. Is that that continues to be the, the block to looking at those studies? The ones I'm looking at are 2020, 2022, McHale. And they again have to do with the variation in response to closed loop versus open loop which seems to be a, a more modern methodology.

Andrea Skelly — Yes, so upfront in consultation with technology assessment program. It was decided to maintain the scope that was private previously established that did exclude studies that compare different methods of spinal cord stimulation to each other. And to not include comparison of say different frequencies or burst vs a non-burst comparison or

open loop versus the closed loop. So that was established a prior in the final in the final key questions. Again, in consultation with the technology assessment program.

John Bramhall Got it. Thank you. Thank you.

Andrea Skelly Yeah. Any other?

Joe Strunk Andrea, I was wondering if I could just ask, you said it was established a prior and I was just curious what led, what actually what metrics led to that decision to exclude that those particular comparator trials then?

Andrea Skelly The scope of the original review was taken into consideration. Again, we discussed with the technology assessment program their desire to either expand or maintain the same scope for the review and those are the primary, primary. Those were the considerations. There is one school of thought that you need to make sure that something is or is effective versus doing nothing or whatever conventional management is. But again, we, did make the technology assessment program aware of the top of public comments. And ultimately, you know, the conclusion was to maintain the scope of this of the prior report.

Janna Friedly I think it makes it very challenging, especially with pain interventions to evaluate effectiveness without a comparator. And so I think that's that fundamentally is, you know, one of the reasons that these, comparators are thought of very carefully.

Andrea Skelly Yes.

Janna Friedly If you have a treatment that is less effective than an existing treatment and you just comparing 2 different methods of doing that treatment, it doesn't really give you the information that you need about how it compares to other alternatives that may be available clinically. So those are questions that can be answered after you've already established clearly that there's a difference between these other treatments but not, not in the evaluation of whether it, it is effective in the first place. So my.

Sheila Rege And I think here we, you know, we as committee members sit with a very specific, very narrow focus. I mean, it's, our committee was established by law. We have to look at the evidence and the evidence like Janna kind of explained and Andrea, is this technique better than not having this technique? And you can just say, oh, well, this is one way of doing the technique and this is another way. So I think hopefully Joe that that made sense and that's a standard we hold for everything, not just this. I mean, when we just discussed during a tactic that was kind of similar, discussions. So we have to keep the same bar for all technology. Conor.

Conor Kleweno Yeah, the direct question to what you just said. So, and, maybe, I don't know if you would answer it or, somebody else Josh, so, are we obligated to make our decisions based on the evidence provided to us within this report or are we free to interpret,

within this report or are we free to interpret, evidence that they've excluded as a committee member?

Josh Morse

That's a great question. The evidence report provides what the law asked for in terms of summarizing systematically the best available scientific evidence that meets the questions. The law also makes very clear that the committee should consider other information provided by, through public comment or from the agency medical directors. So, you know, all the information that you've been provided is relevant to your decision making. And I think your questions to our technology assessment center to our experts on the evidence are excellent questions. I think their answers are excellent answers. I think the public information that's been provided is excellent information that needs to be considered. I, you know, I don't envy the position you're put in to make these decisions with the complex information that you're given. But it's all on the table for you. Conor, you're selected to be on the clinical committee. By law based on your abilities to interpret the evidence and based on your clinical experience. So it's that combination of what you all judge to be most relevant to care for a huge population, right? These are not, these are weighty decisions. And that's why, you know, this is a complex and constantly interesting process, but I would to answer your question the information provided is not limited to the evidence report. It's everything that you have been given and you're now asked to synthesize that. Thanks.

Conor Kleweno

Thanks, Josh. That was my assumption. I just wanted to make clear to the public. So there was not any, thought that, you know, you know, if something our prior change the comparators or some way to swing it because you know clearly you already know the answers because the data is published so if you asked to constrain the report in a certain way it could be conceived as you're trying to swing the interpretation by the committee but just to reassure the public that we are free to review everything and listen to public comment so thank you.

Josh Morse

Yes, but I mean, let's be clear, the report in the epidemiologists and that are hired to do this, that's based on the science of evidence, right? So. That's why the law emphasizes the report. So I am not trying to say don't consider the other information. I'm saying there's a reason why. We ask for these independent pieces to come forward this way.

Sheila Rege

So.

Andrea Skelly

I can stop sharing if if you're done with me.

Sheila Rege

Now, let's, any other questions for Andrea because I think we, needed to go back and here, you know, the, the reasons of the 3 studies I remember, the, the Kapural and I'm probably mispronouncing them so the McHale and the reasons that kind of collect I'm sorry are evidence report kind of discussed the other studies. Conor, was that clear, answered your question? Any other questions, Andrea? Let's go ahead and put the agenda back up. So now we are back to the discussion we're, we're in good time,

right? No, we're little, we're a little late. Let's, let's go back and look at our straw pull. Did the the medical directors plan to present? I can't hear you, Josh.

Josh Morse — Apologize. I was muted. Yeah. Dr. Chen has a presentation of what you asked to be to come back with, which is criteria. There is the straw polling that you did on the evidence that we looked at at the beginning is also available and has been summarized, I think. When you're ready for, for Chris, for Dr. Chen, I think he's ready.

Sheila Rege — Do, do we want to internally discuss things? Or do we want to have the medical director kind of? Come in with what we had asked them to based on our last discussion. Any thoughts? Preferences?

Conor Kleweno — I'm ready for Dr. Chen. I felt like us. Myself and several others may have done some discussion during the evidence report. So.

Sheila Rege — Yeah, let's do that.

Josh Morse — Okay, I will stop my share.

Christopher Chen — Good morning, everyone. I'm sorry, Josh. I, Are you guys presenting the slides?

Josh Morse — I can certainly do that, Chris. Okay.

Christopher Chen — That'd be great. Thank you.

Josh Morse — Take me a second here. Did I have that open?

Christopher Chen — Sorry, I think you have the most recent version. Great, thank you. Yeah, so, morning, everyone. We were, and sorry, you might want to switch your.

Josh Morse — That reversed.

Christopher Chen — Yeah. So we, we were asked to come back with options, for consideration. Coverage criteria as is standard during all of our, HTCC reviews. And so I'm back here today with some of those coverage criteria that we have seen in other policies as well as just options for committee deliberation. So jumping right into it here. So just to help structure the conversation and this is not by we were suggesting is confined to, but we thought there were a few ways that the committee could approach decisions around coverage. So one option here is non coverage for all conditions. This was the decision during the last review back in 2010 and so that is an option. An option is coverage with criteria for certain conditions. We reviewed mainly 3 conditions, painful diabetic neuropathy, failed back surgery syndrome, chronic back pain, and chronic regional pain syndrome, the committee has an option to decide on coverage of criteria for some of them and not others. And then another option is coverage with criteria for all reviewed conditions. And, so again, the committee, certainly this is your decision to

make and are not confined to this. But, this might be one helpful way of framing up the conversation. On the next slide, we have our recommendation here, the AMDG, group we recommended that spinal cord stimulation is not a covered benefit for chronic back pain, including failed back surgery syndrome, painful diabetic neuropathy, and complex regional pain syndrome. This was on the basis of, of low certainty of evidence around efficacy and concerns for safety including multiple recalls by the FDA as well as a high cost for the intervention itself and lack of convincing evidence on the cost effectiveness. And I'll just say, based on the, just from the conversation around precision before, and a couple of specific studies the imprecision there was around one, one metric for that clinical trial, which was pain, but reminding the committee that they're that we did not see convincing evidence of long-term outcomes, on, not just pain, but also function. So just want to remind there's, multiple metrics that we're considering and did not see convincing evidence for, but. And moving on the proposed criteria development process. So were the committee to decide that to cover spinal cord stimulation with conditions. We proposed a number of different criteria part of this process was reviewing other payer policies. And we also, reviewed inclusion and exclusion criteria from studies that were included in the evidence review. This was in the spirit of the committee's mission to make decisions on the basis of evidence and adhering to what has been studied.

On the next slide. So this is kind of goes without saying so just the we would for if that committee were to decide to cover specific conditions, there would be call find diagnosis such as fail backs or your syndrome chronic racial pain syndrome with Budapest diagnostic criteria, painful diabetic neuropathy. Just as a and, and then out of scope would be dorsal root ganglion stimulation that was not in the scope of this decision. The next slide we have some proposed exclusion criteria as well. So many of these were drawn from the from explanatory tear from the trials, including life expectancy being less than one year. Having a concurrent substance use disorder, including alcohol, or illicit drugs. Dependence or addiction to prescription opioids or benzos related pending or existing workers compensation claim or pending or existing litigation. Substantial pain in other regions that have required treatment in the past year. So those were 5 that were drawn from the exclusion of trade theory of many trials as well as burst stimulation. And this was based on feedback this is not generally available in the market and concerns about the relevance to today's technology.

The next slide we have proposed coverage criteria and this so I'll just walk through these so patient has moderate to severe neuropathic pain. As, defined by greater than 5, score of greater than 5 on the VAS pain scale. As objective neurologic impairment with documented pathology related to the pain complaint. So the neurologic impairment would be defined as objective evidence of one or more the following, markedly abnormal reflexes, segmental muscle weakness, segmental sensory loss, EKG, or a nerve conduction study, evidence of nerve root impingement. Another criteria would be that the members functional disability is assessed using those, went through disability index, the ODI, and member has an ODI score grid, and are equal to 21. A psychological evaluation to evaluate substantial mental health disorders. These

are all kinds of common criteria that are currently implemented. 12 months of conservative medical management defined as regular attendance participation and compliance with multi-disciplinary approach. Including a full course of physical therapy and cognitive behavioral therapy and another modality of conservative management such as acupuncture or chiropractic care, but not limited to those. And, the, and the fact that a patient underwent a 7 to 14 day trial of percutaneous spinal cord stimulation experienced a significant pain reduction, 50% or more, and either had a 50% reduction of chronic opioid medications. If applicable or showed objective and clinically meaningful degree of functional improvement. And some of these were to try and build some more objective parameters around, improvement in the pain leading to improve in other outcomes such as decreased use of opioid medications or improvement in function. So those are just proposals. Again, these are the committee's decisions to make. And yeah, happy to take any questions.

Sheila Rege — I'm on mute. Jonathan was first, I believe, and then Conor and then John.

Jonathan Sham — Thanks, Dr. Chen. Just a question about the exclusion criteria you presented or potential exclusion criteria. Is there present or is it common to have pending litigation worker's comp and excluding? I just I haven't seen that I just wanna know kind of have some context on that.

Christopher Chen — You know, personally I haven't seen it very often in as exclusion criteria in the literature. For example, you know, that was not seen it very often in as exclusion criteria in the literature. For example, you know, that was not in SBRT, and it wasn't, in self-routine. I think it has to do, but it was an exclusion criteria in many of the trials. I think it has to do potentially more with the population that's being studied and the muscular skeletal complaints. Can often be related to workers compensation claims but yeah I don't know if there's other comments from the AMDG group. Gary I don't know if you have anything specific to say to this? But yeah.

Gary Franklin — Well, the only other thing I would add is that the only study ever published on in the workers come population is a study that was conducted at the University of Washington with Judy Turner. And an independent team, I was not involved in that, except we funded it. And it showed a little improvement at 6 months but no improvement at all after that. In pain or function and that was patients with failed back surgery who received the stimulation, patients who failed back surgery went to pain clinics and patients with failed back surgery with routine medical treatment. So we had 3 different studies. We looked at outcomes that were individual outcomes pain function and opioid do something. A combination one that had no effect at all of all 3. So that we do have data from our prospective study. In workers compensation. It's the only study like it that's been published. So that's the only other thing besides these exclusions here.

Jonathan Sham — I guess my only just comment then would be given how long litigation can take in certain circumstances, you know, years. I would be a little hesitant to, if we do end up

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| | voting on some type of coverage, I'd be a little hesitant, including that, given it may exclude people who could benefit. Over a long period of time. At least some litigation inside. |
| Sheila Rege | Next, Jonathan, I hear you, but let's, move on because we, need to you know, looking at whether we as a committee are gonna cover with conditions cover without conditions not cover before we start that discussion in the weeds. Go back to. So is I know we had 2 other questions should instead of picking out these proposed coverage criteria and you know kind of going through it. I'd like to go back to the big picture of where we as a committee feel before we go. So if your question was directly into some of these coverage criteria, can we hold those? I can't remember who, it was John. |
| Josh Morse | Conor had his hand up and, Dr. Bramhall, Conor and John. |
| Sheila Rege | Okay. |
| Conor Kleweno | Yeah, yeah, my question was specific about this, so happy to wait. |
| Sheila Rege | Okay, and John, you same thing specific to this. |
| John Bramhall | No, I just want you, a little, and it's the right screen on now, a little flashing out of this documented pathology in particular, you know, the use of an MRI. |
| Sheila Rege | But we're not, we're not there yet. We're not there yet. Where this is, so let's go back to. |
| John Bramhall | So I just want to be clear. Oh, I beg your pardon. Okay, hold it then. Hold it. |
| Sheila Rege | A spreadsheet of when we, kind of our analytical tool that we started with. Can we put that spreadsheet back on? And now that we've heard the evidence again, let's make sure we're all comfortable with our straw poll. |
| Melanie Golob | And Sheila, is that on the, cover not covered that spreadsheet? |
| Sheila Rege | No, you know the spreadsheet you opened with we start with. |
| Josh Morse | Yeah, I can share that. I have that open here. |
| Josh Morse | Sheila, if correct me if I'm sharing the wrong thing, but I think this is what you were. |
| Sheila Rege | No, that's the one. Just look back on your individual and I don't know if you can make it smaller so we can see everybody. On the cost effectiveness to grade. If everybody is okay with the way we were, in this safety efficacy and cost effectiveness for failed back surgery. I personally am on the safety. I've been chatting with some colleagues and family medicine mostly about their patients and I didn't realize that this medical device |

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| | is still this and hip, some metal in the hip is, what they're seeing as a problematic for their patients. So I'm gonna stay at medium there, but I'm a little more aware of the risks. Is everybody okay with this? Safety efficacy's cost effectiveness? |
| Laurie Mischley | Yes. |
| Sheila Rege | Okay, let's move on to diabetic. And it looks like everybody was pretty similar. Conor in terms of safety, we seem to have come up with the same. Moderate risk but just a confidence level was a little different. I'm inclined. I don't know. This is a something you can change if it's a spreadsheet. I'm inclined to move mine on efficacy to low. After looking at the data again today. |
| Josh Morse | Your vote here, you would change to less. Is that what I'm? Okay. Okay. |
| Sheila Rege | I'm sorry, and and keep it lower yeah. |
| Janna Friedly | Yeah, and Sheila, I'm in the same, but I think I voice this the last time that I have pretty serious concerns about the Peterson trial. And you know, I think for me, I, while it did show, that there was a positive effect, I'm so I'm confident in, the in the trial and the they comparator and the risk of bias with that with that trial I think one of the things that stands out to me and many of these trials is that. You know, there's industry sponsored trials, which I, there's huge value to industry sponsored. Trials clearly, but there's also industry performed trials, and that I consider an industry performed trial, in that the people who were doing the study, analyzing the data, presenting the work, were, employed by industry, and I that design of, of choosing a comparator of people who have already failed. The comparator treatment makes me even less, confident. So I'm going to move mine to equivocal. And low confidence. |
| Sheila Rege | Is everybody else comfortable with where they are? In which case one move. Good hearing nobody then we'll move on to And next. Oh |
| Josh Morse | We're doing this by condition, right? So we started with, we had no changes on failed back surgery syndrome. |
| Sheila Rege | Correct. |
| Josh Morse | We went to peripheral or painful diabetic neuropathy and there were 2 changes here, which I've indicated with the highlights. And we're now moving on to chronic regional pain syndrome. Okay, please stop me if I if I make a mistake along. Thanks. |
| Sheila Rege | Is everybody okay with that? Okay, then we'll move on to coverage. |
| Val Hamann | Josh, that time is for the end. Polls are done. So there's the different coverage breakdowns for each individual vote. And that's from. Yes. |

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| Josh Morse | This was the draft from last time. Excellent, thank you. |
| Sheila Rege | Correct. That's what I want. That's what I was. I am moving mine to not covered. 4, so which one is this? What's on the top left? |
| Josh Morse | Looks like. Go back. |
| Sheila Rege | That's for, yeah. I'm moving that to not cover. And then for, regional pain syndrome, same. Is there a else happy with where they are? Is there anybody that's not here? Clint Daniels is not here. |
| Clint Daniels | There. |
| Sheila Rege | Oh, sorry. So is everybody here? Was there somebody not here or? |
| Val Hamann | Chris, Chris Hearne. Christoph and Tony. Which there's another coverage breakdown tabs if you would like to start fresh and go. Ask everybody. |
| Josh Morse | Gotcha. |
| Sheila Rege | Okay, so this is just the people that I hear now or no, this is still from last time. |
| Josh Morse | No, no, this still has from last time. So I can. |
| Sheila Rege | Okay. Okay, no, let's leave it. Let's go ahead and well, I could have waited, I guess, to, do it for today. Why don't you call out today and see if, start with John and see if today he's good, you know, kind of let's call it out again. John, are you okay with starting with you? |
| John Bramhall | Yeah. |
| Sheila Rege | Okay, let's go ahead. |
| Josh Morse | Okay, so we'll start in the upper left. For Sponk or similar for failed back, Dr. Bramhall, you have covered with conditions. |
| Sheila Rege | But no, we need to start over because we don't have everybody. So I think you need to. |
| Josh Morse | You wanted to do a refresh? Okay. |
| Sheila Rege | A new, you know, the coverage breakdown. Another one, yeah. Because we don't have those other people. |
| Josh Morse | Fair enough. |

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| Sheila Rege | Okay. |
| Josh Morse | I will call you by last name. Well, do like, do you want to do one condition at a time? Sheila? |
| Sheila Rege | I think we can answer for all of them. |
| Josh Morse | Answer for all. Okay, Bramhall? |
| John Bramhall | And this is, so just to be clear, we're talking about fail back and neuropathy with talking of the 3 conditions simultaneously. Is that right? |
| Sheila Rege | Oh no, you're gonna you're gonna do individually. So she's gonna save. Then you're gonna do regional pain syndrome, then you're gonna do diabetic and then. |
| John Bramhall | Do them individually. Alright. Okay. So I'm gonna couple with conditions for a spinal. For failed back I'm going to be covered with conditions. For peripheral neuropathy I'm, gonna go not covered for CRPS. And I need clarification and it'll come up in the discussion. I'm going to leave it as covered with conditions for refractory back pain. |
| Josh Morse | Thank you. Daniels. |
| Clint Daniels | Yeah, I'm, struggling between not covered and covered with conditions. We're looking forward to some more discussion on this. Particularly I'm starting with the lack of improvement compared to sham. So at this point, I'm just gonna be like, same as John actually, covered with conditions, failed back surgery syndrome. I like what they proposed as well covered peripheral Not covered, regional pain. |
| Josh Morse | Sorry, covered with conditions or covered unconditionally. Thank you. |
| Clint Daniels | I'm sorry, with conditions. Yes. Not covered regional and with conditions for refractory. |
| Josh Morse | Thank you. Friedly. |
| Janna Friedly | Not covered. For any of the conditions. |
| Josh Morse | Chris Hearne is not present. |
| Conor Kleweno | And just so I'm understanding this is our first pass, and we're gonna have discussion. |
| Sheila Rege | That’s right. |
| Conor Kleweno | Okay, so I'll do not covered for failed back not covered for CRPS. Covered for peripheral diabetic neuropathy. |

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| Josh Morse | Covered with conditions or covered unconditionally? |
| Conor Kleweno | With conditions And then, not covered for refractory back pain. |
| Josh Morse | Thank you. Christoph Lee is not present. Laura Mischley. |
| Laurie Mischley | I'm going to put covered with conditions for all of them right now, but I might be able to be talked out of the bottom right now as a cover with conditions for all of them, but I'm also looking forward to the discussion |
| Josh Morse | Thank you, Rege. |
| Sheila Rege | Not covered for all of them. And just we've talked about it the. Concern about safety and just know long term. Efficacy. |
| Josh Morse | Thank you. Sham. |
| Jonathan Sham | Cover with conditions for FPSS. Cover with conditions for PDN. Not covered for CRPS. Cover with conditions for product. |
| Josh Morse | Alright, thank you. |
| Sheila Rege | Is that it? Those are all of us here. |
| Josh Morse | I believe did I miss anybody? I apologize if I did. |
| Sheila Rege | No, I think that's it. Okay. So let's go with. CRPS, the regional pain syndrome is. Laurie, do you wanna try and convince us? |
| Laurie Mischley | No, I'm looking at the review and I think we downgraded it largely because of the difference in it was a small. I think we downgraded it largely because of the difference in, it was a small study. |
| Sheila Rege | You wanna change it or do you wanna? |
| Laurie Mischley | I'm happy to say not reviewing that. Yes, yeah, go ahead and change it to not covered. |
| Sheila Rege | Then we then we won't have to discuss that if that's okay with everybody. Let's do the other one. |
| Laurie Mischley | Yeah. |

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Sheila Rege — Which is diabetic neuropathy. Anybody want to talk to us all with conditions is what We've got 1, 2, 3, 4, 5. And Janna, do you wanna try and explain your reasons and then I can?

Janna Friedly — Yeah, I mean, I think. You know, I, I have it just, and then this is sort of generally, but I have concerns that you know as people have concerns about downgrading trials for certain reason I have concerns about just completely throwing out. Or sham controlled trials. I think for something like this, I'm really struck by how little evidence that we have from sham controlled. You know, trials with a comparator. And so, and the industry sponsored trials that have been done, which are large trials and multi-center trials all or have similar issues, both from a, you know, back helping me to understand the true effective, that the treatment, which is that you're, you're selecting patients that have failed, the comparator treatment to compare to, the other treatment and they're unblinded and there's so much potential for placebo effect and bias and things. without any long term evidence. So I sort of wait for me, I'm waiting. That I know that there's complications. I know that there's risk. This is a high cost procedure. It's it I don't I don't know what the for these chronic conditions where we're looking at a condition that is either stable or progressive, it's not going to go away. You know, if you've got a procedure that you, That was studied that that effect can be replicated in a in a sham controlled study and point us in that direction. I don't feel confident at all now with the data as presented. So that's, you know, specific to purple neuropathy, but that's my rationale for, for each of the decisions that I've made.

Sheila Rege — And for me, I think similar, you know, we had the Peterson. And then we had for Con with conventional the slang and the divorce both. Old 2014 trials but it is surprising to me that we don't have a newer trial given and that's not industry sponsored. That can definitely show long-term relief and you know, wound infections, epidural abscesses, the, the breakage of the leads and all that kinda comes to mind especially in the diabetic population. Which is what led me to my thinking about and, and saying not covered. But anybody else in the other kind of cover with conditions, any discussion of and we'll go back and look at the medical directors recommendations next.

Conor Kleweno — Yes.

Sheila Rege — But it looks like this committee will cover with conditions would be the recommendation. Conor?

Conor Kleweno — I just have a comment. You know, I definitely, have concerns in general and in principle about industry involvement. You know, we have a long history of this having some problems, negative studies being withheld and not published, negative studies being withheld and not published, influence on data conclusions, etc, but given this is an expensive device, I think it would be hard to have a trial without some funding, to some degree. But I would say that, you know, given that, the involvement with a lot of the providers in our region, you know, maybe there are some options for future trials within the societies that have an interest in this that could, could fund something,

cause you know, as the devices are expensive, it's not so easy just to say do an unfunded trial without industry support. So I do am sympathetic to that challenge. As a surgeon, the second thing I would say is long-term follow-up in general is extremely difficult and extremely difficult to do without funding. So it gets back to my previous comment and I guess I agree with Janna and those concerns, but I recognize the real world challenges of doing that in a procedural or surgical setting, but maybe with the sort of massive amount of, of interest that we've observed by this committee that may be something that can be done by these groups.

Janna Friedly — Well, and Conor, I wanna clarify, that it's, not industry sponsored that I, you know, it clearly, you know, there's a lot of, literature about this, but, but, industry sponsored and in and of itself is not in my mind a concern necessarily and in and of itself is not in my mind, in and of itself is not in my mind, I can concern necessarily and some of the best research that we have and in some of these technologies. Not in my mind, I can concern necessarily and some of the best research that we have and in some of these technologies, comes from industry, sponsored research. It's the industry performed research and the involvement. You know, it's funding is one, one thing, but then I in my mind I have to look at who's doing the, the data analysis and the collection of the data and the reporting and whether it's a blinded or unblinded and all of that and the people who are doing this study and enrolling the patients and interacting with the patients, have significant, ties you know financial interests and ties it makes it hard for me to sort out placebo effect and, and other influences from what's actually happening.

Conor Kleweno — You're saying when the author's report conflicts?

Janna Friedly — Yes, and so when you look at these studies, they clearly, each of the authors, and, and when you look at the attribution of what they did in the study and how and what their role was in the study.

Conor Kleweno — Yeah.

Janna Friedly — I think that's where for me the potential for bad for bias, it becomes even higher and higher.

Sheila Rege — And Conor, we, I mean, the industry understands the device the best. So I think industry involvement and. Financial support is definitely is definitely the only way a study can happen. I would have liked to have seen. You know some more academic involvement. In some of those, but. But no, I think we need to move on and say cover with conditions. Is everybody okay with that?

Conor Kleweno — I had one more question and maybe to the expert witness and one of the things I struggled with Sheila's just the term failed back syndrome or I've heard post laminectomy syndrome other times. It's, it's the first one failed back is not even

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| | familiar to me as a, as an orthopedic surgeon. I'm not a spine surgeon. But, I just wonder any comment from committee members and on, Is that some massive bucket? |
| Sheila Rege | We're not there yet. Conor, we're only on diabetic. So let's move on. |
| Conor Kleweno | Oh, excuse me. |
| Sheila Rege | Let's move on though now to the failed back surgery. And so if everybody's okay with cover with conditions for diabetic neuropathy and now we move on to failed back surgery which is 4 to 3 and surgical refractory chronic back pain and let's take them both together because they'll probably both, you know, they brought both similar in terms of coverage. So go ahead now, Conor. Sorry. I just wanna make sure we differentiate. |
| Conor Kleweno | Yeah, sorry for jumping ahead. So, question is even as an orthopedic surgeon, I'm still, I'm not sure how to categorize what you know what that means and so is there just a giant bucket of anybody that has back pain or their specific parameters that you know if we if we have an intervention we want to be clear about patient selection and so you know, that was just my concern with some of these is what, what does that mean, field back syndrome or non-surgical back pain. |
| Joe Strunk | So it's a really great question. So failed back surgery syndrome is where a lot of this historically started with patients that had gone through surgeries that had persistent back or limb pain that was neuropathic in nature. And now we really actually tend to use the term persistent neuropathic pain after spinal surgery. You will see post-laminectomy syndrome as a term use as well. But the, the thing that that description underlies is this neuropathic pain state that is persisting after someone has had a spinal surgery and when there isn't an identifiable, treatable, surgical option and they failed and often they failed all sorts of other modalities. And so they end up in that neuropathic state that we, it, it kind of fits within that syndrome. And then that's who we. Treat with this kind of therapy. Non-surgical refractory back pain is now a another subset of that patient population, but those who for reasons whether from a medical complexity or from just the lack of. Of objective or identifiable. Lesions that could be treated surgically have been treated and that's where that Kapural study looks at it specifically that patients that haven't had spinal surgery and still have pain that that comes in the back that is neuropathic or in the limb that is that category. |
| Conor Kleweno | So in my world, you know, somebody that crashes a car and has a fractures unstable spine and has surgery to fix it but says some sort of lasting neuropathic pain that would be included in one of those categories, I'm just. |
| Joe Strunk | So you're saying would have, are you talking about spine? |
| Conor Kleweno | Yeah, so you know you have somebody that has some pain and there's some tightness and they get a laminectomy and they still have pain that's you know that's one subset but then you have a subset you know somebody crashes their car and has an unstable |

thoracic spine injury or lumbar spine injury and they stabilized it with surgery, the fractures healed. But the sequela of the trauma and the injury to the spinal column is left them with neuropathic pain.

Joe Strunk That's correct.

Conor Kleweno So would that be included in trying to understand how that would be?

Joe Strunk For, yes, the definition would be in that would be someone that has had a some sort of injury or has developed some sort of pathologic state that has undergone surgery and has persistent low back pain.

Conor Kleweno So would that be FBSS or would that be non-surgical refractory for you?

Joe Strunk If they've had spine surgery, it would be. Under that persistent post operative.

Conor Kleweno Okay.

Joe Strunk Category.

Janna Friedly How do you, how do you define neuropathic back pain and diagnose that?

Joe Strunk So it is a, a state that is primarily a clinical diagnosis. So it's gonna be patients that have pain that has some quality of presentation that would be either ridiculous or in a in a kind of nerve distribution pattern. That is often lanceating associated with parasitis or some sort of change in sensation. Those are kind of under that umbrella of neuropathic pain and then it's also a diagnosis of exclusion as well making sure that we're not dealing with, with an sort of acute process. Many of the studies that we've been discussing, look to, quantify that with various metrics, whether that's the DN 4, others where they look for those specific identifiers to help, qualify as neuropathic pain.

Janna Friedly Yeah, I, I guess my question is neuropathic back pain. So are, are we talking radiculopathy or radicular pain or the term neuropathic back pain has been used in some of the study and in some of this I'm just trying to understand how you determine that somebody's back pain if it's not radicular? In a particular nerve distribution, how you decide that that's neuropathic versus other pain. Yes. Yeah.

Joe Strunk So it's also a diagnosis of exclusion. Look, there are many. Yeah.

Janna Friedly Right. So I think that's my point is that there's no there is no way to know that something is neuropathic back pain. That's why I'm just, that term is a little bit, confusing to me and something that I think is hard to operationalize because there is no There is no diagnosis of neuropathic back pain. So I'm just trying to understand that in, in this context. That's all.

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| Sheila Rege | I'm muted, sorry. Let's go on who had a question. There was somebody before me. |
| Josh Morse | John had his hand up. |
| Sheila Rege | John. Okay. |
| John Bramhall | Yes, sorry, I couldn't. I, just, the example that kind of raised of a patient who comes has an obvious spinal injury, let's say, and that's corrected surgically and then has persistent pain afterwards. So this is the this is the, the patient and my question really relates to Dr. Chen you, you, you're a suggestion is that, that the for coverage and now we're getting towards that you intimated the MRI, for example, or imaging studies were involved in the in the coverage determination pathway and I'm what I'm wondering is Let's say Conor's patient the, the, the lesion is demonstrated by imaging, the lesion is corrected surgically. And now presumably imaging then shows no further compression of the spinal cord. For example, she's just picking that as a, as a clinical example, it, and yet there's persistent pain neuropathic, whatever adjective you want to use. So when, when the time comes to make a decision about whether that particular patient, is likely to benefit from spinal cord stimulator. What, what is the, what is the, the MRI type evidence? How is that process the presumption is that imaging shows no compression or no stenosis or no, no objective criteria and yet the pain persists. So help me with what your thoughts are Chris in terms of the inclusion of those imaging studies as part of the pathway for, for coverage. |
| Christopher Chen | Thanks, thanks, Bramhall. Yeah, I, you know, I, we didn't we didn't specify in the criteria that the MRI findings had to be you know, concurrent with the pain complaints. I think personally if I were to be reviewing a request and, maybe not specific to spinal cord surgery, as spinal cord simulator, but just generally if I were to interpret whether there was documented pathology related to the pain complaint. For something as like complex as neuropathic pain, I wouldn't necessarily need to see that there was like an ongoing abnormality, concurrent with that paint complaint. I guess, like in my mind, I would interpret that related to the pain complaint as at some point there had been an after that was that made sense. As being really connected to the neuropathic pain and even if there was like subsequent resolution on imaging that I would still consider probably related but |
| John Bramhall | I get it. Okay, so a historical imaging or a history of damage that's subjectively displayed. |
| Christopher Chen | Okay. |
| John Bramhall | Is what's in the back of my mind. Okay. Thank you. That's really helpful. |
| Christopher Chen | Yeah. They're just thinking about nerve damage can be complicated, but yeah, I don't know. |

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| John Bramhall | Thank you. |
| Sheila Rege | Okay, so, I think it's my turn. John, it said on FBSS that he was, willing to be swayed perhaps so I'm gonna try and see if we could go get Aggregate Analytics slide 10. 11, is that something we can project? John, when you first started, you said, well, I'm debating between not covered and covered with conditions. |
| Andrea Skelly | Sheila, are you wanting slide 10 or 11 from the summary or the full report? The full presentation? |
| Sheila Rege | You're presentation. Oh, the one that you had today. |
| Andrea Skelly | Okay. |
| Josh Morse | I will, I can either. Show that or I can. Give control over to you, Andrea. |
| Sheila Rege | Oh yeah. |
| Andrea Skelly | If you can show it more quickly, go for it, Josh. |
| Josh Morse | Is this the slide? |
| Sheila Rege | Yeah, that's the slide. So I was looking at this and also go, go to slide 11 the next one. And this is why I kind of was looking at this and trying to wrap my brain around cover with conditions versus not cover and ultimately landed on not cover. And, you know, went through the studies. There was the 2018, crossover, so call both were insufficient and then there was the 2019, Rico art or somebody in Kumar from 2007. And I really, struggle with covering with conditions given, this. Anybody? |
| Conor Kleweno | Could you, could you expand on that Sheila? Just to. I'm interested in here. You have to say a better concern. |
| Sheila Rege | Well. It's, it's an expensive procedure. With a risk of you know, some complications, wind complications or epidural lead things and the evidence just long term, 12 months is not there. So I'm struggling with kind of cover with conditions when I'm just not convinced that there's evidence. So that's kind of where I was and I think one or 2 people said that they were leaning, you know, color conditions versus not cover and they're waiting for the discussion. So don't know, Andrea, if you have any thoughts on this, am I missing something here? |
| Andrea Skelly | No. Yeah, there is no evidence because of the intentional crossover and the parallel trials. The previous slide looks at the crossover trials against sham. And. Again, there's no evidence long term. The evidence was insufficient looking at the various comparisons of frequencies versus sham is insufficient. The one trial that looked at |

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| | back pain after surgery that was continued, continued. Did show similar effects versus sham. |
| Clint Daniels | Is there a, versus sham study for radiculopathy? Because this one is just back pain where I think slide 11 is radicular. |
| Andrea Skelly | So one patient population was chronic radiculopathy after surgery. The other the other 2 were failed back surgery syndrome and those are all versus sham. There was one study of grips, which was a parallel, which was a crossover study versus sham. But it was in sufficient. If that answers your question. |
| Clint Daniels | Yes, thank you. |
| Sheila Rege | I know there's raised hands if anybody wants to help on this. Just on this. This topic. Go ahead, speak up. |
| Janna Friedly | Well, I, I was just going to. I wanted to make a comment about the study and I think that's that is this one up in the top with a similar RCT chronic. So that's the Hara. So I know that that one was brought up as being problematic from the clinical standpoint because of the burst, the burst stimulation that they use, but I did want to, there, there was a follow up study. That was that they did a follow up analysis, where they allowed patients then to switch from the burst to patient controlled type of stimulation and, they, showed no difference in outcomes when they did that. So I just wanted to know if that was. That follow up analysis was included. in this discussion, because that was one study that was brought up repeatedly as one that we should discount because of that burst, technology. There, there were some issue, you know, the longer that you go out there is less follow up. So it's not complete, complete data, but they did allow patients to use a different kind of stimulation. |
| Andrea Skelly | That, that follow-up was not included. It may have been out of the time of our search. Or if it was comparing. But it was not included. Bottom line. I'd have to look it up. |
| Sheila Rege | Okay, so, if everybody, is, so I think it's a for to cover with conditions and 3 to not cover and if we're all okay with where we are. Then, I like it. Not as close, but if it's gonna be this close, it is. So we'll go ahead cover with conditions for. Is that okay? |
| Josh Morse | Yeah, and can I speak to process here for just a minute? |
| Sheila Rege | Correct. Yeah, yeah, please do. |
| Josh Morse | So, typically what you'll do is you go through this exercise as you have to get a sense of where people are. You've gone into greater detail this time than usual which is great but at the end you know when you develop your criteria for coverage the vote is still at that point you're doing one of 3 choices at the end. Probably it looks like for each |

condition where you know if the conditions don't anyway you know what I'm saying I think you're still gonna vote one of 3 ways when you have the conditions before you.

Sheila Rege — Yeah, pretty well.

Josh Morse — Thank you.

Sheila Rege — Right. So everybody okay, right? With we can close FBSS. Now Joe, are you gonna talk specifically, F you had your hand raised and.

Joe Strunk — Initially I was just gonna comment back to Dr. Bramhall's comment about the MRI saying that, the, the MRI is often going to be used to validate that there isn't a surgical lesion. And then in terms of failed back syndrome, I agree it's a, it's challenging to look at those older studies. And one of the things that is helpful for more modern studies, but it wasn't included in our analysis is more like studies like the EVOKE trial. Which is actually, looks at, low frequency and that's, that's the one with the, the action, EVOKEs potentials and that does show benefit there and shows some more durability, but I just that was really my only comment there is there is some evidence it's just not against what the committee has been talking about, against what the committee has been talking about, which is complete sham. It's just against, 2 therapies that are blinded because they are both. Tonic base stimulus, but one is, is actually used to gate and actually modulate the therapy so that they're getting more consistent action-based, action potential based. Therapy. So there is some data, but I do agree it is challenging.

Sheila Rege — And then Andrea, if we could. So. When you looked at chronic back pain, you categorized it as failed back surgery syndrome versus non-surgical refractory back pain, correct?

Andrea Skelly — We did not categorize it. We use the categorizations as listed in the studies. So if they called it fan back surgery syndrome, we called it that.

Sheila Rege — Okay.

Andrea Skelly — Most none of them really provided specific criteria for how that was determined or diagnosis of that. The Harris study we just discussed. Talk about having surgery. But chronic radiculopathy after surgery and then the Kapural study was non-surgical candidates. So be class, we did not classify them. In any different way than authors classified it.

Sheila Rege — So for our cover with conditions or not cover. We've created a category called failed back surgery syndrome and then another category non-surgical refractory back pain, is that what we've done in our spreadsheet. Josh. We could go back to the spreadsheet.

Andrea Skelly — And she let slide port team summarizes. Again, how they were categorized by the study.

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| Sheila Rege | Yeah, that's where I found it, correct? That's what I pulled too try and figure it out. It's like 14. So, so this is chronic back pain and should be, you know, when we're doing our and maybe Chris Chen can help us. When we do a covered with, with, not, cover for all but cover in some how, how to phrase that? But I wanted people to be aware of what the studies were showing. Any other comments before we go to our final decision? Josh helped me out with the analytical tool now on where we're going. I think we flush things out. We kinda know where we're going. So let's go to safety. |
| Josh Morse | So. You have completed, you mean you have. |
| Sheila Rege | Yes. |
| Josh Morse | Voted through this section. Is this what you're asking for, Sheila? |
| Sheila Rege | Yeah. Let's review. Yeah, that's good. So. Now let's, is everybody comfortable with which was the one that we are not going to cover? Let's make sure everybody's comfortable with that and it's discussed. I should write notes. |
| Josh Morse | Right, so typically, so this is this is my opinion of where you are. You have, you know. In a general direction, I think you have a sense, committee of, your where you are going with these 4 conditions as they're currently grouped. You may choose to vote on each one of these as far as cover not cover or cover with conditions you have not formalized your, your conditions here, right? So. This is typically your next stop. Since you It appears you're headed to many of you are considering coverage with conditions. I don't think you know or have agreed on what those conditions are unless you think these are the conditions that you're working from. Does that make sense? |
| Sheila Rege | Yes, yes. |
| Josh Morse | And then what would happen with the decision aid, your next, once you have your draft coverage your conditions. You would then move on to your vote here, which is your formal vote for the draft determinations. You'll probably do it 3 or 4 ways it appears based on how you've grouped the conditions. And you'll be voting to cover not cover or cover with the conditions as you've drafted them. That would conclude having a draft determination. |
| Sheila Rege | So let's. Oh good, I'm not on mute. So let's look at this and now I think Conor, you and was Jonathan and you had some insights on this document. |
| Conor Kleweno | I just had a concerns last question about the trial period. I, I know it sounds like potentially a good idea. I just have a concern if that's, something that could be also taken advantage of. My understanding is that the trial period procedures placement can be quite lucrative as well. And maybe our expert can comment on it. I just what I don't want is in terms of cost, all of a sudden we have a double dip phenomenon here |

where we do a trial and that's cost a lot and then we do the thing and that cost a lot so If somebody has better information on, no, those don't cost very much. Or maybe even comments on how, really important that would be maybe from Joe or any other committee members.

Joe Strunk

So in terms of the, the risk of these procedures that's where a lot of that, you know, that compensation is gonna come from undertaking that risk, the delicacy of placement for the leads. There would there's really no risk of. I would say double dipping based on that duration that that you're talking about. I would as I've looked at the studies that we've been talking about that range for that trial period. In like the Peterson trial for perfect peripheral diabetic neuropathy, painful diabetes is 5 days to 14 days, so And that would be the only other comment I have there in terms of what that duration looks like compared to the other evidence that we that we've all reviewed is it falls somewhere in that window and that's really allowing patients the opportunity to trial different programs. So they undergo the risk of the procedure when they place the leads, then for somewhere in this window that we're discussing, they go through several different iterations of programming to identify does this make a huge difference for this patient? Do they get that 50% or more improvement? And then that would allow the clinician to have that discussion with the patient about proceeding to a permanent implant. So, hopefully that answers your question about the idea of double dipping.

Conor Kleweno

Yeah, it does. I shouldn't have said double digit. I guess what my thought was, are you gonna just select out anybody and say, well, we can just trial this. And your threshold then is even lower because the compensation comes from the as you've correctly identified it's the placement. So I say anybody that comes in well, we gotta trial it so now my threshold for inclusion is everyone And it doesn't matter that the okay it didn't work okay well that's fine and so And just, I'm trying to play this out in terms of our, you know, tax paying concern for cost is all.

Joe Strunk

Yeah. Yeah. So.

Conor Kleweno

So. If we allow a trial with no threshold and that's that would be the sort of the main driver or a main driver of cost. Is that a prudent thing to have on there?

Joe Strunk

And by threshold, you're talking about all of these other criteria that we're talking about.

Conor Kleweno

Well, so if you say to have the procedure authorized and paid for, there needs to have, you know, XY, and Z, you know, non-surgical treatments or whatever. Or a trial period, but then if you have no threshold for the trial, then you're, you allowing payment for the trial period. And then do you see what I'm getting at?

Joe Strunk

Yeah, so all of these steps are the practice that the, the pain physician would go through to get to that trial stage.

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| Jonathan Sham | I think it's an and Conor, not an OR. |
| Joe Strunk | So this would be going through all these proposed criteria would be part of that process of, of evaluating and getting to the point where this is the only option that this patient has and then that's the point at which this would be on the on the table as, hey, should we try this technology? Cause we failed everything else. And then in that case, it's not, it's not a scenario of. |
| Conor Kleweno | But they |
| Joe Strunk | Of patients just walking in the door and being like, hey, this is way to make a, you know, a bunch of money by just stemming everyone. No, that's why we'd have these guardrails and why. |
| Sheila Rege | Conor, the FDA actually, in their ruling asked for a trial. So that is something. |
| Joe Strunk | Yeah. And a clinician who does this would not want to implant this device. This has this is a just like you as an orthopedic surgeon wouldn't want to replace someone's knee without justification for it. |
| Sheila Rege | That |
| Joe Strunk | No one wants to be putting these devices without evidence that it has opportunity to provide some real significant benefit does. |
| Conor Kleweno | Well, you can't unreplace a what I'm saying if I if it was just something I'm placed in there and okay it doesn't work okay fine we'll take it out But the sort of the cost is accrued at that point. Yeah. And I'm just playing these out. These are what we're discussing, these aren't. |
| Joe Strunk | Yeah. |
| Josh Morse | So I'm gonna, there are 3 hands up. We passed through a break. We had one kind of, accidental break early on we had another scheduled break for an hour ago. I wonder if we want to take 5 minutes and then continue the critique and honing of these criteria. |
| Sheila Rege | I think let's, let's take 5 min for whoever wants to go. I am going to actually put a subcommittee together who is going to stay. And I want Janna to stay. Conor, you have spoken a lot. I'm gonna have you stay and Jonathan. And while you guys are gonna try and help us move through this a little faster. So everybody go on break. This is still being recorded. We said no coverage to diabetic neuropathy. So somewhere in this we have to, to reflect the committee's discussion primarily and then we can, we'll do our final voting. |

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| Josh Morse | Well, okay. So when you vote. I'm sorry. Did you say no coverage for? |
| Sheila Rege | Yeah, it was, I'm sorry, not, oh no, no, you're right. No coverage for complex. I'm wrong. For the regional pain syndrome. I'm wrong. Okay, so no coverage for regional pain syndrome. |
| Josh Morse | Right, so I guess. So there's multiple ways to do this Sheila, but one way to do this is. If this is, this is the same thing you're seeing on that slide, these are the proposed criteria from Dr. Chen's slide right here. If Perfect. Okay, that's already done it. Then we can take a break. I wanted somebody. I think what's yeah, but I think what you need to do is go through these criteria and if these criteria need to be different for each of those conditions, that's that will be important. And then when you do if they're generic, I mean, or you know, if they're correct enough for PDN and the 2 back conditions, they don't need tweaking then you can do a, when you get to your final vote, you'll be voting to cover with the conditions as you've drafted them or not covering or covering unconditionally, which nobody had proposed. And you'll do 4 votes potentially or if you group the back condition you'll be doing 3 votes just as an example, does that make sense? |
| Sheila Rege | Okay. That makes sense. Then we can take a break. Come back at 5 after. And, if you keep that, yeah, projected so we can see. That for anybody who is here. Thank you. If you can go up a little bit. So just we can see more of that. Can you make it smaller? So we can sneak. Okay. |
| Josh Morse | Can, yeah, I can try to get rid of the. I think that's all of it. |
| Sheila Rege | Okay, 5 min after we'll come back. |
| Josh Morse | Yeah. Thank you. |
| Conor Kleweno | And Jonathan, Janna and I are supposed to stay here. Is that? |
| Josh Morse | I think you should take a break. |
| Sheila Rege | I think you should take a break. I think he's already done what I was looking for. |
| Conor Kleweno | Okay, thank you. Okay, thank you. |
| Sheila Rege | Is everybody back? Alright, let's get started. Do you know how, Joe, this is a question for you. Do you know how the FDA, has categorized the label indications. |
| Joe Strunk | Okay. |
| Sheila Rege | For spinal cord stimulators. |

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| Joe Strunk | The label indications, you mean like which, which are on label? |
| Sheila Rege | Like. Yeah, you know, they, they usually have the categories when they approve things. I'm just trying to see what, what labels they use, do they use failed back surgery syndrome? Do they use complex regional pain syndrome? |
| Joe Strunk | You know, I don't know the FDA labels with a hundred percent. Click. |
| Sheila Rege | And, Andrea has a hand up, Andrea. |
| Andrea Skelly | Appendix K in the appendices the report sas a list of the indications. That we could find as described in the FDA for indications for various devices. |
| Sheila Rege | Appendix K, I'm gonna pull that up on my. |
| Joe Strunk | That should include failed back and CRPS for FDA indications. As well as non operative back pain. Sorry, it took me a moment. |
| Jonathan Sham | Andrea, what page is appendix K on in the evidence report? |
| Andrea Skelly | It's begins in my version on page 178 of the appendices. There are different devices and again, cut and paste basically from what we could find. For the approved indications, most of which are related to failed back surgery syndrome and retractable low back pain or leg pain. Some specifically mentioned CRPS. Once specifically was for diabetic neuropathy. |
| Sheila Rege | So that's good. So we have complex regional pain syndrome which we've done. Diabetic neuropathy, failed back surgery syndrome and the only one I'm not seeing is that, the one on the bottom right of our spreadsheet. So let's, let's, let's go ahead and do these. So. I just wanna make sure that. It's, you know, it's, what the FDA has approved the device for and it sounds like it is. |
| Joe Strunk | That's correct. |
| Sheila Rege | Let's pull our. Josh the document was seeing during our break, proposed criteria. |
| Josh Morse | Clint has his hand up. |
| Sheila Rege | I'm sorry I missed you. Go. |
| Clint Daniels | I said, for conservative management, there's been a lot of talk in this being sort of the treatment of last resort. So I think we should make sure that's what it is. So I would advocate separating acupuncture and chiropractic and requiring both of those individually as well instead of coming. A category. |
| Sheila Rege | Any, suggestion on how to put that in there? |

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| Clint Daniels | I'd do something that would send for PT and CBT. I would just do it and and do same sort of language. |
| Janna Friedly | Are, are those covered conditions for? |
| Joe Strunk | Yeah, that was a good question. |
| Janna Friedly | Okay. |
| Conor Kleweno | Yes, maybe. |
| Janna Friedly | I mean all of these things are all of these. I mean, is conservative medical management. Joe, do we need you do need to think about the different diagnoses? I don't know the answer to that. |
| Joe Strunk | And I would also just as a pause to as we think about these specific diagnoses. So painful diabetic neuropathy would not probably be a appropriate indication for chiropractic patients that have had lumbar fusions probably aren't gonna benefit from, you know. The like I like that idea of really coming at this with as many guardrails or guide guidance as we can, but there may be some indications that are really hard to encapsulate. If we use extensive and then require specific therapies in trying to do this all in a very neat fashion. |
| Clint Daniels | Yeah, I agree with that to the proof of neuropathy. I would not include parenting in that group. I disagree with regard to the patients with prior fusion though or refractory back pain as well. So I wouldn't include it for both of those. But not for the. |
| Laurie Mischley | I'll just as the one of the representatives of integrative medicine, I would vote against making it in and I think you really it is not going to be easy for or not everybody is going to have access to all of these things and to meet the person where they're at, we're certainly setting up some guardrails. Just to say they've attempted some other conservative management. Approach I think is I was pretty happy that even that made it in there as it was so I also like where you're going with it, but I also would like to not set up a series of hurdles for each one of these things you don't know if acupuncture works for 6, 8 weeks. We're not talking. Anyway. |
| Conor Kleweno | Yeah, I'd agree with that because as it's written, would that mean 4 years? So 12 months of PT, 12 months of CBT, 12 months of Becky. So I just, I think I'm agreeing with you, Laurie. I think that we recognize that there many different faces of conservative medical management and their, different options maybe more appropriate or better access for different people. |

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| Christopher Chen | And I'll just say, as for and it was not intended for each of those bullet points to be 12 months on their own. I think the 12 months was supposed to encapsulate that and if we can, you know. |
| Conor Kleweno | But even that, so you got one day a week, 2 days week PT, one to 2 days a week of cognitive therapy, one or 2 days a week of acupuncture, one or 2 days a week of car. So that's just a very difficult ask for a patient I would, I would think. Time effort, finance, seem very challenging. |
| Sheila Rege | Let's start, let's start with the first criteria and then we'll debate the ends. So, all the trials and I think on the FDA, they, it's for patients 18 years to 80 years. I'm just pulling up some of the FDA things. Should we say that here the age group and that's I think the trials also were meeting an age of 60 Is that acceptable to everybody? |
| Joe Strunk | I would, as a clinical, I would advocate that an 80 year old cutoff. For some of these patients that are non-surgical back pain, sometimes this is the therapy that is the really the only option for them. Because part of the reason they can't get surgery is because of their medical complexity. So I agree with 18 and that's reinforced by the evidence. But an 80 year old cutoff seems like it might inappropriately affect our elderly population. |
| Sheila Rege | I would, I would agree with that. I'm just looking at what some of the study criteria were that the FDA used. But as long as we're okay with but let's say over 18. Does anybody feel strongly about 80? That wasn't some of the FDA documents. Okay. And then we, I, what somebody said about this is kind of a last resort so something about chronic intractable pain. |
| Joe Strunk | I think you have that right there in your proposed criteria as moderate to severe. That and then you've got it. 12 months of therapy. So you have right there the definition of chronic pain which is over 3 months and you've gone through 12 months of therapy. I, I think that covers your bases. |
| Sheila Rege | Okay, then. A lot of the other trials had some scales. The visual analog scale, is that I, this is not my field of expertise. I mean, we just say markedly abnormal. Is that good and leave it up to the clinician? I see Janna and Jonathan having their hands up. And I don't know if I. |
| Jonathan Sham | I guess to answer the question you just asked, I think that's just defined as. That's greater than 5 on the proposed criteria. |
| Sheila Rege | Okay then. |
| Jonathan Sham | That's how I would refer to Dr. Strunk about, about the purpose of that. My question was just whether or not we might be able to see Dr. Chen's proposed exclusion criteria at the beginning of this conversation, cause I think it might kind of inform. Perfect. How we talk about each one of these in the background of our minds. |

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| Sheila Rege | Oh, there. That's good. |
| Janna Friedly | And, and Sheila, I was just going to mention there is actually that I can see no specific mention of chronic and definition of how long you need to have pain there is the 12 months of treatments which implies I think that you have chronic pain but I didn't that wasn't explicit in here and I guess I'll just say you know when you talk about criteria I still I have a little bit of thanks about the definition of neuropathic pain and the some of the operationally some of the definitions of these. There's a, there's a lot of uncertainty about a lot of these criteria in terms of how to operationalize them. In my mind. |
| Sheila Rege | I mean, what I was proposing was chronic intractable pain of, you know, the trunk or the limb or something, something there refractory to conservative therapy but that would be up on top but Laurie, you had your hand up. |
| Laurie Mischley | Yeah, my question has to do with this dependence on opioids. Obviously one of the reasons that we are getting people to get this scarce to reduce their dependence on opiates and that was one of the outcome measures and some of the studies at least secondary outcome measures. I'm just curious where we draw the line here at use abuse, addiction dependence. I mean, what, what is required? Here, what is our goal by saying people are not allowed to be dependent on or leaning on opiates and where do we draw that line? |
| Joe Strunk | I think that when I look at that statement and as I look at the evidence that we have been reviewing the kind of most of these trials have excluded patients that have been that have active substance use disorder, which I would probably qualify as defined by the DSM 5 or the current DSM criteria. And then that would encompass the data that we have and the idea there is that we want to make sure that we're treating the most important issue first and someone that has untreated substance use disorder needs to be adequately treated before undergoing this kind of procedure. It's also important that we think about the fact that dependence is, is a physical but you know pharmacological status and especially we talk about later as criteria that they have a reduction of opioids. So I don't think those 2 criteria can exist in the same document because one would exclude you if you were on opioids to start with but the second one would say well now you got to show me that you can come down by 50% so I think I would refine that to be. You know, current substance use disorder that's untreated. And then from there, we could talk about other criteria. |
| Christopher Chen | Thanks, Dr. Strunk. I'll just come in. I think I might have forgotten. It greater than, a certain threshold of MED in there, there, which I think we have seen in some of the exclusion criteria as well. So, yeah, for the committee's consideration, but I think, we have seen a threshold of, 120 MED, after that prescription opioids. So yeah, thank you. I also recognize that conflict. |

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| Laurie Mischley | So can we add that in or change it? Here is any can we have a discussion about that or do we want to come back to that? I just know that time is going to be. |
| Sheila Rege | Yeah, what would you like it to say, Laurie? |
| Laurie Mischley | Just replace it with substance use disorder. I think is reasonable. Instead of dependence. |
| Sheila Rege | So you like, oh, So do you have concurrent substance use disorder? On the second line. |
| Laurie Mischley | Anyway, I don't need to spend a ton of time on this. I just, you know, for a person who is dependent on. Is to control their pain and they're hoping this procedure might allow them some reduction. I would like them to not be caught in a place where obviously I agree with TREAT the underlying substance abuse disorder first that all makes sense to me I just wanna be clear that we are obviously going to have people who are using opiates and field and then on. And I don't know where that literal line gets drawn. |
| Sheila Rege | That's a good point. |
| Josh Morse | And is this, is this what I heard a combination of recommendations one was to change it to substance use disorder. I think you're still referring to this line around prescription opioids and I heard Dr. Chen proposed a MED of 120 is that. So what you want in this draft for now? |
| Conor Kleweno | Can't we just make both just one thought. Because I think I'm agreeing with others like do you really think people are gonna come to your practice without Benzos or opioids on board? You know, maybe Joe can come in, but I feel like this client tell are gonna have high likelihood of having these as prescription medication. So what we want to separate as is substance use disorder as one thought and then we include alcohol, illicit drugs and then whatever specifications you have on. Otherwise prescription medications if you have some parameter of that, but I can't imagine that somebody It's prescribed at Benzo for some sort of anxiety and then comes into this would be an exclusion. |
| Joe Strunk | We also have. |
| Conor Kleweno | We're trying, we're, thought our thought process here is we're trying to exclude some sort of substance use disorder that needs to be treated? |
| Sheila Rege | Let's not get, I think it says concurrent substance use disorder, including alcohol or listed drugs. We can just say including alcohol prescription or illicit drugs. Is that acceptable to everybody? Okay, so we're gonna just add. Okay. |
| John Bramhall | Oh, is it, can, can we add? So, Sheila, can we add the word untreated? Can we, can we add the word I'm just untreated concurrent substance use disorder? |

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| Janna Friedly | I think I guess I'm a little bit uncomfortable. Straying too far from again thinking about the evidence as as presented to us in the patient populations that were included in the study. So I just caution us, to remember what the You know what the evidence shows in the patient populations and to try to mirror that as best we can. If possible. |
| Sheila Rege | The other thing I would add here is a coagulation. Which I'm sure the clinician will be checking for. But maybe we don't need to go into all that. That's why we have physicians. So let's, is everybody okay with this exclusion criteria? Can we go back up? To the |
| Josh Morse | We, so I'm happy to add with Dr. Bramhall added or just let me know, be done here. |
| Sheila Rege | I, John, do you feel strongly? Are you good? Good here. |
| John Bramhall | Yeah, that's fine. I just, I mean, I'm on the same page as all of you. The Conor points out the clientele here and A Janet to the clientele. For this procedure. I think it's it's too exclusionary to simply say we're not gonna include somebody who's got a opioid use disorder. I think if you if you added the word at the beginning of that second sentence. Untreated concurrent substance use disorder that that would just soften it a little and allow more people to be considered. |
| Sheila Rege | Hands up visually if you want to add on treated? I actually, John, worry that if you say untreated, these people may not be able to afford to get treatment, so. |
| Janna Friedly | I'm thinking operationally, like I keep going back to how are you going to with many of these criteria, they need definitions and criteria for each of these thing?. How are you going to operationalize that? That's what I'm I keep going back to and maybe Dr. Chen can take them? |
| Clint Daniels | This is quite perfect. I'm looking at that, on this and they call it, does not have any untreated existing substance use disorders. And then it says per American Society of Addiction Medicine guidelines. That'd be, you know, one potential way it could be handled. |
| Sheila Rege | Oh, that's good. |
| Laurie Mischley | Let's do that. |
| Conor Kleweno | I think that sounds great. |
| Joe Strunk | I agree. |
| Conor Kleweno | Because how this will play out is not that the treating physician is necessarily gonna diagnose all these they make come with this diagnosis or not and you know they may |

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| | ask but they're not going to necessarily be obligated to do all of that work. Is that accurate? |
| Joe Strunk | Takes a multidisciplinary team to help treat these patients. So absolutely. |
| Sheila Rege | We're good with that. |
| Jonathan Sham | Just a question of the expert. Is anyone using burst stimulation? |
| Joe Strunk | Yes. Yes, it is probably the largest technique used in the US. |
| Jonathan Sham | That's just a what we mean in our exclusion criteria about. Maybe I miss reading that. |
| John Bramhall | And not to resurrect. |
| Jonathan Sham | Maybe Dr. Chen since this was in your slides, just a clarification. |
| Christopher Chen | Yeah, maybe I'll clarify with you, Dr. Strunk then. I think in the public comment turn the last the earlier portions of this meeting. There was a significant bit of feedback around the horror studies to that first stimulation was outdated or not the appropriate technology to be studying. |
| Joe Strunk | Hmm. Yeah |
| Christopher Chen | So can you just clarify that? |
| Joe Strunk | Yeah, so in the Harrah study they used a different pattern that we don't use here in the US. The burst that's used here in the US which does it different. And so that's where the data that we that we look at has shown efficacy and why it's used fairly extensively here in the US. |
| Christopher Chen | How is it different again? |
| Joe Strunk | But it's not. So it's a, the technique that's used here is a 5 spike first and the technique that was used in the Harrah paper was a 4 spike first and it. |
| Jonathan Sham | So. |
| Christopher Chen | Okay, and there's a there's a, there's a reasonable path of physiologic reason why? |
| Joe Strunk | That is correct. |
| Christopher Chen | Or spike would be significantly different than five spike? |
| Joe Strunk | That's correct. |

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| Christopher Chen | Okay. |
| Jonathan Sham | So it seems like the AMDs are just trying to eliminate the protocol in by listing it here. I guess I would say we're just simplifying and say if no one's using that, we just kind of leave it off and, and leave the discretion of the physicians. I mean, unless you think that people are out there doing the Hara protocol still. |
| Joe Strunk | No, it's not available in the US. |
| Jonathan Sham | Okay, so. I would go just to eliminate that then? |
| Conor Kleweno | Second. |
| Sheila Rege | Any other discussion on exclusion criteria? |
| Joe Strunk | One question I had is for maybe here, Dr. Chen is the substantial pain in other regions that have required treatment in the past year, would that be excluding a patient that has had a total need replacement in the last year? Or a had of risk fracture? I think my thought when I read that is what we're trying to get that as we don't want to be treating the patient has fairly you know, moderate back pain when they have, you know, terrible pain in another region. So my thought would be that and most and as a clinician I totally agree with that but I think the way I would say that is that you would be excluded if you have more severe pain in other regions. That have required treatment. |
| Conor Kleweno | Would you want the qualifier of chronic on there, Joe? Would that make some clinical sense? |
| Joe Strunk | I think so. Yeah, if you, you want to make sure that you're. Yeah, substantial, maybe, yes, substantial chronic pain in other region or just more severe. Because I don't think that I would that. Folks are implanting patients that have pain complaints or trialing them that have much more significant pain in other regions because we wouldn't it would be very hard to distinguish benefit in that patient population. And so just some definition around what substantial means. I think is where I start to get hung up. |
| Sheila Rege | Okay, we have a half an hour left. I know we are gonna lose 2 people. So I don't know if I'm gonna be able to finish this. And. Josh, will look for some input but the substantial pain in other regions. Okay. |
| Josh Morse | I think. When you get to this level of definition, this becomes an implementation question for the agencies. How will the agencies implement this, interpret substantial pain in other regions. So, I don't know if Dr. Chen has further thoughts on this or if the origin of this was inclusion criteria from studies or existing payer policies. Chris do you have thoughts. |

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| Christopher Chen | Yeah, I don't know. And maybe if Gary, if you want to speak to this one too, we did see in a number of different studies including Kaparal, Peterson, that there were exclusion criteria related to pain in other areas that would interfere with accurate pain reporting. And so that's why this was incorporated as a potential criteria. |
| Gary Franklin | I think it's okay to add substantial chronic pain in other regions. |
| Laurie Mischley | I would feel better with them. |
| Sheila Rege | Jonathan? |
| Jonathan Sham | Yeah, and again, sorry, I know, sure I'm short on time, but just, the litigation workers comp line, I guess I just wanna make sure we're consistent with other coverage decisions and again I can imagine that someone gets hit by a car, has back surgery, has pain, there's litigation ongoing for years. I just don't think it doesn't seem reasonable that person should be omitted from this treatment if they need it so again unless this is something common and other decisions. I favor ruling at least litigation. I understand workers comp is a little bit different, but I guess looking for guidance from the AMD is on that one. |
| Gary Franklin | These were common in the studies, is that right, Chris? |
| Christopher Chen | So the only other study, Peterson study, had an exclusion criteria involved in an injury claim under current litigation. The same study also had and separate exclusion criteria for a pending or approved workers compensation claim. |
| Jonathan Sham | Yeah. |
| Laurie Mischley | Jonathan had his hand up first. |
| Sheila Rege | Alright. Oh, sorry, jump in. |
| Jonathan Sham | It was it was residual hand up but I guess I would say like that we're much stricter again as a clinical trial us with that hat on. We're obviously much stricter and inclusion criteria and clinical trials, for obvious reasons. Again, unless we think there's some sort of path of physiologic difference in those patients or we think that, they would be described in a different way by the provider. I guess I was so favor of removing it. |
| Laurie Mischley | I also favor removing it. That's all I was gonna add. I don't think it's appropriate to ever put a patient in a to where they have to decide between their health care and their legal life, I mean, I don't think that, a patient have to be forced to choose between 2. |
| Sheila Rege | So removing everything after claim or pending or existing litigation? |

Janna Friedly I think there is some concern that there are potential financial motivations for people to have spinal cord stimulators when they are in the midst of litigation because that can influence the outcome of a trial or the settlements. So I think that there's some financial implications and most of the studies do exclude those, that patient population. So something to consider on the cost side. I don't know that there's any guardrails, that, can be put up reasonably, but. I do think that's.

Jonathan Sham We need just like a timeline. I'm just trying to think of how to balance those. Competing interests.

Janna Friedly I'm not sure that you.

Jonathan Sham Understanding that, I mean, we all know how long litigation takes. I mean, it could be 3, 4, 5 years. I would just, I understand, I just hate to exclude someone who's quote unquote in need of this over. A multi-year period just because of kind of a blanket.

Janna Friedly Yeah, it's a good again, hard to operationalize.

Sheila Rege Conor, are you gonna help with this or?

Conor Kleweno I wish I'll just to echo how difficult this is. That how it actually plays out in real life. Something I'd involved with a lot as a trauma person. So. It would be difficult to put parameters as Jonathan mentioned because I can guarantee the legal apparatus will sort out when that deadline is and extend things until the deadlines up and then as Janna mentioned, a lot of this type of litigation is done, you know, civil and done with settlements and driving the cost of the settlements are primarily involved with what are the medical costs projected more likely than not in the future. And so something like this would definitely be a high driver of sort of the settlement price. So I think it's a very big challenge. Obviously we don't want to restrict care for people, but as it plays out, there's definitely a cost consequence to whether we put this in or not, I would say.

Jonathan Sham And I guess the question is if they actually met all of those other criteria over the course of the year, all the other guard, we're not looking at right now. Would we trust a provider to then make the right decision in that context? Because the other day we still have to trust the provider to use their, technical decision making. I guess I would be comfortable. It's not just like we're letting anybody have it. It's there's all these other guardrails up above. I guess that's kind of swaying me to be less restrictive here.

Sheila Rege Do you, Jonathan, do you want us to take a poll or I've, this is beyond my pay grade. We have to go with the evidence and then trust people who hired by the state, we're just here for a day.

Jonathan Sham It's, it's an operational question. Like does this litigation or workers claim?

Sheila Rege So I.

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| Jonathan Sham | Does this, any other decision? And like in HTCC. Okay, I'm Rose. |
| Christopher Chen | I. |
| Josh Morse | I've never seen this, these criteria prior. Go ahead. I think that was Chris. |
| Christopher Chen | Yeah, I have not seen it in, other coverage criteria, as I mentioned before, but we also have not seen it in other exclusion criteria for clinical trials. So. |
| Janna Friedly | Yeah. |
| Laurie Mischley | Let me just, maybe. |
| Sheila Rege | So are we looking, so there's 2 questions I have. Are we looking at, are we, is everybody okay with workers comp? Being in exclusion. Depending on existing workers comp. Is that a vote? And then the second is depending on existing litigation. Do we want 2 votes? |
| Laurie Mischley | I would vote to remove them both if I had. |
| Sheila Rege | Okay. Let me need 2 votes. So. |
| Jonathan Sham | And yeah, I know, I don't know, time, but I just don't know much about workers. Is that the same timeline as standard litigation? Is it? I don't know, Gary, if you have and put on that. I mean, is this multiple years? Is it a 6 month process? Like what? I just got familiar with it. |
| Gary Franklin | Yeah, so. Just remind you that we did publish a study and workers. Specifically that showed no improvement beyond 6 months. And also not cost effective. So there is some other evidence on the workers comp piece. I guess what I would do is move the litigation piece to a separate line. As your voting wanted if you keep it in we could come back with some possible operational words that might help here. Like I was thinking, penny or existing litigation related to the condition at hand the condition that this is being used for. That's a possibility, but these are these are from these studies. These people were excluded from these studies. But I have maybe put it on a separate line, right? So to me that makes a little more sense than like whether you have a lawsuit with your wife. |
| Sheila Rege | Yeah. |
| Jonathan Sham | Yeah, it does say related in the bullet point. So I thought it kind of covered that. But I hear what you're saying for sure. |

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| Sheila Rege | Okay, so we'll vote let's remove it then from that so we'll go related pending or existing work as comp claim period and then we'll have a separate bullet line pending our existing litigation for the condition we treated with. So you're gonna delete it You're gonna, no, not the whole thing. Sorry. |
| Josh Morse | You delete the original line. Just the tail of it? |
| Sheila Rege | Do we do everything after the claim. That's it. And now we're gonna vote. So. |
| Conor Kleweno | And Sheila, just to be clear for we're voting because of precedent, as Jonathan said, or because of the evidence that we have as either strong or insufficient to support this excluding. |
| Sheila Rege | Well, so there's one school of thought saying that the trial excluded it and Jonathan's, I think Laurie asked for a vote. Among the committee members about whether the committee would like to keep that in or not. |
| Jonathan Sham | Yeah, I think it's like before. And Josh prescribing it's the proponent and said the evidence or requirements of everything. Are the precedent data implementation. Is that right? |
| Josh Morse | I think that's what you're weighing. |
| Jonathan Sham | Right. |
| Conor Kleweno | Right, I'm just trying to play out this reasoning. We have a study published specifically about workers compensation as evidence. And then we, and with respect to litigation, we just have one exclusion and one study amongst many. So is that playing out what kind of your thought line is on it. |
| Sheila Rege | Question to me. |
| Conor Kleweno | You and Jonathan. |
| Sheila Rege | I tend to go with the evidence and I also have served on the claims committee for physicians insurance and know that, you know, lawsuits. I mean, you use something that's a last resort. It does play out. That the injury or whatever was more serious. So I see it being played too. So. I'm looking. That book. |
| Jonathan Sham | Yeah, Ted, I can't, I guess. I view them a little bit differently personally just because of the timeline. And the data presented. |
| Conor Kleweno | Okay, so should we do, Sheila, maybe the do the workers count first and then |

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| Sheila Rege | Yeah, let's do the workers come first. Josh, you had you were starting a spreadsheet. And this time let's go from the bottom. So we won't put John on the line. So Tony is not here. Jonathan. Would you like to remove that? 4 workers comp? |
| Jonathan Sham | Yeah, so I, I would leave the workers comp and I would remove litigation exclusion list. |
| Sheila Rege | Okay. |
| Josh Morse | I'm going to say include as an I and remove as an R. |
| Sheila Rege | Okay, I would say include both. |
| Laurie Mischley | So, that's, that's, that's include. |
| Josh Morse | Good stuff is not here. Conor. |
| Conor Kleweno | Include so. Exclude. Exclude workers comp. |
| Sheila Rege | Keep it. |
| Josh Morse | Yeah, you're including the language that would make workers comp claim in exclusion. |
| Conor Kleweno | Great. And then I would do the same for the litigation. |
| Sheila Rege | He would keep it the way it is. That's included. |
| Josh Morse | Chris is not here, Janna. |
| Janna Friedly | Include, include. |
| Clint Daniels | It includes. |
| Josh Morse | And, John available. |
| John Bramhall | Yeah, I think, include both work as compound litigation. |
| Josh Morse | So you're, the majority. If not close is, voting is leaning to include that. So. |
| Laurie Mischley | Great. |
| Sheila Rege | So that's how the exclusion criteria would read. Any other discussion on this? |
| Laurie Mischley | Yep. |
| Sheila Rege | Okay. |

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| Clint Daniels | Okay. Should we include the parenthetical about, the American, going to be a American Society of Addiction Medicine guidelines? Hello, if that's necessary or not, but I'm gonna go, let's mention it before we've gone. |
| Sheila Rege | On. Oh, yeah, part of the American Society of Addiction Medicine, ASAM. |
| Clint Daniels | Through that untreated substance use disorder. |
| Sheila Rege | And you'll spell that out, right, eventually the American Society of Addiction Medicine. Okay. |
| Josh Morse | Yep, can do that. |
| Sheila Rege | Is everybody good with that? |
| Gary Franklin | I'm sorry, this is Gary. The I'm pretty sure H does not define this as treated or untreated. It's just a case definition. So I think if you want to use ASAM, it's a case definition of those things. But I'm not sure I'd modify it by treated or untreated. And also I think it's gonna that would be an operational problem for the agencies to implement. |
| Sheila Rege | Let's just remove it then. If everybody okay with that, we know what we are trying to say. |
| Conor Kleweno | Wait, is Gary saying remove the word treated or remove the ASAM guidelines? |
| Sheila Rege | The guidelines because what are the guidelines change? You're leaning on another organization. |
| Gary Franklin | No, I was leave as some remove untreated. |
| Sheila Rege | Oh, you will leave, how to who brought in untreated? Was it Laurie? |
| Josh Morse | It was John and Laurie, I think. |
| John Bramhall | Yeah, I brought it in simply. It's just to deal with this issue. That was the patient population that a couple of people have already commented on. |
| Josh Morse | John initiated. |
| John Bramhall | So. What I was hoping for was that the alcohol or listen drug, illicit drugs, a different thing, but you know opioids. And alcohol would be recognized and, that the patient would be under some form of, some form of treatment for that or at least recognition of the of the problem. |

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| Joe Strunk | And that is consistent with the trials that we've looked at their guidelines are untreated within the last 6 months. |
| Sheila Rege | You, but Gary, you're seeing an operational issue? We leave on treated there. And implementation issue. |
| Gary Franklin | We can talk about it and come back to you when you finalize this. You know, I do think it might be an operational problem. |
| Sheila Rege | Okay. Okay. So you'll get back to us. Okay, let's. |
| Gary Franklin | Yeah |
| Sheila Rege | I do not think we're gonna be able to finish this and I know we're gonna lose 2 members in 10 min. I would hate to get started and then. Josh, any advice? We're not gonna have quorum. |
| Josh Morse | Yeah. Oh, so we know that people are leaving at noon. Is that true? |
| Sheila Rege | Correct. I've heard from 2 people that leave. |
| Josh Morse | Okay. Yeah, no, I this is, you know, if you are If that is true, we have 10 minutes. That is not a good idea to rush through this. If you feel that we're at a good stopping point, we can stop here and you know, explore a way to finish this. You know, either a meeting between now and May or at the May. Yeah, May, I'm looking up thinking about the date at the next meeting, which is in May. I just think you wanna make sure you get this right. So. |
| Sheila Rege | How do the committee members feel? I don't want to rush it in 10 minutes. |
| Janna Friedly | We can't make 10 minutes. |
| Jonathan Sham | I agree not to rush, but I would just maybe do a asking if anyone can't be here in May, cause it'll be even worse if we have to kind of redo. Okay. |
| Josh Morse | Yeah, I think, that's a great question, Jonathan. I, you know, my team and I have been thinking about this just this morning. We're having some attendance issues and you know this is not finger pointing this is just scheduling challenges that we're all experiencing lately, I think there are significant questions about that, making sure we have a quorum making sure we're aligned on, you know, who was present for previous conversations related to extensions and things like this. So we'll do a better job of that. And we can, you know, outside of this meeting, we can look at that and see if we can get some, find a date where we're assured that we'll have you know, 10 people or 11, the full membership able to present or something close to that. Does that make sense? |

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| | Also than 6 or 7, which is a quorum, but you know, it presents these risks of people not being able to attend the next meeting, etc. |
| Jonathan Sham | It also was such a tight vote. I mean, like there's theoretically one person being gone, another person could just switch the decision. |
| Josh Morse | Right. |
| Sheila Rege | I know, that's what's worrying me. So let's figure out Josh, your team will ensure that people are able to make the May 17. I do remember one email from one person could not. And so we'll have to see if that's you know. That we only have one missing member, not multiple. We'll talk about that. |
| Josh Morse | Yeah, and if we can find, ideally I mean, the ideal to me would, we would find a date between now and the end of March where we can. I guess another 4 hour, it seems like we wanna schedule more time than we need. I think, I'm surprised they frankly that this took 4 hours this morning and we didn't get to a conclusion. So I apologize for that. So we can you can explore that. |
| Sheila Rege | And we have, we have a stereotype. We have a stereotypes in, to do finish too. |
| Josh Morse | Yep. |
| Sheila Rege | So we will, Josh and his team will get back to us and try and figure out on whether put it in May or something sooner so we still remember this. |
| John Bramhall | Yeah, if you could do it soon. Yeah, I mean, soon as better in terms of keeping the momentum and you know we're more than halfway there and we have the literature in our heads and things. |
| Josh Morse | Right. |
| John Bramhall | And by the time it gets to May, it's 2, 3 months. And. |
| Gary Franklin | Josh, I think you could do it in a 2 hour meeting. |
| Sheila Rege | No, Gary. I thought we'd do it in a full. |
| John Bramhall | Okay. |
| Gary Franklin | Okay. |
| Josh Morse | Dr. Friedly's trying to be helpful, safe time. |

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| Jonathan Sham | No, but I think it's a good point though. I mean, what's left to do reasonably? I mean, essentially ironing out this language. I mean, is that's not gonna take 4 hours, is it? |
| Laurie Mischley | No. |
| Josh Morse | I don't think so. |
| Jonathan Sham | I mean, we don't need to, I mean, what's left to do, the data review, re voting, if we're gonna, if it's the same group of people. |
| Conor Kleweno | Right. Well, that's what I was gonna throw out there should we just constrict it to this group since the other people couldn't make it today and move ahead or I don't know what the procedure is at on Josh. I just, I want to be efficient with this, you know, where we have an obligation to get this sorted out. |
| Josh Morse | That's a good point. What we can do is attempt to schedule, I mean, if you think 2 hours is sufficient, we can look for it'll be easier, I suspect to find a 2 hour block of time in the next, you know, 2 to 4 weeks or the 7 that are present now and plus the clinical expert, Dr. Strunk. We can be more, maybe more flexible with the time if we need to be and other committee members can be optional for attendance. And they may want to abstain from, from final votes. You know, I think there were some that had I wouldn't want to restrict people from participation in some way were present before, but we can prioritize the 7 here as far as finding the right time. Does that make sense to you? |
| Sheila Rege | That works, that works well. But we should invite the other committee members who couldn't make it because some of them were on the first call when this was discussed. |
| Josh Morse | Okay. |
| Gary Franklin | It would be helpful to be beginning of that meeting for those that did not come today to just kind of summarize the essence of what we what happened this morning. So you'd have to go over everything again. |
| Sheila Rege | Bye. |
| Janna Friedly | Yes, this is recorded, right? They'll have opportunity to review. The meeting as well. |
| Josh Morse | There will be. Hopefully it's recorded and there's a transcript. Yeah, that's where we started with the technology problems this morning. Yeah. So, we do hope that we have a record that they can review and we can make that as easy as possible for them to access. |
| Sheila Rege | We still, just to let everybody know we, do have 89 total participants. It says, so there is interest so we will have to you know what a way our processes on letting people |

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| | know and whatever our guidelines I would have to adhere to that. To make sure everybody has an opportunity. |
| Josh Morse | Oh, for sure. No, these are all public meetings. There will be nothing that's happening outside. Yeah, that's. Thanks for pointing that out. Yeah, this is all done in the public process. |
| Sheila Rege | Just wanna reassure everybody. |
| Josh Morse | Thank you. |
| Sheila Rege | Alright. So we will reconvene and, Josh, you and your team will, Give us some dates. |
| Josh Morse | Okay, thank you. |
| Sheila Rege | Thank you. Bye. |
| Laurie Mischley | Bye everybody. |