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Health Technology Clinical Committee Public Meeting

July 10, 2020

BRITT REDICK: So, I am going to go ahead and start the broadcast. And I think that should allow me that I gotten most of the committee over. To work on Laurie, and then yeah, I think we can get started. So just one moment. Good morning, everyone. Thank you for joining us. This is BRITT REDICK:. I'm the HTA Program manager. We're just getting set up with our committee members and program staff here. So just give us one moment, and then we will get started. Thank you.

This is Britt Redick, again. I think I've got most of the committee members set up with their audio. Sheila, if we want to go ahead. And get Sheila and Josh. I think we're ready to get started, and we can test audio as we do roll call and render the roster if that's OK.

JOSH MORSE: Sounds good. Thanks, Britt. OK. Should we get started with a roll call? looks like Dr. Rege is muted. Sheila, can you hear me? Are you there?

BRITT REDICK: This is Britt again, and maybe what I can do is start to go through the list and people can say hello while we're kind of struggling for people to speak.

JOSH MORSE: OK.

BRITT REDICK: OK. John Bramhall?

DR. JOHN BRAMHALL: Yes, here. Present. Thank you.

BRITT REDICK: Janna Friedly?

DR. JANNA FRIEDLY: I'm here.

BRITT REDICK: Good morning. Chris Hearne?

DR. CHRIS HEARNE: I'm here

BRITT REDICK: Alright. Connor Kleweno?

DR. CONOR KLEWENO: Here. Can you hear me?

BRITT REDICK: Yes. Thank you. Laurie Mischley?

Laurie, I see you're unmuted. OK. Got a moment. Sheila Rege, were you able to...
OK. We'll just keep going down the list and I'll go back. Seth Schwartz?

DR. SETH SCHWARTZ: Yep. I'm here.

BRITT REDICK: Great. Mika Sinanan? Looks like you're muted.

DR. MIKA SINANAN: OK. Can you hear me now?

BRITT REDICK: I can. Yes. Excellent. Thank you. Kevin Walsh?

DR. KEVIN WALSH: Here.

BRITT REDICK: And Tony Yen? Good morning.

DR. TONY YEN: Here.

BRITT REDICK: Good morning. OK. So, I just need to troubleshoot Laurie and Sheila. Just one moment. Sheila, are you available now?

DR. SHEILA REGE: I believe so. Sheila Rege.

BRITT REDICK: Yes, I believe. Excellent. Thank you. And Laurie, are you able to speak? I will maybe troubleshoot on the side with Laurie if you want to get started, if that's OK?

DR. SHEILA REGE: Yes.

JOSH MORSE: Looks like Laurie is going to call in.

DR. SHEILA REGE: Welcome everybody. And today should be relatively short. So I really appreciate you giving up your morning for this. We're going to first start with the program updates from Josh.

JOSH MORSE: Thank you. Good morning, everyone. This is Josh Morse the program director for the HTA program.

I've just a couple housekeeping notes. This morning in our presentation as most of you know it's a good idea to keep your bandwidth use down and have your other windows closed. Please make sure that you're unmuted when you're trying to speak. Hopefully you're familiar with the webinar controls, but here is a quick preview of some of the options that you have. Sounds like everybody has just about figured out the audio this morning.

So today's agenda is a wrap up look at the draft determinations and the comments that have come in on the tinnitus decision for non-invasive non pharmacologic treatments. Comments received on the Vagal nerve stimulation for epilepsy and depression. And any comments that were received in the stem cell therapy from musculoskeletal conditions. We'll go through each of these along with the minutes

from the June meeting. And we'll do it just a quick update when we get through that about what comes next after today's meeting.

So some reminders for everybody. This meeting is being recorded. A transcript will be made available on our website a few weeks after the meeting. When participating in any discussions please remember to state your name, and of course use your microphone. And to provide public comment during today's meeting. We don't have public comment today for this wrap up meeting of these topics, but in the future if you're interested in commenting on topics our contact information is here on our website. You can see how to sign up to receive email updates from the program, and you can use this program email address to email any questions to our program. And those are the updates. Dr. Rege, so I'll turn it back to you.

DR. SHEILA REGE: Thank you, Josh. If we will open up the previous June meeting minutes. And if you will kindly project that for us. Thank you. That was June 12th. And if we could look through it, and I will entertain a motion to accept.

JANNA FRIEDLY: So moved. This is Janna.

DR. SHEILA REGE: Thank you, Janna. Any second?

MULTIPLE UNIDENTIFIED: Second.

DR. SHEILA REGE: Any discussion? Otherwise all in favor of say "aye".

EVERYONE: Aye.

DR. SHEILA REGE: Anybody opposed? Anybody abstain? OK.

Our next item of business is the tinnitus non-invasive non-pharmacological treatments. If you are on the PDF just as background look at page nine which has what we've done so far on this and public comments were being accepted till June 2nd. And Josh, will you lead us into...

JOSH MORSE: Yes.

DR. SHEILA REGE: The comment part.

JOSH MORSE: Yes. We received one comment from an agency colleague at the Department of Labor and Industries, Ian Zhao who reviewed the decision and Ian emailed a recommendation outside the comment period. But we do consider comments outside the comment period. This came in a couple of weeks ago. So Ian has recommended adding some definitions to your decision, and his email is in the packet.

DR. JOHN BRAMHALL: Josh, is there any way to zoom that in? It's quite small font for my old eyes.

JOSH MORSE: Yes, I can. Of course, thank you. Is that better?

- DR. JOHN BRAMHALL: Yes. Great. Thank you.
- JOSH MORSE: And we did prepare a draft that shows what this would look like in the decision if you'd like to see that as well.
- DR. MIKA SINANAN: Mika Sinanan. I didn't see this changed the decision. It just added more precision to the definition, and as was commented by Dr. Zhao it allows us to use the appropriate terms of art in the recommendation.
- DR. JOHN BRAMHALL: Yeah, I agree, Mika.
- DR. SHEILA REGE: Josh, can we see how it would look with the language of this recommendation and you will make that bigger for all our eyes.
- JOSH MORSE: Yes. So this is what I'm taking Dr. Zhao's comments and putting them into decision would look like. And then the definitions fall down below. Is that big enough?
- DR. SHEILA REGE: Yes.
- DR. MIKA SINANAN: I would move to...
- DR. SHEILA REGE: Open for discussion. Thank you, Mika. Any second?
- DR. LAURIE MISCHLEY: This is Laurie. I second.
- DR. SHEILA REGE: Is there any discussion on this?
- DR. TONY YEN: This is Tony. Do we... (interrupted)
- DR. SETH SCHWARZ: This is Seth. To be clear, are we just talking about this addition or we talking about the entire thing right now?
- DR. SHEILA REGE: Let's go first just to this addition.
- DR. TONY YEN: OK, then I have no discussion. I approve of it.
- DR. SHEILA REGE: So let discuss, let's vote. And the motion is to approve this additional clarification language.
- Everybody, I'm going to have to go through the list. Well let's do this. Everybody in favor, and then we'll go through. Josh, do you want me to go individually for this?
- JOSH MORSE: You're doing the first vote on whether to accept the change before you do the final vote?
- DR. SHEILA REGE: Correct.
- JOSH MORSE: I'm comfortable with not doing it individually for that first vote.

DR. SHEILA REGE: OK.

JOSH MORSE: Did Dr. Yen have a comment? I heard him...

DR. TONY YEN: Yes. Sheila, I'm curious. Do we actually need to have these additional definitions, or is it just does it help the agency in any way? I'm curious.

DR. SHEILA REGE: I'm hearing it helps the agency avoid questions is what I got from that the other the initial email or the document we reviewed. And I'll have Josh or anybody at the agency is available to comment on your question.

JOSH MORSE: I think that specify... Are you asking about this piece down here, Dr. Yen, Tony?

DR. TONY YEN: The definitions that Dr. Zhao suggested up there.

JOSH MORSE: Yeah, I think the agency is suggesting that having the clarity of what the terms apply to is very helpful when they're adjudicating decisions around these, rather than have to go and look them up.

DR. TONY YEN: OK. I got it. Thank you.

JOSH MORSE: It's easier for the providers and it's easier for the people working on the claims.

DR. TONY YEN: Alright.

LAURIE MISCHLEY: This is Laurie. The only comment that I'll make is I don't really love calling out Neuromonics, the company in particular, in the definition. I'd rather be a little more generic than company specific, but that's not a tremendously important to me.

DR. TONY YEN: I agree with that.

DR. JOHN BRAMHALL: Yes, I do as well. Because I found the term a little confusing Neuromonics. It's a registered trademark, correct?

DR. SHEILA REGE: Right. It is patented.

DR. JOHN BRAMHALL: Yeah. But hey, I would support whatever is helpful for the agency to clarify. I think I can get specific questions about a particular device, a particular treatment that happens to be patented. I think they want to be able to answer the questions definitively.

UNIDENTIFIED: I tend to agree that we should avoid making reference to specific companies' product and the incidence.

DR. SHEILA REGE: Should we say "Neuromonics" or similar? I mean, it's kind of like overnight delivery is FedEx. Even if you use U.P.S, in my mind.

- DR. LAURIE MISCHLEY I think we could just remove the phrase Neuromonics tinnitus treatment, and not change the meaning or the clarity of the definition, I mean.
- DR. SHEILA REGE: Is anyone from the agency here is that going to make your call volume or confusion greater? Is that what you're seeing?
- JOSH MORSE: The representatives from the Department of Labor and Industries can't be here today to comment on this. Their agency is completely furloughed on Fridays this month. So we're not going to have input from them today. But what I'm hearing you is suggesting is deleting it from here. And would you be comfortable also deleting it from this definition?
- DR. SHEILA REGE: Yeah.
- JOSH MORSE: OK.
- DR. EMILY TRANSUE: This is Emily. I just thought. Just would it be OK to have it kind of been a parenthesis or something saying, for example. I understand not wanting to have it be in the definition, but I suspect that, and I did call this out because this name comes up a lot. So just wondering if that would be a compromise that would feel comfortable to people?
- DR. SHEILA REGE: Yeah, I understand our reluctance to call out a patented and or company specific term, but I do want to help avoid confusion between people that, you know, physicians and other healthcare providers that are going to use this. So I would like some compromise to let everybody know that this was the intent was not to cover treatments such as that. So I'm looking to committee members for help.
- DR. JUDY ZERZAN: This is Judy Zerzan. I was on mute. I don't know if anyone could see my chat. But I was the clinical expert that reviewed this, and I understand not wanting to use the industry trademark name, but I will say that that was what was in the review. And we specifically, the technology reviewers looked at that. And so I like Emily thought about saying it may be an example which is maybe what's in here. But I do think that the specific kind of therapy was particularly called out in the review.
- DR. SHEILA REGE: So Judy if we put it in this page saying these included... Can you unaccept what we deleted?
- JOSH MORSE: I can. Yes.
- JUDY ZERZAN: So up here it is, you know, this includes, but is not limited to. Because I think there's not evidence that these are helpful for tinnitus. And so I think it could either be as an example, you know, that could be down here. But it was included in the review. So I think that's helpful.
- DR. SHEILA REGE: Anybody, I share the group's, our committee's reluctance to use patented terms. But it was included in the review, and the agency feels that it will help avoid

confusion. Based on that input anybody here have large heartaches about keeping it on the first page?

DR. LAURIE MISCHLEY No.

DR. MIKA SINANAN I think it's fine. Mika Sinanan.

DR. SHEILA REGE: Yeah, let's divide the question, and I'm going to actually go through one by one, and I'm going in the middle. So Laurie, warning you're going to be first. If yes or just a straw vote.

DR. LAURIE MISCHLEY Yes.

DR. SHEILA REGE: Yeah. If you have great heartaches and no.

DR. LAURIE MISCHLEY This is Laurie. I have no heartache leaving it.

DR. SHEILA REGE: Conor?

DR. CONOR KLEWENO: No heartaches. Sorry, I was muted there for a second.

DR. SHEILA REGE: Chris?

DR. CHRIS HEARNE: No. That should be OK.

DR. SHEILA REGE: Janna?

DR. JANNA FRIEDLY: That's fine with me.

DR. SHEILA REGE: John?

DR. JOHN BRAMHALL Yes. I'm fine with that. Thank you.

DR. SHEILA REGE: Sheila. I'm fine. Seth.

SETH SCHWARTZ: Yes, I'm fine with it.

DR. SHEILA REGE: Mika?

DR. MIKA SINANAN Yep. Fine with me.

DR. SHEILA REGE: Kevin?

KEVIN WALSH: Yes.

DR. SHEILA REGE: Tony?

DR. TONY YEN: I'm fine.

DR. SHEILA REGE: So, I'm going to assume if we're fine with keeping it there. We're fine with keeping it on the next page. And now we're going to go for a discussion. Anybody can call for a vote of just this addition.

DR. MIKA SINANAN: Mika Sinanan. Call for a vote

DR. SHEILA REGE: OK.

JOSH MORSE: Alright. So, it'll be the original document as we showed it to you where it said Neuromonics in the definition.

DR. SHEILA REGE: Correct.

JOSH MORSE: OK. Thank you.

DR. SHEILA REGE: I'm just going to switch it out on the vote just on this addition. We're going to start with Seth.

UNIDENTIFIED: This is just before we go, can I just make one point. This is unrelated, but just with the actually the way this is the statement itself is written. I just was wondering if there should be a comma in the actual statement. Can you show us the actual statement? Let's see. Oh, the comma is in there. It's interesting. It wasn't in my original... OK, forget it. Scratch my point.

DR. SHEILA REGE: Any other (INAUDIBLE)? OK, Seth. You're back for a vote. Yes or no?

SETH SCHWARTZ: "Yes".

DR. SHEILA REGE: Mika?

DR. MIKA SINANAN: Sorry, I'm confused. Are we voting for the language before us, or the language that we just wordsmithed?

DR. SHEILA REGE: The language that's before you.

DR. MIKA SINANAN: OK and scroll down again.

JOSH MORSE: Right. There's one deletion I need to undo which would put it back to the original. See if I can get there.

DR. MIKA SINANAN: OK. Well with that up... Yeah. OK. Yes, I support that.

DR. SHEILA REGE: So it's back to the original that we were presented with?

JOSH MORSE: Yes. As it was submitted.

DR. SHEILA REGE: Thank you, Mika, for pointing that out.

JOSH MORSE: I was afraid to go back in and do all that for fear the ticks would go away. So it worked out.

DR. SHEILA REGE: Seth, you're still good?

DR. SETH SCHWARTZ: Yeah, I'm still good with it.

DR. SHEILA REGE: Mika, good. Kevin? Tony?

DR. TONY YEN: Yes.

DR. SHEILA REGE: Sheila's good. Laurie?

DR. LAURIE MISCHLEY: I'm okay with that.

DR. SHEILA REGE: Conor?

DR. CONOR KLEWENO: OK.

DR. SHEILA REGE: Chris?

DR. CHRIS HEARNE: I'm good.

DR. SHEILA REGE: Janna?

DR. JANNA FRIEDLY: With everything.

DR. SHEILA REGE: John?

DR. JOHN BRAMHALL: Yes. Good. Thank you.

DR. SHEILA REGE: OK. So, we just did that for the portion in red. Now let's look at it really carefully. You're going to pull up the first page again. And now we need to look at our decision aid. This is page 11. Proposed findings decision and public comment based. Is this a good time to do that, Josh? Would you like me to do it that way? Based on public comment was evidence overlooked in the process that should be considered?

JOSH MORSE: Yeah, I just noticed something. OK. Yes. That is the next step.

DR. SHEILA REGE: So, it's open for discussion. Was there any evidence overlooked that was really no public comment suggesting that any discussion on that point?

UNIDENTIFIED: No.

UNIDENTIFIED: Agree. No evidence overlooked.

DR. SHEILA REGE: Does the proposed finding and decision document clearly convey the intended coverage to nomination based on review and consideration of the evidence?

UNIDENTIFIED: Yes.

DR. SHEILA REGE: Wait a minute. What is being projected?

JOSH MORSE: This is the decision still.

DR. LAURIE MISCHLEY: I think the crossed out Neuromonics tinnitus treatment be put back in.

JOSH MORSE: I don't know what happened. OK. This is what I was concerned about. I apologize.

DR. SHEILA REGE: Now that's good. It's hard with all of us being electronic. You are doing all the hard work. We're the backseat drivers just kind of watching.

JOSH MORSE: OK. Now need to go backwards.

DR. SHEILA REGE: So right now, for discussion of, does the proposed findings and decision document clearly convey the intended coverage determination based on review and consideration of the evidence?

Anybody opposed to this speak now. If not, we're going to move on to the final vote. That we approve the findings and decisions document as projected with the changes that was recommended by the agency director. And I'm going to go through votes. Open for discussion. For five seconds, four, three. OK. Laurie we'll have you start with a vote. Yes or no?

DR. LAURIE MISCHLEY: Yes. I vote yes.

DR. SHEILA REGE: Thank you. Conor?

DR. CONOR KLEWENO: Yes.

DR. SHEILA REGE: Chris?

DR. CHRIS HEARNE: Yes.

DR. SHEILA REGE: Janna?

DR. JANNA FRIEDLY: Yes.

DR. SHEILA REGE: John?

DR. JOHN BRAMHALL: Yes.

DR. SHEILA REGE: Sheila. I say yes. Seth?

DR. SETH SCHWARTZ: Yes.

DR. SHEILA REGE: Mika?

- DR. MIKA SINANAN: Yes.
- DR. SHEILA REGE: Kevin?
- DR. KEVIN WALSH: Yes.
- DR. SHEILA REGE: Tony?
- DR. TONY YEN: Yes.
- DR. SHEILA REGE: OK. So, we have concluded the tinnitus non-invasive non-pharmacology treatments. We will move to vagal nerve stimulation for epilepsy and depression. And in this we did have some input from the public and I am opening it up. We can open it up for this discussion. And I did ask Josh to check with the evidence experts about some of the studies that were included as public comment but opening it up for discussion.
- DR. MIKA SINANAN: So, Sheila, Mika Sinanan. As I understand it from reading through the public comments, the supplementary public comments. The two questions are if somebody has an implant already, will we support changing a battery? Assuming that it's sort of a legacy thing or put in elsewhere or...
- Paid for by other means. And the second question is they believe that we did not review all of the evidence around this treatment for the management of refractory depression. And they provided additional comments about that. And their criticisms were one we didn't include relevant literature. And two, we did not have a psychiatrist as one of our, as an expert. We had somebody who was a specialist in epilepsy, a neurologist. So that was my takeaway. I just wanted to sort of set the stage. Thanks.
- DR. SHEILA REGE: No, that was very succinct way of putting, outlining the concerns. Any other kind of thoughts, discussion, and when we can then decide whether to discuss this as point one, a legacy. But the end point two about the evidence and the expert. The expert is not there for as an expert on the evidence, the expert is there just for the clinical content questions about the clinical aspect about it? And Josh, you could say that better about how the expert is viewed.
- DR. MIKA SINANAN: Yeah, because one other comment, the Medicare coverage point that they make about vagus nerve stimulation for treatment, refractory depression. In detail, it's really only in the setting of a clinical trial. So, I thought that was a bit off the point. Because they're only saying that they're just pointing out what Medicare in much more detail in a copy of the information they provided, really says that this is supported in the setting of a clinical trial, because we don't know whether it is helpful or not.
- DR. SHEILA REGE: And like if you remember, we did discuss that we'd review that coverage of the Medicare policy during a meeting.

- DR. JANNA FRIEDLY: Hi, this is Janna, I just want to make a comment. I agree with the previous comments for me looking at the evidence that they also submitted that we did not include, included essentially a registry and observational registry with five-year data. That to me, did not significantly add to what we had already reviewed, or change for me. The evidence there were there's fairly significant limitations and, in that registry, and some challenges with interpreting the observational data. Without randomization for me.
- MIKA SINANAN: Yeah. me considering, I would say that this is obviously a group of patients who are desperate, who have few good choices or any choices because they've excluded the likely things that will work. And for those reasons, although they have highlighted the importance of not excluding anything that may work. There's also the highest risk of bias in that situation and placebo effect, which is exactly why the evidence review focused on high quality evidence that would minimise the risk of bias. And I would agree with Janna that this does not change that it simply emphasises to my mind the risk of bias and the fact that these are desperate people with a terrible disease.
- DR. SHEILA REGE: Right. And if we could, you know, we did have a timeline and the draft report was published in December and public comment was open till the end of January before meeting and this kind of was not brought up at that point. Josh, would you like to add anything based on your conversation with the group we had hired the vendor.
- JOSH MORSE: The vendor pointed out that one of the studies that's referenced the Aronson study is included in the report in the draft and the final report and one of the publications that was submitted was an extension of that. But that you did see the original evidence. That's what our reviewers told us about that. I have nothing else to add beyond that. Thank you for the discussion. It's really helpful.
- DR. SHEILA REGE: So, we are already doing what we're supposed to based on public comment. Was evidence overlooked in the process that should be considered so continue on that discussion.
- DR. KEVIN WALSH: I did not find that this was essential evidence that was overlooked.
- DR. SHEILA REGE: Would anybody like to speak? Who feels that any evidence was overlooked? If not, we'll go on to the second question.
- DR. LAURIE MISCHLEY: Yeah, this is Laurie, I don't feel that any evidence was overlooked. But I will just reiterate that our charge is to evaluate the available evidence and see if it supports any given intervention. And it is going to be a while before we have results of double-blind placebo controlled multicentre trials of this as an intervention. And here we have something where nothing else works for desperate population. And it looks like the intervention in question increases risk improvement 39% to 63%. And it's not great evidence, it's not as much as we would want.
- But it does look like the evidence that is available does support that it might help a couple people that can't otherwise be helped. So, I believe I voted for it last time,

and I don't, that's a separate issue. That was I was out voted last time. I'm OK with that. So, I don't think anything was overlooked. But I do just want to call out that I agree with the, I disagree with the decision to not cover depression in this circumstance.

DR. KEVIN WALSH: I went back and looked at that the report and what struck me was that table C8, on page 140, looks at health related quality of life measures, comparing vagal nerve stimulation plus best medical practice compared to best medical practice. And the only factor that had a reasonable p value, I found was not very supportive of the improvement in quality of life, demonstrated by DNS.

So, I respect what Laurie is saying, but I think the evidence that we were provided just does not support the use of DNS. And just to reiterate, Medicare is approving it in clinical trials. And our agency medical directors have the prerogative to allow coverage in clinical trials. So, we don't have to decide that in itself, because they already have that prerogative.

DR. SHEILA REGE: I'm going to go around the room for just to make sure everybody has a turn, just to say a sentence about based, you know, with evidence overlooked and whether I'm just, you know, you want to speak to that I'm going to go with anybody who hasn't spoken. So, Laurie and Kevin have spoken to. Seth, set any comments on that?

DR. SETH SCHWARTZ: No, I mean, I really, I think it's interesting point. But I think it's good to know that the vendors went through and looked and saw that we already looked at the version of this data. I don't think this was these changes the underlying decision for me.

DR. SHEILA REGE: Mika?

DR. MIKA SINANAN: I agree with the original decision, I do think that we should separately consider the question of battery change support as a separate question after this.

DR. SHEILA REGE: Kevin?

DR. KEVIN WALSH: I don't feel that essential evidence was worked out. And I agree with Mika it's, we should consider the battery change question separately.

DR. SHEILA REGE: Tony?

DR. TONY YEN: I don't have anything new to add to the discussion. I think the evidence that we're given was sufficient.

DR. SHEILA REGE: I don't have anything else to add Laurie. Anything else?

DR. LAURIE MISCHLEY: Nope.

DR. SHEILA REGE: Conor.?

DR. CONOR KLEWENO: Yeah, I agree with Mika on the battery issue as a separate itemization. I did think the comment of not having a psychiatrist was a valid critique. I think that again, we did review the evidence. I thought that we had in front of us what is out there? I do, this was a tough decision for me just given the desperate clinical nature of these patients compared to some of the other things we've reviewed and I think in all of our specialties and subspecialties, we've seen quote randomised controlled trials that were later proved to be a bias or a confounding variable that was missed that the conclusion was then refuted. So, something we do struggle with, even sort of what we feel like top tier studies don't always provide us with the answer that that we need.

But what we have out there and what it is given to us, it really, really struggles to make a compelling case to definitively make a coverage decision in favor. But I do acknowledge that even in the best intents to conduct a randomised control trial, that those whether it's study design, or just missed confounding variables can be later shown to be inaccurate. So, I guess in some, I don't think that I have any disagreement with what we're doing.

DR. SHEILA REGE: Thank you, Conor. Chris?

DR. CHRIS HEARNE: I think that this sort of situation is, is really high risk or bias and the introduction of placebo effects and things like that. And so, the addition of more observational evidence that seems to go against our earlier decision, and that doesn't make me want to change my mind on it. I do agree that it would have been nice to have a psychiatrist. But the limitation is that there is there's only one clinical expert at a time. So that's just one of the limitations of our setup, I think.

DR. SHEILA REGE: Thank you. Janna?

DR. JANNA FRIEDLY: I don't have anything to add that hasn't already been said, I have not changed my view on this. I don't feel that this evidence changes my initial or original decision.

DR. SHEILA REGE: Thank you Jan, John?

DR. JOHN BRAMHALL: I think the letter from living off is well organised. It's well represented. I don't think it changes. Anything can be in my head. I had a so when we discussed this originally. I think we all had a visual understanding of the desperate nature of intractable depression. So, I saw the issue of as to whether a psychiatrist was there to advise us, it is not mood, but it doesn't influence me particularly strenuously now. I mean, I think we had good expert testimony, we had access to what I thought at the time was a cogent, well presented, comprehensive review of the literature available by the vendor. I didn't have any problems with that. And, yes, my tendency as a human being is to think favorably of a possible treatment for something that has no other option.

But, you know, time and time again, we're faced with that in the community. And time and time again, if we're disciplined about it, we return to the concept of what we're doing here, which is to review the scientific literature that's available and

make a decision on that basis not necessarily distorted by our own sort of human tendencies.

So, I sympathise, but I think we made the right decision. The company's like leaving over at national companies, they're well organised, they know the literature, and they know what they want to do. And they're totally appropriate for them to communicate with the committee in the future, as more information comes available, but at the moment, I'm happy with the decision we made.

And by the way, I do agree with Mika statement about the battery change. I mean, people have these devices and they're going to be in their body dead with no power. That doesn't make any sense. So, I agree with Kevin.

- DR. SHEILA REGE: Well, let's, actually that leads us into the intended coverage determination, can we project that?
- DR. EMILY TRANSUE: Can I? This is Emily, can I sort of address in just a little bit for context? How we typically handle these situations if there isn't a specific comment about them in the decision?
- DR. SHEILA REGE: Yes, thank you. Yes, Emily?
- DR. EMILY TRANSUE: Yeah. So typically, I think there often isn't something about kind of revision replacement repair, since that isn't usually within the context of the evidence that you review. And what we generally do in that situation is think of that as being outside the scope of the decision itself. So usually, decisions about repair would sort of fall to the existing policies within the plans or an individual determination. And I think typically what happens in that situation, following common sense is that if something is working well for somebody, and it's better is run out, we refill the battery. And likewise, if there's a relatively simple procedure to fix something that's not working that would generally be covered. So just that you understand that we would, our default would not be to say that this determination, if you didn't change it, meant that we couldn't change the battery.
- MIKA SINIANAN: So, Emily, Mika Sinanana. Thank you for that clarification. I am concerned that somebody reading this might interpret and not even ask or request support. So that's why at least some comment to say that battery changes or equipment malfunction needs to be addressed on an ad hoc basis or something like that, would be...
- DR. EMILY TRANSUE: Outside the scope of this decision.
- DR. SETH SCHWARTZ: So, this application does not apply to people who have already been implanted to supportive devices already implanted.
- DR. CONOR KLEWENO: This is Conor. I definitely agree with that. I think that would be a as Mika pointed out. I think that'd be easily overlooked or assumed otherwise.

- DR. SHEILA REGE: Do you want an asterisk on that and I'm going to let Emily. Do you want to help us with some language that may reflect the concerns of the committee members?
- DR. EMILY TRANSUE: Sure. I think the language that (UNKNOWN) is working on that now looks good. I think that clarifying it as a scope issue is helpful. I really liked the language that someone just said that I should have written down as they were saying, to previously implanted devices requiring. You said that a second ago. It was perfect.
- DR. SHEILA REGE: Somebody wants to resay that?
- DR. SETH SCHWARTZ: Yeah, this is Seth. I just said, "this does not apply to support of previously implanted devices."
- DR. SETH SCHWARTZ: Looks good.
- DR. SHEILA REGE: And that could just be an asterisk on our intended coverage determination. So now how are we going to project. Josh, how are we going to project a revised coverage, determination for the committee to review?
- JOSH MORSE: Yeah, I can do that. If you just give me a second to hunt around for the word version. Just take me a second here.
- DR. SHEILA REGE: No problem. The rest of the committee members feel free to stand up and stretch or...
- JOSH MORSE: So how does this look?
- DR. SHEILA REGE: And where does the asterisk go?
- JOSH MORSE: Yeah, I was debating that myself. I think the asterixis may go right here. Emily, do you have a thought on where the asterisk might be most helpful?
- DR. EMILY TRANSUE: I think that's a really good place for it.
- DR. SHEILA REGE: Any discussion on this revised?
- UNIDENTIFIED: I think that looks good.
- DR. SHEILA REGE: OK. Anybody else? I will entertain a motion to begin the approval, the vote process of final vote.
- DR. MIKA SINANAN: Mika Sinanan here. Motion to approve.
- DR. SETH SCHWARTZ: This is Seth, I second.
- DR. SHEILA REGE: OK. let's go ahead. Seth, I want to start with your final vote.
- DR. SETH SCHWARTZ: Approve.

DR. SHEILA REGE: Mika?

DR. MIKA SINANAN: Approve.

DR. SHEILA REGE: Kevin?

DR. KEVIN WALSH: Approve.

DR. SHEILA REGE: Tony?

DR. TONY YEN: Approve.

DR. SHEILA REGE: Sheila? Approve.

DR. SHEILA REGE: Laurie?

DR. LAURIE MISCHLEY: Approved.

DR. SHEILA REGE: Conor?

DR. CONOR KLEWENO: Approved.

DR. SHEILA REGE: Chris?

DR. CHRIS HEARNE: Approved.

DR. SHEILA REGE: Janna?

DR. JANNA FRIEDLY: Approved.

DR. SHEILA REGE: John?

DR. JOHN BRAMHALL: Approved.

DR. SHEILA REGE: Now in my mind, that was the final vote for the entire what was projected. Everybody's good with that. Then we will go to Vagus nerve stimulation. I'm going to give it to anybody who wants for their action on this a minute. Not a minute, but a few seconds to speak up. OK. Moving on to STEM cell therapy for musculoskeletal conditions. Emily, thank you for coming in on that call. Committee members should know that I think a lot of the state agencies are being furloughed. Because of the pandemic and budget issues. So, we really appreciate what you are doing to help support the committee,

DR. MIKA SINANAN: Sheila, while we're getting to this, Mika Sinanan, just a comment to Emily. You know, the term of art question that we dealt with in the first issue. That would be a helpful review point for you and your group. When you're reviewing these things. If you are aware of terms of art that we should be considering in any policy decision. that would be helpful to tell us at the time.

DR. EMILY TRANSUE: Great feedback, we appreciate it. So, we will be attentive to that, thank you.

DR. SHEILA REGE: Coming to STEM cell therapy for musculoskeletal. We did not get and I think Josh is projecting. The decision we did not get any comments. The public comment period closed June 29. So going through our decision aid it would follow that. Did any of the committee members feel any evidence was overlooked?

UNIDENTIFIED: No.

DR. SHEILA REGE: And as the proposed finding and decision document clearly conveyed the intended coverage determination and we'll project the...

UNIDENTIFIED: Yep

DR. SHEILA REGE: And if there's no further discussion we could go for a vote.

UNIDENTIFIED: Motion to approve the original statement.

DR. LAURIE MISCHLEY: This is Laurie. I second.

DR. SHEILA REGE: If no discussion Laurie, I'm going to start with you for a vote. The final vote.

DR. LAURIE MISCHLEY: Approve.

DR. SHEILA REGE: Conor?

DR. CONOR KLEWENO: Approve.

DR. SHEILA REGE: Chris?

DR. CHRIS HEARNE: Approve.

DR. SHEILA REGE: Janna?

DR. JANNA FRIEDLY: Approve.

DR. SHEILA REGE: John?

DR. JOHN BRAMHALL: Approve.

DR. SHEILA REGE: Sheila? Approve.

DR. SHEILA REGE: Seth?

DR. SETH SCHWARTZ: Approve.

DR. SHEILA REGE: Mika?

- DR. MIKA SINANAN: Approve.
- DR. SHEILA REGE: Kevin?
- DR. KEVIN WALSH: Approve.
- DR. SHEILA REGE: Tony?
- DR. TONY YEN: Approve.
- DR. SHEILA REGE: That concludes STEM cell therapy for musculoskeletal conditions.
- JOSH MORSE: Excellent. Thank you.
- DR. SHEILA REGE: And now Josh, I will turn it over to you for program works in progress. The report.
- JOSH MORSE: So the only update we have. We had hoped to bring you some information about topic selection. The agency is in the final step of reviewing proposed new topics. Also, a host of petitions for topics to be updated and a long list of topics that were considered for a new review or for re-review. And we're not quite ready to share that publicly. We're awaiting a final decision from the director of the agency. As soon as that's done, we'll be posting that and sending you an email and asking for any feedback you have on topics that are proposed for next year.
- We'll be working with Dr. Reagan and Dr. Walsh on plans for a committee retreat type meeting in September. And given the current state of public meetings and meeting in person. We'll likely be planning something that's via this technology. And probably not a full day, but we can talk about that and make plans for that. And those are the updates that I have. And thank you very, very much for your attention today and the great discussion on these comments that were received.
- DR. SHEILA REGE: Thank you. Go ahead.
- JOSH MORSE: When you're thinking about the retreat topics. You know the issue around having a psychiatrist and what that person would have said that might have changed our perception of the evidence. I think a review of the charge to the invited expert. And how we think about their input and the kinds of questions we ask of them. Would be a helpful thing, at least it will be helpful for me.
- DR. SHEILA REGE: So we'll discuss that at the retreat and Josh brings up a good point. If we have to, we have ideas for what the committee members want to bring up as a retreat. Can they send that to you and Brit?
- JOSH MORSE: Yes, of course.
- DR. CONOR KLEWENO: Yeah. This is Conor. I really agree with Mika on that comment on the expert. You know, for example, we may not have a clinical background to note the critiques within the subspecialty of certain articles that have been presented. We can look at

it from our eyes and the methodology of the study. But there may be some clinical relevance of something that. You know, although this study was designed well, actually, if you look at X, Y, and Z, which is clinically relevant. It makes the interpretation, you know, different. So, I just wanted to add that.

- DR. SHEILA REGE: That makes sense. Anything else otherwise, I'm going to actually, Josh is not aware of this. But I'm going to go around the room. I know there's a pandemic. Give me one word of your mood today. Or if you look around your desk one word to describe your desk. I am going to, last time I started with Laurie. This time I'm going to start with you Seth. Just one word. And I haven't thought of my word yet. I just thought of this.
- DR. SETH SCHWARTZ: "Busy".
- DR. SHEILA REGE: Mika?
- DR. MIKA SINANAN: "Imperfect."
- DR. SHEILA REGE: Kevin?
- DR. KEVIN WALSH: I'm going to go with "gratitude".
- DR. SHEILA REGE: Tony?
- DR. TONY YEN: I'm going to go to the opposite of Kevin. Mine's a little bit depressing.
- DR. SHEILA REGE: So Sheila? I'm actually thinking TGIF. Thank God it's Friday! Laurie?
- DR. LAURIE MISCHLEY: I'm going to go scattered.
- DR. SHEILA REGE: Conor?
- DR. CONOR KLEWENO: I'm going to also say busy. I also just wanted to thank everybody for welcoming me on the committee. It's a little bit difficult to get to know folks over zoom, as opposed to in person. And then it really appreciated everyone welcoming me on.
- DR. SHEILA REGE: OK. Thanks for being here Conor. Chris?
- DR. CHRIS HEARNE: I will say "slow".
- DR. SHEILA REGE: Janna?
- DR. JANNA FRIEDLY: "Flathead".
- DR. SHEILA REGE: John?
- DR. JOHN BRAMHALL: I'm going to say cluttered for both the desk and my mood.

DR. SHEILA REGE: Britt?

BRIT REDICK: Oh, I'll say "green" for my pants.

DR. SHEILA REGE: Christine? Christine must be muted. Josh?

JOSH MORSE: The word for me at the moment is "grace".

CHRISTINE MASTERS: I'm unmuted. My desk is described as "scenic".

DR. SHEILA REGE: Did we miss anybody who was on the call?

DR. MIKA SINANAN: Sheila, Mika. I just want to make a comment. If you look behind John on some of these talks. There's a dog in that sofa and other ones there's no dog. And so pay attention to the whether the dog is there. Because I think that alters John's mood.

DR. JOHN BRAMHALL: The question is, is he a virtual dog or is he a real dog?

DR. MIKA SINANAN: I don't know, comes and goes.

DR. SHEILA REGE: It's tough. Thank you for humoring all of us. Connor we look forward to meeting you in person. At some point.

I will take a motion to adjourn.

DR. SETH SCHWARTZ: So moved.

UNIDENTIFIED: Second.

DR. SHEILA REGE: Bye bye.

ALL: Bye everyone, have a good day.