Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Acupuncture for Chronic Migraine and Chronic Tension-type Headache

March 18, 2022

DISCLAIMER

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Sheila Rege: Good morning. It's 8:02 am, and welcome everybody, please know that this meeting is being recorded, and we have a fairly full agenda and but we hope to stay on time. First, we're going to approve minutes of both November 5th that I wasn't present at so if there's any questions, there, then I may have Janna who chaired that meeting um lead it and November, 19th and that was noninvasive cardiac imaging for coronary artery disease, stress ECHO, SPECT, PET, CCTA on November 5th and cardiac MRA on November 19th and will look for any comments and then approve that and then acupuncture, but before we get there, Melanie, can you call out on anybody who's missing so we make sure? Ah.

Melanie Golob: Yeah, he did do that. OK, I think I have too many windows open, there, we go. Ah, OK, so the only people I have missing from my list, uh Larry Birger and Chris Hearne, which I think Chris Hearne, let me know he was not going to be able to attend.

Sheila Rege: Great.

Melanie Golob: Not hearing any response.

Sheila Rege: Great then we'll assume everybody else is here as per the login and now Josh, we are ready for updates to the program. Thank you.

Josh Morse: Great thank you. And can you confirm that you're seeing this slide screen? Great OK, so welcome this is our March 18th, Health Technology Clinical Committee meeting. It's finding the right buttons here. And as you can tell if you're seeing this screen, you've successfully joined the webinar as stated already and I think as you saw in your entry screens, this meeting is being recorded. Couple different webinar controls we're

using teams at this meeting. We've previously used zoom so the functions are a little different and I think the most important thing is if you are attending only by phone, it is star 5 to raise your hand and star 6 to mute and unmute yourself and if you have any questions about the functionality, please let us know as we're as we're going here. I think another important note would be to try to keep yourself muted if there's any background noise where you are when you're not speaking, thank you. OK so here's another reminder the meeting is being recorded. We generate transcripts from these meetings and a transcript will be available on our website following the meeting. It takes as sometimes a few weeks to have those generated. When participating in discussions, please state your name and of course use your microphone. So, some background on this program, the Health Technology Assessment program is administered by the Washington State Health Care Authority. The program is designed to bring evidence reports to the Health Technology Clinical Committee to make coverage decisions for certain medical procedures and tests based on their evidence. The evidence of safety, efficacy or effectiveness and cost effectiveness. Multiple state agencies participate to identify the topics that are considered here, and those agencies include the Health Care Authority that manages the Uniform Medical Plan and Apple Health, the state's medical Medicaid program as well as the Department of Labor and Industries and at times, The Department of Corrections is participating as well. State agencies implement the determinations that result from this process within their existing statutory frameworks. The purpose is to ensure that medical treatments, devices and services that are paid for with state health care dollars are safe and proven to work. This program provides a resource for state agencies that purchase healthcare. It developed scientific evidence-based reports on the medical devices, procedures and tests for the Health Technology Clinical Committee and we support the HTCC to make these determinations for the selected devices procedures and tests based on the available evidence. There are many ways for people to participate. We have a Health Technology Assessment website on the Health Care Authority's webpage. Anyone may sign up to receive HTA program notifications via email using our Gov delivery system, which is a Listserv, people may provide comments on proposed topics key questions draft and final reports and draft decisions, and these are open public meetings, and anyone may attend the HTCC public meetings and present comments directly to the committee and we also have a nomination process people may nominate topics for review or for re-review. So, for public comment, attendees scheduled to provide public comment will be temporarily

assigned as a panelist or a presenter and provided the option to unmute and turn on their camera if desired and a pop-up window may ask you to rejoin the meeting as a panelist. Please limit your comments to 4 minutes when you are finished providing public comment your role will revert back to an attendee there will be a pause potentially in the meeting while you're rejoin. If not signed up in advance, please indicate your interest by providing a comment using the chat function prior to the comment period. The volume of signups will determine the available time for each person. We have 40 minutes reserved today for public comment and we ask that you please disclose any conflicts of interest prior to making a comment. Today's agenda is at the the new topic is acupuncture for chronic migraine and tension type headache. This is an update to the topic as it was previously reviewed and as you've seen on the agenda, we'll start with the previous meeting business and then move into the technology review, which will include the agency medical director's presentation, public comments, the evidence report presentation and then committee question and answers with the evidence report presenter and then discussion and decision discussions. After today's meeting, we will publish a draft determination if the committee makes one today. Draft determinations are then available for a 2-week comment period between now and the next time the committee meets and if there are any questions here's some contact information. That's our presentation this morning. Any questions for me?

Mika Sinanan: Josh, Mika Sinanan, you mentioned the Corrections, sometimes participates, is that at their discretion or is that legislated?

Josh Morse: Uh they, it's good question when they have availability and they have been extremely busy. They have not been participating in our weekly meetings, but we do stay in somewhat regular communication with their medical directors, and they do use the decisions from the committee, so we've had participation in the past from Corrections staff in our, basically, our weekly consultations on the program but again, they're availability has been limited due to the workload there. So, in the original legislation, Corrections was not named. In the original budget proviso, Corrections is named so they have they are not legislatively directed to use the determinations, but they can and that's a little complicated, but that's the way that it was done at the origin of the program.

Mika Sinanan: Thank you.

Josh Morse: You're welcome.

Sheila Rege: Any more questions for Josh? And I'm just as guilty, this is Sheila and if committee members could identify ourselves as we speak, so Sheila Rege. Uhm I'm looking at the chat box and Conor has said he's having trouble with mic. The committee members, our panelists and can speak, non committee members do have a time allocated during the public comment period. Conor, can we test out whether he is a panelist and whether he can speak?

Conor Kleweno: Yeah. Can you hear me now? I think when I first joined, I was, did not have access but I think it's since great OK.

Sheila Rege: We can hear and see you and it sounds like everybody else is good. So, moving on up to meeting minutes. Uh the November 5th meeting minutes and Janna, I was not present so I will have you lead the approval.

Janna Friedly: Do we have a motion to approve the minutes?

Mika Sinanan: So, moved, Mika Sinanan.

Janna Friedly: Right and the second?

John Bramhall: Yeah, second, John Bramhall.

Janna Friedly: Great and all those in favor of approval?

Mika Sinanan: Aye.

Tony Yen: Aye.

Conor Kleweno: Aye.

Clint Daniels: Aye.

Janna Friedly: Any opposed? Great we have approved the minutes.

Sheila Rege: Great moving on to November 19th. Uh or actually do we need a separate discussion on previous determination, Josh? From November 5th?

Josh Morse: That, that will follow unless you would like to do those first?

Sheila Rege: OK. So, we'll do both the meeting minutes will do the meeting minutes first and then we'll do the determinations. So, let's do a meeting approval of meeting minutes November 19th.

Janna Friedly: So, moved. This is Janna.

John Bramhall: Second. John.

Sheila Rege: Everybody in agreement say aye.

Mika Sinanan: Aye.

Janna Friedly: Aye.

Tony Yen: Aye.

Sheila Rege: Anybody who is not an agreement say nay. Any? Ok, now for previous determinations. Josh, can you let us know if we've had any comments? Or Melanie?

Josh Morse: Yes, so we'll start with the noninvasive cardiac imaging, this is from November 5th.

Sheila Rege: Correct.

Josh Morse: And you'll see so this is our normal document where we document the timeline of the review and when it was originally proposed and published all the way through to the meeting in November. We did receive one comment. See on here and the the the person who responded Lindsey Lemanski is from representing Regence. And just a reminder that this is the process that we go through when we finalize a coverage determination. The questions the committee is considering here is based on the comment, was evidence overlooked in the process that should be considered? And does the proposed finding decision document clearly convey the intended coverage determination based on the review and consideration of the evidence? This comment, as we've noted up here did not cite to evidence just as a reminder and then the comment is here in the attachments.

Sheila Rege: This is Sheila Rege, I'm sorry can, we zoom that for our screens, please?

Josh Morse: Of course.

Sheila Rege: So, it's a scope issue and it just says what what was not reviewed out of scope and Janna, this was from the November 5th meeting. So, it just is clarification that I can see but if you want to speak on this on behalf of the committee.

Janna Friedly: So, I think the the so the question is, are there any other any additional scope clarification missed I'm I'm not I'm not sure I quite understand? And um what the, what the meaning of this question is exactly? Uhm. Ah.

Sheila Rege: What I'm what I'm reading is that, uh Regence just wants clarification that asymptomatic individuals were, not, was out of scope.

Janna Friedly: Yes, so I I think that that's you know from from my from my perspective, that is true and um so, I'm I don't know if anyone else has any other thoughts about if there are other clarifications that we need to make in terms of the the scope.

Josh Morse: And staff have prepared a suggested implementation of this in a in the draft determination and I'm happy to share that when you're ready to see it if you'd like to.

Janna Friedly: I think that would be helpful if it would if it would help clarify to make sure that we are addressing this question about scope.

Sheila Rege: I will also take that up so there was one also on November 19th and we're looking at that together Josh.

Josh Morse: We were going to do that.

Sheila Rege: Separately, right.

Josh Morse: Next, separately. Yeah.

Sheila Rege: Right, that helps.

Josh Morse: So, this is the decision, and you'll see that what we've done. Based on this comment, we looked at that comment and prepared this draft for you, if it's helpful so the proposed edits here are highlighted no other changes were made. Uh. The comment does reflect a somewhat regular ask to the program about some decisions, which is what was in or out of scope. So, part of our deliberation, and thinking about this was to add key related documents with links so that people could could quickly find the scope as defined in the key questions and the final evidence report and then of course, the transcript, which is sometimes helpful and then these are the notes that reflect a comment and then review and discussion with the agency medical directors about those comments on scope issues.

Janna Friedly: This is Janna that that that wording seems to address the the issues from my perspective make it clear and it's consistent with a report.

Mika Sinanan: Josh? Mika Sinanan, the only issue that I would suggest is in in the first line out of scope slash. I would say data not reviewed for this decision rather than not reviewed to just to make it clear. Yeah.

Janna Friedly: Are there any other comments or concerns about this wording? [pause] Alright, so Josh do we need, do we need a motion to approve this? Uhm this draft as written then or?

Josh Morse: Yes, so considering this comment, if you're ready to move to this as the final findings and decision, I think you can just move to the final findings and decision as presented here. I think you just need consensus, verbal, as if from folks that this is what they're going to vote on.

Janna Friedly: Do we have? Everyone in favor of voting on this, this version as the final version say yay.

Laurie Mischley: Yay.

Tony Yen: Yay.

Conor Kleweno: Yay.

Christoph Lee: Sure.

Mika Sinanan: Yay.

Clint Daniels: Yay.

John Bramhall: Yay.

Larry Birger: Yay.

Janna Friedly: And any opposed? OK, great, so we'll we'll move on with with voting on this, this one is the final version.

Mika Sinanan: Motion to approve this as the final version, Mika Sinanan.

Larry Birger: Second it, Larry Birger

Janna Friedly: Second. OK all those in favor, say aye.

Mika Sinanan: Aye.

Laurie Mischley: Aye.

Larry Birger: Aye.

Conor Kleweno: Right.

Clint Daniels: Aye.

Tony Yen: Aye.

Janna Friedly: Any opposed?

John Bramhall: Aye.

Sheila Rege: And I will abstain because I wasn't there.

Janna Friedly: OK.

Josh Morse: Thank you.

Janna Friedly: Great. OK. That's an improvement right.

Josh Morse: So, is that 10 in favor, 10 abstained, Melanie, or one abstained?

Melanie Golob: Ah, there would be 9 in favor, one abstained, one absent.

Josh Morse: Thank you.

Sheila Rege: Thank you Janna. Josh, if you could just go to previous determination of them November 19th meeting on the cardiac MRA?

Josh Morse: And did you want to see the comment or you want to see the comment OK?

Sheila Rege: Yes, please if you see the comment and all these are included in the package so. Uhm. We we have, we have that in our package and again who was just for discussion who was this from?

Josh Morse: So yeah, I'll scroll through the previous meeting document here. So, this is the determination as it was published for comment and then we received. Here is the history of cardiac magnetic resonance imaging, one comment was received same individual. Again, the two final questions to consider and then this is the same comment document, but this is the portion here. For the November 19th meeting this is the comment and I'll bring up the suggested staff edit here separately when you're ready for it.

Sheila Rege: Any questions before we move to is just again a scope clarification, any if there's no questions in the next 10 seconds, we can move on to those staff recommendations.

Josh Morse: So, you should be seeing the cardiac magnetic resonance and resonance angiography decision with the proposed changes.

Sheila Rege: And we can take Dr. Sinanan's recommendation on the notes about data not reviewed if we want to stay consistent and it's just cardiac stress MRI because we just talked about MRAs. Uh I mean?

Mika Sinanan: Motion.

Sheila Rege: Yeah, thank you Dr. Sinanan.

Mika Sinanan: We could check.

Sheila Rege: Yeah, second.

Janna Friedly: Janna, second.

Sheila Rege: Any discussion or questions about this clarification that will be added to our final determination? If not everybody in favor say hey or I I.

Mika Sinanan: Aye.

John Bramhall: Aye.

Tony Yen: Aye.

Janna Friedly: Aye.

Sheila Rege: Anybody opposed? Anybody abstaining?

Larry Birger: I'm abstaining, I wasn't involved in that one, Larry Birger.

Sheila Rege: OK, thank you Larry. So, and we have no absences do you want to clarify our votes, Melanie?

Melanie Golob: Yeah, happy to. So, there were nine ayes or yes's with the CMRA final decision, one absent and one abstain.

Sheila Rege: So that would end our HTA previous meeting business and about 20 minutes ahead of time. If the agency representatives are available. Uh we would love to start the acupuncture of chronic migraine and chronic tension headache type headaches. Uhm our topic of discussion right away if everybody is good with that. Welcome, hi.

Emily Transue: Thank you. So good morning. I'm Emily Transue. I'm one of the medical directors at HCA and we'll be presenting today. Let me share my screen. Can you hear me OK?

Josh Morse: Yes.

Melanie Golob: Yes.

Laurie Mischley: Yep.

Emily Transue: Always the anxiety. Alright. Yeah, and are you seeing my screen now? OK, great, so I'm just gonna move this around so that I don't. So, they seem to be staring off wait one second. Hold on one second sorry.

Mika Sinanan: Sheila, Mika, our guests are here. Should we have the intro?

Sheila Rege: Right. That is a great idea. Yeah, thank you very much Dr. Sinanan in an in-person meeting, I always remember because they're new at the table, so I appreciate it. Uh if everybody is OK in the interest of time, we will not introduce the regular HTCC committee members but if we could introduce if we could have just a couple of minutes of your name, uh

you're uh your day job I guess so to speak or expertise, whether you have conflicts for our guests or actually our clinical experts who are committee members. Uhm. Dr. Lumiere can, we start with you?

Kathleen Lumiere: Yes, thanks happy to start yes and just I want to say thank you for inviting me to be at this at this group today. I'm very happy to answer your questions and help the committee in any way that I I may and also potentially all of the the people who are affected by chronic headaches and migraines in state of Washington, these were under your auspices. Uhm I am an associate professor at Bastyr and the clinician. I've been practicing acupuncture for over 20 years. And I have a a special interest in acupuncture research. So again, I look forward to your questions and thank you.

Sheila Rege: And no conflicts to declare with industry or any financial?

Kathleen Lumiere: No financial conflicts, I mean, I am an acupuncturist that.

Sheila Rege: Right well that's why that's why you're here, thank you.

Kathleen Lumiere: Yeah.

Sheila Rege: Or anybody else, Josh that we need to have introduced? Besides the regular the you know, Emily of course, we've seen you guys speak.

Josh Morse: From our technology assessment center, perhaps Erica can introduce. Erica Brodt is here, and I think Erica do you have Dr. Murinova with you today?

Erika Brodt: Yeah, she should be joining, I'm not sure if she's on yet. I think she was going to join about 8:30. Oh, there, she is.

Natalia Murinova: I'm I'm actually here. So yes, Natalia Murinova, I'm the director of the headache clinic at the University of Washington. So, welcome everybody so hopefully, it's a good meeting and happy to help in any way I can.

Sheila Rege: And no conflicts no financial conflicts to declare, correct?

Natalia Murinova: So, so the only thing I'm here with the vendor team, but I don't have any other conflicts of interest? Yeah.

Sheila Rege: Thank you.

Josh Morse: Dr. Murinova was the clinical expert when this topic was originally reviewed, and it included other modalities as well and we've narrowed the focus on this one to an update on acupuncture. Thank you Dr. Murinova for for being here with our contracted team today.

Sheila Rege: And just for process does any of our committee members, HTCC committee members have conflicts to declare? Or for us to be aware of as a committee?

Laurie Mischley: No.

Clint Daniels: This is Clint Daniels. I am trained in acupuncture but did not have any conflicts.

Sheila Rege: Thank you. Dr. Transue back to you. Thank you Dr. Sinanan again for the reminder.

Emily Transue: Perfect. Perfect.

Josh Morse: Yes, we're seeing the slides.

Emily Transue: Are you hearing in echo or is it just me? Are you hearing an echo or is it just me?

Melanie Golob: Yeah, I can hear it echo.

Laurie Mischley: I hear an echo.

Emily Transue: OK. Now can you hear?

Sheila Rege: Can everybody put themselves on mute if you are not speaking?

Josh Morse: I think the echo was resolved when everybody muted themselves.

Emily Transue: OK, good, yep that's all there. OK, good. Yep, that's all there. Can you hear me? Can you still hear me now?

Melanie Golob: Yes, we can.

Emily Transue: Or my muted now OK good alright thank you. I I feel as though I'm technology issues sort of the the icebreaker of the modern presentation. Thank you all for having me here today. It's always a pleasure to present to this group. As mentioned, I'm Emily Transue, one of the medical directors at the Health Care Authority. Yeah. We are here. That didn't do bear with it. Alright we are here today to talk about chronic headaches. Chronic headache, headache disorders are a leading cause of disability and diminished quality of life. They are a very common reason for patient visits in primary care neurology and emergency departments. While, intermittent headaches are extremely common chronic headaches, which are typically defined as 15 or more headache days per month are much less common. Chronic migraine and chronic tension headaches, each occur in about one to 2% of the population. However, they have an

extremely high impact or morbidity and quality of life for those affected. They're also extremely expensive, so medical costs of chronic migraine or estimated new around $8500 to $9500.00 a year and there's also a high impact on absenteeism and presenteeism for these conditions. The methodology of acupuncture things solid needles are inserted at specific acupuncture points. The placement and technique can vary between practitioners. These can be inserted in the arms, legs, back, head or face typically left in for about 10 or 20 minutes. There's also a technique of auricular acupuncture, which is a little bit distinct. It involves sites on the ear with dart-shaped needles that are left in for 2 to 5 days. I call that out because one of the studies today doesn't all that current color acupuncture, specifically. Electrical stimulation of the needles is sometimes but not always used. In terms of mechanism to traditional understanding of Medicine, Eastern Medicine. It's it, it adjusts the flow and balance of Qi or vital energy in the body. From a western perspective this may stimulate nerves muscles and connective tissue. It may also release endorphins and modulating a response. You suggest technique for headaches is pretty common about one in 10 people who are using acupuncture are using it for headache. As was mentioned earlier this was reviewed as part of the 2017 HTCC Review, which looked at a number of modalities for treatment of chronic headache that included botulinum toxin as well as acupuncture, and a number of other therapies massage trigger point injections etc. The outcome of that determination was that botulinum toxin was covered but all of the others were non covered and the rationale for the non-coverage of acupuncture at that time was with the evidence was not felt to be sufficient to justify coverage. This was selected for re-review today on the basis of newly available evidence as well as petition and public comment. The new evidence includes three new randomized, controlled trials evaluating chronic migraine. There were no new studies or chronic tension type, headache and no studies were identified for chronic daily headache. Looking at current state agency policy all of the state agencies follow the existing HTCC so for Uniform Medical Plan, which is our largest plan for the PEBB and SEBB programs. These are now known collectively as employee and retiree benefits or ERB, uh, as well as for Medicaid and Labor and Industries, this is non covered currently. Looking at acupuncture for any indication, so moving away from headaches, so Uniform Medical Plan covers up to 24 visits per calendar year for any indication, other than chronic headaches, so in general, this is on just covered but it's excluded because of HTCC for chronic headache. In Medicaid fee for service acupuncture is not covered currently. The Medicaid MCO 's are able to cover this at their discretion

and a few of them do. A new benefit for Medicaid for acupuncture was created in legislation just this year and that will begin in 2023 because this is brand new legislation, the specifics at that are not yet determined. Labor and Industries currently covers acupuncture for low back pain, only and then it's up to 10 visits per client. Looking at utilization for acupuncture for any headache indication, we suppressed numbers under 11 and numbers and Medicaid fee for service and L&I were too low to report. Uh we saw a very small amount of utilization in the Medicaid managed care organizations. A few dozen patients per year, receiving about 10 sessions each and then in UNP we had a few 100 members per year, averaging just a little under 20 visits each and that's been relatively steady over the last four years. The costs associated with that utilization in seen here looking at cost per member in purple and total costs at a program in red so we see an average about $300.00 for patient in Medicaid and roughly double that in Uniform Medical Plan.
The total cost to the programs collectively comes in a little over $100,000.00 annually on average over the last four years. Agency medical director concerns around this issue are low for safety, medium to high for efficacy and low to medium for cost. The key questions we will be familiar from the structure of our key questions generally and I will read them in detail but essentially, we're looking at the efficacy and effectiveness of this technique as well as the harms relative to comparators and then any evidence of differential impact on different populations and costs effectiveness. There are couple of data considerations that I think are particularly important around this topic. You will have noted that the literature around this topic is somewhat different from what you're used to, revealing in this committee. Many of the studies presented any evidence review or of low quality, according to the grade methodology. A few of them are moderate that many or low. Well, I think it's important to remember that funding for research on health technology in this country at this time tends to rely heavily on a for profit model with heavy investment by companies that stand to benefit financially from marketing expensive new technologies whether those are drugs and devices etc. There is some funding available for research into alternative therapies through the National Institutes of Health National Center for Complementary and Integrative Health, but those funds are limited so for example, in 2019, the NCCIH received a total of about 0.3% of the NH budget. This does impact the size and number of studies as well as design expertise and other issues. So, you will see that generally low quality of evidence in the studies reviewed, according to the grade methodology and just need to think about that in

the setting of this research environment. So, I think considering whether these lower ratings represent a systematic bias. It would skew the results of studies versus methodological flaws that might increase in certainty, but don't necessarily invalidate planning. These are a couple of slides from the evidence reviewer's presentation, and I won't review them in detail but I wanted to call out some trends in chronic migraines specifically, but we found particularly important in making our recommendation. So here you see treatment responders so folks who had at least a 50% reduction in mean headache days and what you see here circled in red is some variability, but across the board, a significant increase in responders in both the short term and the long term and these are really big reductions so 64% versus 15%, 81% versus 35, 30%, 15, so again, noting us low strength of evidence here. Here we see a similar assessment of looking now or reductions in headaches days per month. Again, there's variation, but almost across the board, a significant improvement when compared to other therapies and here we have some moderate strength of evidence. This is kind of the Grand Summary slide. Again, I won't go in this over this in detail, you'll get that later but for almost all of the outcomes studied in chronic migraine, there were improvements seen. Most of these outcomes are self-explanatory. The MIDAS test score is the migraine disability assessment, which looks at impact of migraine and quality of life. In terms of chronic tension type, headache, there was no new evidence that was identified since the prior review. All of the existing evidence was deemed to be of insufficient quality and pulled data on short term impact really didn't show any statistically significant difference from sham treatments. There was only one long term study that was identified and that stated that there was improvement, but actually didn't record any data from you. Looking at chronic daily headache, there was no evidence that was identified. Moving on to safety, there were no serious adverse events reported in any of the studies that were reviewed but these four are fairly small studies. Non serious events were generally lower than for comparator treatments such as botulinum toxin or Topamax. In general, the non-serious events were related to needle insertion, so things like tenderness, and bruising or occasionally presyncope. I think I would be in the presyncope. Because we had limited numbers in our review, I'm calling out here a 2021 meta-analysis on acupuncture for all indications that wasn't part of the evidence reviews since it doesn't apply specifically to migraine, but I thought it was useful. This analysis synthesized over 7000 studies from around the world and found a rate of serious adverse events at 8 per 1,000,000. Any adverse event requiring treatments with things

like infections was at 1 per 1000. Their summary statement on this was that acupuncture can be considered among safer treatments. Differential effectiveness that was really limited data on subgroups so one randomized, controlled trial, suggesting that those have more severe symptoms had more improvement with acupuncture, another suggesting those with higher baseline frequency showed greater improvement, but both of these were insufficient and there were no other pieces of evidence around differential impact. Looking at cost and cost effectiveness there was no new evidence since the prior review, data was very limited there are a couple of UK studies on acupuncture for chronic migraines, suggesting that it's cost effective so in the incremental cost effectiveness ratio of ICER are ranging from 800 to 12,000 pounds. That's roughly 1000 to $16,000.00 per quality adjusted life year, which is generally under the thresholds that are considered appropriate. I would note that that higher number assumed that general practitioners would be performing this procedure, which is probably not typical here. Of course, the generalizability of UK data to the US experience is limited. Holding out a few coverage comparisons, what are we seeing in terms of coverage elsewhere, Medicare has a national coverage decision that this is non covered the only place for Medicare covers on acupuncture currently is for low back pain. Aetna doesn't cover for chronic headache designed this headache for 12 more weeks, it's not covered, however, for tension headache. Cigna covers for both migraine and tension they apply general medical necessity standard. Kaiser covers for chronic headache with a self-referral up to a limited number of visits can be defined by each plan and then they have PA on this. Regence follows Evercore guidelines, and it's non covered for headache under them. That applies to their book of business as opposed to UMP which is administered by Regence. In terms of guidelines, you'll see these details in the evidence review but four of the five guidelines that were reviewed support use of this technology. See uh did VA and Department of Defense guideline is neither for nor against it. Pulling out the NICE guideline National Institute for Health and care excellence, which was updated in May of last year. They recommend considering a course of up to 10 sessions for tension type headaches and for migraine if standard treatments, including propranolol and topiramate or unsuitable or ineffective that this should be considered for up to 10 sessions over five to eight weeks, according to patient to on preferences and that current conditions. So, what is our recommendation from an agency medical director group perspective? Our recommendation around scope is at this apply to adults 18 and older 's and so since under the review and that this would supersede the 2017

decision only for acupuncture, otherwise of course, the 2017 decision would be unaffected. Our recommendation is that for chronic migraine acupuncture be a covered benefit with conditions and those would be first, that criteria for chronic migraine are met I.e., headache, occurring on 15 or more days a month or more than three months and that on at least eight of those days, they had like half the features of a migraine headache. There needs to be a referral from a qualified provider and that would be anyone qualified to diagnose according to Washington state standards. That includes MDs, PAs, etc., but would not enable soft referral and recommendation of coverage for up to 24 sessions over the course of 12 weeks. For chronic tension type headache and chronic daily headache our recommendation as that acupuncture being noncovered and the rationale for our recommendation and really, for chronic migraine, the evidence suggests a modest but significant benefit. The risks are low, and the costs are moderate or modest, particularly relative to the degree of disability and the expense of this condition. All the evidence quality of evidence is generally low, we feel that the evidence is adequate to make a coverage decision. I'll also called out; we use the 15-day definition for chronic headache that follows the International Classification of Headache Disorders. Our evidence review, I would note did allows that he's down to 12 days per month. For chronic tension type, headache and chronic daily headache, we recommend non coverage. We felt with chronic tension type headaches that the evidence was really insufficient quality and also what there is doesn't suggest a significant impact and for chronic daily headache, there was really no evidence available. Any questions for me?

Clint Daniels: I have a question. So, this is Clint Daniels. I'm curious a lot of the studies compared acupuncture to usual care, meaning physical therapy, topiramates, Botox are those covered items currently?

Emily Transue: They are. So, Botox is covered, according to the 2017 definitions, so it's got some conditions on it, but it is covered essentially in anyone who would meet these criteria. And then the other standard medical treatments are are absolutely covered.

Clint Daniels: And then I just second question, I think he said 24 visits over 12 weeks. Why the limit at 12 weeks, instead of say, 24 visits over you know 52 weeks or 'cause, it seemed some patients may prefer it spread out if the purpose is to prevent migraine just curious?

Emily Transue: Yeah, we looked at the typical courses that were covered in the studies that were reviewed and that was kind of that was where most of them

were there were there were one or two that were a bit longer but that was kind of generally where things down. That was the basis for that. If you can change, these if you choose to as a group of course.

Clint Daniels: Thank you.

Conor Kleweno: I've had it this is Conor Kleweno. I had a question on utilization. One of your early slides showed some numbers and it seemed to have a high variance as well as sort of a peak, maybe in 2017, perhaps and that was lower now. I just didn't know if you had any um data or explanation as to what that I think it was the next slide, in terms of dollars, yeah, and any comments on the variance there, whether it's negotiated reimbursements or utilization?

Emily Transue: So, I think, looking at the costs per, per member overtime they stay relatively studied they study it. First off, let's actually start with this slide. 'cause I would just call out how how really low these numbers are. So anytime there are tiny numbers, we're going to see a certain amount of variance, particularly on the Medicaid MCO side, really just a small handful of members involved. The drop from 2017 to 2018 and specifically in UNP I suspect reflects the implementation of the 2017 HTCC so we, we lost all the chronic headache patients here when that was implemented so I think that's the reason for this drop and then it's remained relatively steady. Since chronic headache is, is excluded, these are going to represent more folks with acute headache and so, the total numbers dropped and then I think looking here, you see a relatively steady in your costs per member overtime, but that drop in the total costs again, reflecting the total numbers, going down from 2017 to 2018. They do bounce around a fair bit and Medicaid but those are such small numbers that I think it's just it's hard to generalize.

John Bramhall: Emily I mean, I was impressed with the, this is John here, the, the, the low numbers like Conor has said, you know, I was under the impression that migraine in the communities are fairly common and these are pretty small numbers do you think that this is speculation on your part you think it it reflects a lack of a lack of a willingness for providers to, uh approve this therapy right at the very beginning so that relatively small number of people are applying?

Emily Transue: I think it's hard to tell when we've had relatively closed policies on this. I think that these numbers may reflect more our unwillingness to pay than anything else. The acupuncture benefit that I described for you, and he is actually relatively recent than the Medicaid MCO 's sort of approved this

on a, um really occasional, they don't have to cover it but every once in a while, they make an exception kind of basis. So, I think that these row numbers may reflect our policies more than they reflect tendencies and the community. Also yeah?

John Bramhall: OK, that's interesting thank you. Thank you.

Conor Kleweno: I had it at a second part to my question so I should have mentioned that I I sort of assumed that in the correspondence with 27, 2017 and, and your decision changed those numbers and so my question to you was with your on your slide of concerns about cost being modest does that include the prediction of you know, we would assume that those numbers would go back up and then increase with population increase, uh expectation so does the, the modest cost include that sort of a a financial predictive model or is it just based on utilization over the last few years?

Emily Transue: That's a great question. It's not based on utilization over the last few years. It's really based on the high medical utilization of this group of patients. These, these folks are using other therapies like Botox, that are expensive that are much more expensive than this with an estimated that kind of estimate of $8500 to $9500, a year average costs associated with these conditions. If this is even, even modestly effective it, it should it should balance itself out pretty well.

Conor Kleweno: Great thank you very much. Thank you very much, says it was helpful.

Emily Transue: Thanks for asking.

Christoph Lee: Hi Emily, this Christoph Lee I did have a question. Uhm, you mentioned the guidelines and NICE did covers a course of acupuncture for tension headaches and I know we're saying that the evidence is low for tension headaches and acupuncture, do you know what NICE is basing this recommendation on?

Emily Transue: That is a great question. I'm I do not, but I don't know if our evidence reviewers or expert has anything to offer on? That's great question.

Kathleen Lumiere: I can speculate that it might be based on the 2016 Cochran review of tension type, headache, which had recommendations for episodic and chronic headaches as well as the strong recommendation a strong recommendation from, from a VA study, but probably it's the 2016 Cochran report.

Erika Brodt: Yeah, this is Erika Brodt, vendor AAI, good morning, everyone. I I think she's correct we can, we can look this up. I can have one of my research

assistants attempt to, to look in a little more detail, but I believe it is primarily related to the Cochran Review. It's often cited for chronic tension headache, but again, it did include both episodic and chronic and did not make a distinction between the two.

Mika Sinanan: Emily, Mika Sinanan underlying the early part of your presentation around the cost and the prevalence of this is I think the suggestion that even though there are a number of treatments available, for some people, they don't work at all, or they work poorly and that they are casting around for some other alternative and acupuncture has come up as another alternative in a more holistic sense. Can you expand on that? I, I don't know a lot about headaches. I thank the good Lord that I don't have them very frequently but I can see people occasionally patients of mine who do, and it appears to be a very disabling thing for which they spend a lot of time and energy trying to fix them or to maintain their functionality despite them and this is also I think a helpful question for that our experts could address as well.

Emily Transue: Yeah, I think that is absolutely a correct um a correct assessment and, and perhaps our, our experts can speak to this better than I can, but, but again looking at that it's, it's one or 2% of the population who, who really has these on a chronic basis but for those who do they are very, very disabling, um. Speaking from experience of a number of patients that I've had in my in my practice, it's a, it's, it's as you say it's extremely hard to, to function with these may impact quality of life dramatically. They impact people 's ability to to work and function and we have a number of of treatments that work well for some people but there is that residual population in which they don't. Uhm. So yeah, I would I would agree. This is just uh, it's fortunately not wildly common but it has it has a huge impact and I think people sort of just try they try all the things that are out there and hopefully find a mix of things that that are able to work but in terms with more specifics on that I'm I'm happy to hand off to our experts.

Natalia Murinova: So, this is Natalia Murinova, so I can tell you that actually 50% of population is not diagnosed. Uhm why have now data on over 10,000 patients since 2015 because I keep all electronic, patients before as they see me, they have to prefill electronic paperwork and I can tell it 80% of patients we see have missed diagnosis of chronic migraine so majority of the people in primary care, miss chronic migraine diagnosis because the International Headache Society has just such complicated diagnostic criteria. There's over 300 different types of headaches and it has changed

to where now since 2005 they changed the card criteria to be arbitrarily as 15 headache days per month but that includes both tension type, and migraine type headache and it I think it's just really difficult for most primary care providers to be able to correctly differentiate the episodic from chronic migraine. So, we see 80% of patients coming to our clinic have new diagnosis of chronic migraine. Majority of the patients, though what they have is medication overuse headache and if you have that nothing works. Neither acupuncture nor Botox, no nothing else and if we don't address the medication overuse piece. We can debate all other available treatment, I can tell you from clinical experience, this makes the headaches, extremely refractory and once you address medication overuse, all of a sudden many treatments become very available and become very effective. So, this is something that we have to deal with in state of Washington decide how do we address that crisis. As far as treatments, you know we don't recommend, or we don't refer right now for acupuncture for chronic migraine to patients have Medicaid because we know that it's not covered. It's as simple as that so you know, we don't bang our heads so if something is not covered you know, we don't prescribe it and so talking to underutilization. If we approve it, you're going to have many more patients and it's not 1% of population. Current estimates more 5% or higher have chronic migraine because total migraine is about 16 to 20% of population and it's a where they talk about billion people in the world problem. That's at least 1,000,000 people in Washington and out of those if you think about it, at least 5 to 10% of people will have chronic migraine. So, it's much, much higher numbers than anyone here estimates and as everybody is totally pointed out, we don't really have effective treatments. Exactly what Dr. Sinanan said is one treatment does not work for everybody, most of these people are very desperate, they're very disabled and they're reaching for anything that could help and for many people, they're very interested in alternative treatments, about a third of my patients would prefer non medication treatments and so they reached a naturopath, they treat to acupuncture, as many pay for it out of pocket because that that's just not covered. So, you can ask me any question. More than happy because this is what I do all day long. So, I'm more than happy to help any of my patients and answer any questions.

Sheila Rege: That was very helpful Dr. Murinova because yeah, we, we need the expertise. I'm just going to remind everybody that it is 9:00 o'clock, which is time for the public comment, and we will be continuing discussion on this as as we keep on the evidence report. If everybody is OK, uh can, we

hold questions until we open up the lines for public comments, please. And as Josh said it is anybody on a phone into the star 5 to raise your hand star 6 to mute or unmute. I believe correct Josh? On teams?

Josh Morse: That's correct we were notified we had one uh individual who notified us in advance and we will elevate that person, to be able to speak here momentarily. If anybody else is on the line who would like to make a comment, if you could please put that in the chat function, the little bubble at the top that says show conversation. You can add a let us know if you are not already in the presentation mode that you would like to comment, and Charis Wolf is the one who notified us about providing a comment. Charis, can you hear me?

Charis Wolf: Yes. Yes, I can, can you hear me?

Josh Morse: Yes, we can.

Charis Wolf: Excellent I can.

Melanie Golob: I would just reminder to please disclose any conflicts of interest as well, and you have four minutes. Thank you.

Charis Wolf: Thank you. My name is Charis Wolf I am a doctor of acupuncture in eastern medicine, and I practice Washington state. I've been a practitioner for about 20 years I used to be the president of our State Association. I am also now on the national board and on the Research Committee for the American Society of acupuncturists. Myself and Mark Sauders submitted um the research for this review and I wanted to thank everyone very much for doing the review. Uh I appreciate your support for the medicine, and I also wanted to offer that we did submit a few tension type uh research papers and they were not considered so if anyone is interested in getting those again and they didn't see that initial, initial list of research. This goes beyond the Cochrane review as well. I'm happy to send them into people and and just on a personal level, I wanted to share my experiences and treating migraines and headaches. I myself was a migraine person and got relief through acupuncture, I don't get them anymore. My mother used to have them really badly it does seem like they do kind of carry on in families and echo that sentiment that overmedication does play a role in this and one of the things that acupuncture has been helpful for is actually helping people wean off of medication as well. This is something that studies haven't been done on, but my personal experience has been rather successful with this. Uhm other than that, um trying to think, Risk Assessment, yeah. Uh you guys touched on everything else that I wanted to make sure everyone knew

that it, yeah, that I'm was very happy to see that Medicaid is going to start covering acupuncture, as well, so we will wait to see what they cover and other than that. Yeah, thank you again for the review and if anyone is interested in those other studies that did not get included in this, they were quite good quality research studies, so I want to make sure that you guys have access to all the information that we shared and that's it. Thank you.

Melanie Golob: Great thank you so much for providing, providing your comment. We really appreciate it. At this time, are there any others who wish to provide public comments, if so, please use the raise hand function if you're in the application, just click the raise hand button, if not, press star 5 if you're on the phone. So, we'll give that just little bit longer to see if anyone else has public comments they want to provide. OK, I see one hand raised. So, allow your mic so go ahead and unmute yourself using star 6 and then state your name and any conflict conflicts of interest you might have and then you will have 4 minutes, go ahead.

Leslie Emerick: Hello this is Leslie Emerick. I'm the director of public policy for the Washington Acupuncture in Eastern Medicine Association and I just wanted to say as I understand that you folks as always, in fact that Medicaid will now be covering acupuncture, and chiropractic and very excited that this population is now going to have access to this benefit and I also want to point out that one of the things that happen from the 2017 review is that we were denied access to the Labor and Industries as well so there is a large population that hasn't had access to acupuncture for migraine headaches that I think potentially could if things go well with this review so thank you for the opportunity to present today and thank you for the participants so I appreciate it.

Melanie Golob: OK great thank you. Were there any others who wanted to provide public comment at this time? Please use the raise hand function. OK and I think we had someone just join uh just reminder if you wanted to provide public comment, please use the raise hand feature and, and you'll be able to unmute yourself. OK, seeing no takers, then Dr. Rege, pass, it back to you.

Sheila Rege: OK and our public comment uh is from 9:00 AM to 9:40, so if anybody comes in or then just stop us and we'll we'll you know accept that because I know everybody 's a bit busy on their schedule and, and maybe counting on coming in right at 9:30 or something. Uh.

Mika Sinanan: Sheila, Mika Sinanan. Both speakers alluded to the fact that Medicaid was going to support this. I think they're misreading the recommendation from Emily as a recommendation it's not uh, it's not determined yet, right Emily? I just want to be sure that this that the people who are listening in are not assuming that your recommendation is already happened.

Emily Transue: Correct. The the um bill around acupuncture, just instructed Medicaid to develop a benefit around acupuncture, with no justification on what it would be for or how how much et cetera. So, I think the assumption, first off, they would absolutely be starting out, you know your your coverage decision would be the basis for anything around headaches and and that that bill might only apply to for example, max function for low back pain or or other established conditions so there's not, it's not about headaches, just to be clear.

Sheila Rege: Josh would you like to clarify as well, I saw a raised hand?

Josh Morse: Uh Dr. Transue covered it. There is a budget proviso, I'll just add a little bit more detail. There's a budget proviso that directed us to develop the implementation plan for acupuncture and adult chiropractic. Those two, kind of went together this past session and it's not funded for coverage of acupuncture and chiropractic in the next, in the coming in the this budget cycle the intention is I understand this budget proviso is for us to be prepared and hopefully in the next budget cycle, it's then funded going forward, but it's not funded to cover the services in the next in this next budget year, starting July 1st. But we will work on the implementation plan so that we're ready for it.

Larry Birger: Hi Larry Birger here. I'm not exactly sure the right time to ask this question, I'll throw it out. You can redirect it to another time, but I would like to know it occurs to me uh that any modality that can remove subsequent use of pharmaceuticals in whole or in part has a unique downstream effect that pharmaceutical interventions don't. Uh you know, we see this all the time, particularly in hospital medicine, how many patients have GI bleeds related to NSAID use, renal impairment due to NSAID use, and other medications and so forth and I'm wondering has there been any sort of formal and high quality even semi quantitative analysis of that with acupuncture uh in this case in particular? 'Because like that's a that's a huge relevance in terms of cost as well, you know as well as other health implications.

Emily Transue: I don't have an answer to that, but I suspect others on the line so I might defer.

Sheila Rege: Conor you had your hand raised was that in response to this question? Or I see Dr. Lumiere.

Conor Kleweno: No, I have another question, so I'll let the guests answer that.

Sheila Rege: OK, Dr. Lumiere were you answering this question.

Kathleen Lumiere: Yes, yes, thank you Larry for your question. Uh there are, uh my analysis ah that that that clearly show a decrease in opioid use associated with acupuncture and those findings were submitted to the Legislature, which were and and approved by the by the governor in a white paper. Which I I'm sure that I can, I can get to this committee. Dr. Transue brought up in native considerations, some of the inherent limitations of, of I'm a modality that doesn't have a lot of profit behind it. These studies tend to be lumped together as as Dr. Brodt mentioned instead of having each condition separate and and study there just isn't enough funding or person power for that so it's so it's not as tidy, but but there but there is an association.

Larry Birger: But in those analysis, thank you for that information. In those analysis of decreased opioid use for example, which is another great example of of potential downstream benefit, uh haves have there been any attempts to try and quantify that like the the reduced use of NSAIDS or the reduce use of opiates has resulted in a uh approximated cost savings of XY or Z because there are fewer downstream, morbidities related to them?

Kathleen Lumiere: Yeah, that's an excellent question. Uhm. I'm thinking of a of a a cost uh of a cost effectiveness paper by by Wit at all that came out of Germany. I think it was 2007, 2008, that did show a reduction in cost but not specific to what you're mentioning, uhm. Yeah, the literature is kind of slender but there but there but there but there are some sort of, there are indicators that point, the right direction as far as this being. Having those beneficial downstream effects. And I wish I could give you a more. A comprehensive answer, but that's that's what it's all what I know.

Larry Birger: OK, thank you. I do think that's a point that in general in these discussions, not just for us, but more broadly, it needs to be considered, not just the immediate context of efficacy at the individual patient but you know, especially since in my field, I am seeing the effects of medications all the time and so one something that may appear to have not as much potency for an individual, you know numerically, may have quite a bit more savings down the road than than meets the eye.

Kathleen Lumiere: Thank you so much for bringing up that incredibly important point.

Sheila Rege: Yeah, thank you Dr. Birger and I am going to ask the discretion of our agency staff. I I know we're in the public comment and I don't know if I see two raised hands. Conor, I know you have another question from the public one has spoken, so I don't know if this, if what the process would be and I'm gonna let Melanie and Josh help guide me here.

Melanie Golob: Perfect I was just asking that as well. I would think since we're in the public comment portion of the meeting. Let's give preference to those wanting provide public comment and then we can move back to the committee a little bit later, if that's OK.

Sheila Rege: Right and we should maybe let who's not spoken speak as anybody, not spoken. I'll let you guide me there.

Melanie Golob: Perfect. OK, great, yeah, it looks like Sharonne O'Shea uhm, I will go ahead and allow your mic and camera so uh if you want to go ahead and unmute yourself and uh stating conflicts of interest you might have and you'll have four minutes to speak thank you. OK and we can see you just go ahead and unmute. K. There we go I go ahead and try now.

Sharonne O'Shea: Thank you can you hear me?

Melanie Golob: Yeah, we can.

Sharonne O'Shea: My name is Sharonne O'Shea and I suppose my conflict of interest is that I am an acupuncturist and I have actually a question for the committee rather than maybe a comment or any evidence to provide you may be aware that this is my first time attending the meeting thank you. Uh so I am somewhat unfamiliar with the process and my question is a more general one. In terms of modalities and items that do not have a proven mechanism of action, such as acupuncture, and Tylenol, are they required and under what basis are they required to demonstrate body part by body part there affect efficacy? Can we say that we know that Tylenol is an analgesic, and it would work on a variety of body parts. Can we say that we know acupuncture has analgesic properties and it would work on a variety of parts, or do we need to have peer reviewed placebo controlled double blind studies for every body part that we would like to use acupuncture on? So that's my question not understanding the background of how you all operate thank you.

Sheila Rege: I'll look for an agency medical director to help but the way I as a clinician think about things and maybe this stems from you brought up analgesics, Opioid they were, you know it gets approved for a certain indication everything else is off label. Ah and so I tend to really focus on kind of that

and the evidence, but I don't know if any of the agency medical directors or our staff, Josh or Melanie can tell us what our guidelines or guardrails are for the committee.

Emily Transue: I don’t, or Laurie go ahead.

Laurie Mischley: Well, I I don't think it's guidelines for the committee that I want to respond to that with but to address that I really appreciate that question because from a we're speaking two different languages. From a Chinese medicine perspective, there is no difference between you know it. That's in your arbitrary distinction between two types of stuff chi along a certain meridian. You're applying the conventional paradigms slicing and dicing and labeling to the acupuncture 's realm, and they're looking at you like what are you talking about like it. Chi is stuck it's stuck, let me free it and the question was an elegant comment so.

Emily Transue: So, I'll take a stab and others can speak to things as well. I think I think in a way, there are two pieces to that one of them is about mechanism and the other is about, uhm, about kind of body parts and location and, of course, they're interlaced. I I would say I think fundamentally mechanism, gonna go out on a limb here representing my own opinions. Maybe doesn't need to see medical records but I think mechanism is irrelevant if something works, it works and if it doesn't work, it doesn't work, and what we're looking for is evidence of of efficacy and I would call out that when I was in medical school, we thought we knew mechanisms for all kinds of things that have turned out to be incorrect, so even when we think we know and mechanism doesn't mean more right. So, I think really what we're looking for is that that kind of bottom line of does this work. We do have, we do frame our questions around certain conditions, and you can argue about whether that's appropriate but I think this, this conversation is around acupuncture for these particular indications and and so I think the the standard that we're looking at is really does evidence support that for people who had these conditions, it I, ultimately works or doesn't and again, I I think you elegantly expressed said that can be problematic, but but that I would say is the standard that we use. I’ll let others comment.

Melanie Golob: Ok great and if everyone is ok with that, we’ll go back to public comments and I know Charis Wolf had her hand raised and I know hasn’t used all four minutes, so I'm fine with, with going back to her all.

Josh Morse: Did Dr. Yen want to respond to the question, right? Saw that he raised his hands?

Melanie Golob: Oh yes. Thanks, Josh.

Tony Yen: I actually did and Connor, I don't know, do you want to go ahead 'cause you actually had your hand raised before me?

Conor Kleweno: My my question is, is to sort of separate so I would be happy to defer that to a later time. I tell if I'm going to continue this discussion.

Tony Yen: Yeah, from my perspective, I think you know as a committee our our charge is really to use the evidence that we have before us to make these decisions and so I think perhaps we're talking about a variety of different sort of things we're talking about mechanism of action with acupuncture on the other hand, we're talking also process of how we actually make decisions within the committee and I believe that our charge within the committee is actually to use evidence that we actually have the with the best quality evidence to make these decisions, sometimes that evidence is actually fairly narrow in scope. But then again again, I think are charged as a committee and I'm I'm willing to be corrected by the medical directors or by Josh is that our charge really is to use the evidence to make the best possible decision for the the people Washington state.

Larry Birger: Larry Birger, here if I might interject. I didn't, I understood the original question to be more along the lines of kind of teasing out proof of proof or explanation of mechanism as opposed to efficacy so I thought the earlier answer, uhm, was I guess how I would look at it. I I don't in the long run, I don't think it makes any difference what the mechanism of action is if we prove that the the use of XY or Z in this context causes you know desirable outcome 123 in this sort of. Uh maybe you know of this sort of magnitude and then what is the evidence for that. I I see our task as being just how compelling is the evidence for this particular outcome and how costly? Or lack of you know, or inexpensive is that intervention and particularly with regard to patient important outcomes is the NIH has put it where it's not a matter of surrogate markers, but you know things that affect as any NIH defined it how we feel how we function or how long we live, I know hopefully.

Sheila Rege: Uhm. That helped a lot and and Sharonne, maybe instead of debating it here and not allowing some of the public comments, maybe we can and and Laurie actually you, you kind of clarified something that I had thought of where you know you, said it's it's different but Eastern Medicine thinking. Maybe we should put this on as a, it's debating it here as a strategic retreat topic and debate it, give it time and debate, it or we can continue. I I don't know, maybe Charis Wolf is talking about the same

thing, and I see committee members. I just, I want Charis to have her time and I see John you have your hand raised too. But it's it's a, it's a crux. I think of it, it's a good question that I frankly had not thought about I just use my cancer lens on it. Uh Laurie, what would you like to do as a committee member and who has expertise in this?

Laurie Mischley: I I'm not an acupuncturist and I actually have some questions about delivery of this intervention, like is this something that is not just for treatment, I'm in pain, help me now but also prevention? And I don't know how chi gets cleared and I don't know if this is something that you go in you get your initial package and you're good to go for the rest of your life or is this once a year, someone goes in for a reboot or you know they start paying out of pocket if the headaches come back later in the year? I mean, I just don't know how this intervention is delivered and if I get, how you set up a study and you strategically set the study out to optimize the best possible outcome. You take the most strongly affected people and deliver the intervention in a way that you think that's going to work for this study results you hope to get but that's different than what clinicians do in clinic to optimize benefit and I don't know I I have some questions to the acupuncturist in the room about how insurance aside, you had a patient with some sort of chronic headache or migraine. What is the delivery dose you would get recommend in an ideal world?

Sheila Rege: And and maybe it since this is still public comment time and I, I we only have 12 minutes. We should debate that as a committee, but let's see if anybody in the audience who may have more expertise wants to raise their hand because and publicly comment is that OK, Melanie? I don't want this to turn into an internal committee discussion cherished side, so if you just look on who's who wants to comment and answer any of these questions and help us.

Melanie Golob: Yeah, that.

Larry Birger: But could I fire out one more question for clarification? Larry Birger again, I'm wondering if the original question from our acupuncturist colleague, that kind of set off this most recent discussion, was that really flowing from a broader concern of kind of a philosophical clash. You know if if those coming from a more eastern perspective are having to prove something within the confines of a Western paradigm. I mean that's kind of how I took the the gist of the question. Correct me if I'm wrong, but it seems to me, that's where the emphasis on outcomes as opposed to mechanisms or you know philosophes of anthropology or whatever come into play.

Sheila Rege: Right and I'll have committee members just because you know, I kind of want to keep this. Let's have committee members raise hands that they wanna speak. Larry, I think that maybe a discussion for a strategic retreat. I I hear that's the question, but let's go to the, uhm attendees not the panelists.

Melanie Golob: OK, great, yeah, thank you and I will ask Charis Wolf, if you'd like to speak again, go ahead and unmute yourself and you will have I believe two more minutes.

Charis Wolf: OK, I will go quickly. First of all, I want to say that this discussion is very exciting for me. I'm very glad that you're having it. This is an ongoing discussion that we have is acupuncturist have as we try and translate our medicine into bio medical terminology as accurately as we possibly can. One of the things too that speaks to this directly in the form of research is actually the work that PCORI is doing, the Patient Centered Outcomes Research Institute, they have been funding a good amount of acupuncture studies and wanting to disseminate them. As we are, you know, kind of pushing the boundaries of research with our medicine, we are looking more at systems-based research so that you can take multiple factors into account at once when you're doing the research and part of the way that we are doing this that integrates so well with biomedicine is when we get into the health care system. This is why it's getting it to health into Medicare and Medicaid actually is so exciting for us because we will then be able to see the real effects that our medicine has for patients over their whole health and that is really what we are looking forward to, so I wanted to make a comment back to the original one that I think was from Larry about reducing pharmaceuticals and how much of an impact acupuncture has. So those kind of once we get those that kind of EHR model data, we can track that at, and it will really show the benefits of this kind of integrated care, and I know that other people want to speak so I don't want to take too much but yeah, thank you so much for having this conversation. I look forward to hearing more about it. Thank you so much.

Melanie Golob: Great thank you so much. Uhm, so before we move on to any comments, I just want to, since we only have a few minutes left in our public comment time, take a moment to see if there are any others who wanted to provide public comment and just as a reminder, please use the raise hand function or if you're on the phone select star 5 to raise your hand and provide public comment. So, I'll pause just a moment to see if there are any others. OK, not seeing any, Dr. Rege back to you.

Sheila Rege: Does the original person who asked us the challenging question that prompted this really good discussion, uh, want because she didn't use her full four minutes and I know she said it was her first time is she still on and would she like to come say anything more?

Melanie Golob: I don't believe she's still on.

Sheila Rege: Alright.

Kathleen Lumiere: I see I see her name in the participant list so, Sharonne O'Shea, but….

Sharonne O'Shea: Hi. Uh I I'm glad that I generated some conversation that was my intention in asking the question. It was not my intention, though, that it would take from the public comment period so by all means, if you feel it's appropriate to table this to another time, please do so and, and just a quick response to Dr. Mischley's questions, I put in the comments, the chat, but I'm not sure that everyone saw that. The short unsatisfactory answer is it depends on the diagnosis. So how it's delivered and what prognosis you would expect and whether people would be expected to come back would, in my opinion depend on the diagnosis, the Chinese diagnosis for why they were having the headaches in the first place so not a short easy answer for you.

Laurie Mischley: Do you think you could give like a 10 second for for people who don't know what you're talking about when you say a Chinese diagnosis? Can you just give the other committee members who have no training in eastern medicine a sample of what two different diagnoses might look like?

Sharonne O'Shea: Sure, uhm, the, the first two things that come to my mind are a liver yang rising or a phlegm obstruction. So, liver yang rising would be in very vague, quick terms, too much stuff going up to your head and you're getting a headache. We will see that oftentimes with people who also have hypertension for example. Uh phlegm obstruction would be kind of what it sounds like but not necessarily. Phlegm has a more broad encompassing definition, then I think most of us think of it as you know, we get a cold and we had more mucus that is phlegm, but there are other things as well so. Uh I had a a patient who is experiencing a lot of Vertigo because she had too much phlegm in her head. Those are very different processes from an eastern medicine perspective and would have similar in terms of we would be using the items within our scope of practice herbs, needles, etc. but the points that I would select the herbs that would be appropriate, those would all be different, and some of it's going to depend on for example, the patient with a lot of phlegm do they insist

on continuing to consume copious amounts of dairy products. That's going to also impact the success of their treatment for phlegm, and I would also be happy to defer to any of my other acupuncture colleagues who feel like I have omitted something critical in this explanation.

Laurie Mischley: That was super helpful thank you.

Kathleen Lumiere: Thank you so much, uhm, Sharonne, they yeah, they are just the just the diagnostics for headaches are very complex. We don't have 300 types of different headaches, but we've got we've got easily 9 and, and probably in many more interventions than just acupuncture that are part of the medicine. It's a, it's an internally consistent, uhm, logical diagnostic system.

Sheila Rege: Why while we're in the public comment I would welcome input from attendees as well as you know clinical experts will be able to discuss this, later on, the question raised by one of the committee members about, uh, you know 12 weeks versus dispersed over the entire year kind of giving the flexibility, uhm, I any anybody from the public who wants to speak to, to, what would what it's accept you know what is more beneficial for our patients, I would welcome that input.

Josh Morse: And while waiting Dr. Rege, if I could make a comment. Dr. Fotinos had her hand raised, but she needed to leave. She just asked me to convey some information about Medicaid and our rule's structure around medical necessity and the fact that when we determine what can and can't be covered in Medicaid and this is separate from the process at the HTCC is applying but it is similar. It is based on an evidence hierarchy so the evidence hierarchy that we have in our Medicaid rule structure requires that there's evidence pointing to health outcomes and then we evaluate based on the quality of the evidence that's available on so Dr. Fotinos, just wanted me to make that comment. It is a an important I guess administrative and procedural definition around medical necessity and how it's determined especially for the Medicaid program.

Sheila Rege: Will Dr. Fotinos be able to come in afterwards, uhm, during the evidence committee question and answer session, in uh at 10:50 if you will message her? I I feel bad that I was trying to give the public, but I would like to go back to the public just because this is as, as has been mentioned, and, and being of Indian origin, I understand Asian you know, kind of the Chinese way of thinking or the Asian way of thinking versus the western way of thinking so I wanna make sure we, we've heard that.

If not, then I will let Conor, who's been very patient ask his question in case there may be input from the public too.

Conor Kleweno: Uh yeah great. Thank you and I I do think that there's a lot of comments made that would be relevant discussion from the committee of their time. My question was perhaps either to Emily or the content experts, could you provide a little information on the regulations and licensure of providers you know that would submit a claim for acupuncture, who adjudicates that that's a sort of an appropriate facility and appropriate provider to submit that claim? Obviously, I'm less familiar with acupuncture than sort of the traditional hospitals and clinics. So just a kind of a question, if we're paying for it. Just want a little bit more information on who adjudicates the licensure and and of those providers.

Kathleen Lumiere: Sure, I can answer that. A licensed acupuncturist who are not an MD's or nurse practitioners or in some cases, PTs have between two and 4000 and sometimes as much as 7000 hours of training, which translates from like three to six years of training on top of an undergraduate degree. In addition, they sit for national board exams, so they're credentialed by a national agency and in order to sit for these national board exams, they have to have gotten their training at an accredited school and all of the all of the the, the schools have have a, a regular medical accrediting body. uh, which regularly goes through curriculum and and education and outcomes. The in order to qualify for an insurance panel, uh each provider of acupuncture would have to be credentialed with that panel, so it's a similar it's a similar process as for MDs. Does that answer your question or is there more?

Conor Kleweno: Uh I think that answers the question of of your experience with the licensure of an accreditation of acupuncturist. Emily is that the only providers that the state will recognize or are there providers that may not have that, uh background eligible for claim submission such as providers in you know, predominantly East Asian communities that provide this service that may not have that same sort of experience and background?

Emily Transue: I muted, um certainly in order to be reimbursed from an insurance perspective, somebody would have to have um appropriate licensure with the scope of practice that included this so, yeah, I I think you can be confident that from that, reimbursement would only happen with people who have that training.

Conor Kleweno: Ok.

Sheila Rege: I'm going to allow Charis Wolf; I will give you one minute to you put in the chat provider equivalency law and Sharonne and I believe your question about raise hand feature gone was before you made a comment if not, please raise your hand. I'm going to as chair give you one minute each because we as committee members took away some time. Thank you.

Charis Wolf: Okay, hi yes, so am I, I'm a little confused about what you're asking. Legally who has the ability to say to treat headache in their scope could treat a headache or are you asking who specifically can perform acupuncture in the state of Washington?

Conor Kleweno: My question was who will the HCA recognized and reimburse claims for in the state of Washington for these services and who, who provides the licensure or what? What body does that?

Charis Wolf: Ok. So currently there are two main practitioner bodies. There are MD 's who are medical acupuncturists, and they generally take a 300-hour, Helms course on top of their obvious medical training so they are, you know it's within their scope to do acupuncture and they take the additional training. There is a board exam for medical acupuncturist, but to mine the best of my knowledge, which is actually from the president of their association, it is not required that they pass their board exam but it you know it looks favorable for them to do so and in the state of Washington, the other main body of practitioners and there are over 1300 of us, 1600 of us now in the state of Washington are licensed acupuncturists. The nurses have declared that acupuncture is within their scope, but they have not established an accredited education for that quite yet. They are working on that. They have been in touch with medical acupuncturists as well but as far as I know that has not been completely formalized quite yet. They haven't advisory opinion out if you wanted to check that out. PTs can dry needling to this date is not allowed in Washington state so the main people practicing would be licensed acupuncture 's and MD 's doing medical acupuncture.

Emily Transue: From the State Department of Health determines scope of title.

Sheila Rege: Thank you over time and we are going in. Emily go ahead.

Emily Transue: It's just the State Department of Health establishes kind of scope of practice for each profession and what training is required for that and.

Sheila Rege: Go ahead.

Emily Transue: Ah. Yeah, sorry go ahead.

Sheila Rege: Wow, uh there was a 360 and I'm just going in because I we, we got into the public comment time that had a hand raised who is 360.

Leslie Emerick: Hi this is Leslie Emerick. I just wanted to say in the person finally said it, uh after subscription licensed by the Department of Health, they have an acupuncture and Eastern Medicine Advisory committee that assists with Department of Health, they have a program manager, they have their own AG that sits in in these meetings and their profession, uh is supervised disciplinary is tasks if they're secretary profession under the Department of Health.

Sheila Rege: Thank you. I don't see anybody in the public comment. I would like to start a break, will only be 5 minutes, in one minute, so Clint, you have one minute.

Clint Daniels: Great thank you. I just set up a quick question. There was a a state recommendation for this to require referral is that how acupuncture is, is handled currently for the other conditions for the non-migraine, do they have to have an MD or NP, PA referral or can patients self-refer currently?

Kathleen Lumiere: For most insurance coverage, patients can self-refer.

Clint Daniels: And then what about the state covered items? Is that the same?

Emily Transue: Uh it varies, um, I know that for massage and number of other things that I believe that for acupuncture under UMP, there does need to be a referral but let me, not 100% sure on that, so we can, we can find that out.

Clint Daniels: Great.

Sheila Rege: Yeah, you could find that out before, before I discussion Emily, that would be helpful. I am going to break, and it is only going to be 5 minutes because I would like to come back to the evidence report and get us back on time at 9:50 because I I am aware that people have meetings right after, so 5-minute break only, I am sorry. Great discussion. Thank you. Bye. If we are all back. Uhm.

Mika Sinanan: Sheila, Mika, I'm just gonna tell you I'm gonna have to double my dose of Flomax if you keep having 5-minute breaks.

Sheila Rege: Alright, so we're just trying to get done on time because I sense we're going to have a lot of time. I had to run to come. Let us go ahead with the evidence report.

Erika Brodt: Seeing my slide.

Sheila Rege: Josh, Melanie maybe, maybe I should have done a 10-minute break.

Erika Brodt: I don't know why I'm not seeing my slide let's see.

Sheila Rege: Thank you Erica, we can see you.

Erika Brodt: OK let's see. I'm sorry, let's see here.

Sheila Rege: And for everybody following on PDF it's page 38.

Erika Brodt: Let's see can everyone see my slides without, without the notes and everything?

Melanie Golob: I think we're seeing with the notes.

Sheila Rege: Uh we see the notes also.

Laurie Mischley: I see the notes at everything.

Erika Brodt: OK let's see here. So. I'm sorry about this. Let's see. This worked the other time. Let's see. The last slide show view see here. Let's see how's that?

Melanie Golob: There we go perfect.

Erika Brodt: Alright sorry about that OK. Alright so my name is Erica Brodt on behalf of Aggregate Analytics, I'm going to be presenting the results of our health technology assessment on acupuncture for chronic migraine and chronic tension type headache and I'd like to just take a minute to acknowledge my colleagues who assisted. So, I'll try to go briefly through a few of these earlier slides since it's been touched on in detail but as has already been discussed the 2017 report included a variety of treatments for chronic headaches. One of which was acupuncture, and at the time a no coverage determination was made since then we have additional evidence that prompted a review of acupuncture only. Otherwise, the scope of the review has remained the same. So again, um Emily did a great job with some of the background but as we know worldwide headache disorders are the second leading cause of years lost to disability. The prevalence and burden of self-reported migraine and severe headache and the US adult population is high affecting roughly 16% of US adults and while chronic headaches are less common, although probably more common than we've listed here, according to our experts. They do have a huge impact on a person 's quality of life, uhm absenteeism that that kind of thing. In general, management of

primary headache is divided into pharmacological and non-pharmacological approaches acupuncture being one of the latter, uhm, that is possible that possibility and while pharmacological treatment is a mainstay of usual care on non-pharmacological approaches are key and very important for patients with chronic migraine who are medication refractory or patients who can't take side effect or can't take medications due to side effects or other medical concerns and additionally as I think has been mentioned people are prefer a lot of people prefer non drug options. So having that available to people for chronic headaches prevention is the focus. So, so some brief background on headache classification, so they're broadly divided into primary and secondary. A primary headache has no known underlying cause so the headache itself is the main problem and migraine and tension type headache are the most common primary headaches and as we know are the focus of this review. Secondary headaches are caused by another condition that triggers pain sensitive areas in the neck and head and we've mentioned, and we'll talk a little more about medication overuse headache, but that would be an example of a secondary headache. Frequency headaches can be classified as chronic. Current definition state 15 days or more per month or 180 days or more per year and episodic is 14 days or fewer per month, again our focus here is on the chronic headache and for the diagnosis of primary headaches, you look at a combination of clinical history, headache diaries and of course, you exclude causes for secondary headache. So, a little bit of background on chronic migraine and tension type headaches and their characteristics so they have different underlying mechanisms and presentations. Migraine is a headache that can cause severe throbbing pain or a pulsing sensation usually on one side of the head. It's often accompanied by nausea, vomiting and extreme sensitivity to light and sound. About one third are associated with aura and attacks are typically moderate to severe and intensity and can last anywhere from four to 72 hours. Chronic tension type headache on the other hand, is characterized by a dull non pulsating pain tightness or pressure generally around the forehead or back of the head and neck and intensity is mild to moderate, and these headaches can last anywhere from 30 minutes to several days. I'd like to point out as well, third headache type that we did look for and was part of our inclusion criteria but found no evidence for in either the prior report or this report and that is chronic daily headache and for the purpose of this report, we classified studies of patients presenting with the coexistence of migraine and tension type, headache in combination that occurred 15 days per more as month, 15 days or more per month. This is not listed as an

official classification, but it's what was used in the prior report with clinical expert input. So again, I'll try to go quickly here because we've touched on some of this background, but acupuncture is part of traditional Chinese medicine that has been around for thousands of years. It's performed by placing needles and specific locations sometimes called Acupoints on a patient skin to achieve a therapeutic effect. In eastern philosophy, the focus again is on activating and balancing chi which is understood as a vital energy source in humans. The needles or solid filiform needles that are thin and flexible and as has been mentioned they can be manually or electrically stimulated so told by hand would be manual or not stimulated at all. Treatment ranges from individualized to standardized and currently there's no FDA guidance on acupuncture as an intervention itself, although several different types of needles have received FDA approval, however, they really just state that the needles need to be sterile nontoxic, labeled as single use and used quote, appropriately by licensed practitioners. Uh acupuncture is commonly used, again, like Dr. Transue said in headache disorders. About 10% of patients who have mentioned using acupuncture have used it to treat headaches. So, our key questions are standard and ask what is the evidence of the short- and long-term efficacy and effectiveness, harms and complications, differential efficacy effectiveness or safety, and cost effectiveness of acupuncture, compared with other treatment options? So, our inclusion criteria again, I want to point out that the population is specifically chronic headache, chronic migraine, chronic tension type, and chronic daily headache was looked at. I wanna take a minute to talk about our definition of chronic. So, the kind of agreed upon definition currently is 15 days or more per month for at least three months, according to the ICHD and uh in the prior report, we did include studies that had a mean of that included patients with the mean of at least 12 headache days or episodes or attacks per month and that's because in the prior report, there were many older studies included and they used some various definitions and time frames and we wanted to be as inclusive as possible, while still trying to stay true to the chronic criteria and we understand that this might you know play some a bit into the relevance of how this is defined today. So again, our only acupuncture and interests or sorry our only intervention of interest is acupuncture, and the comparators are listed there. We included RCT 's as previously and publications had to be full length studies published in English in peer reviewed journals. Our primary outcomes, which were prioritized via clinical expert input are listed here for efficacy. It primarily relates to some kind of reduction in the number of headache days as well as

function and disability. Adverse events are always a primary outcome and then of course, we have cost effectiveness. I've listed here our definitions for follow up, short, intermediate term and longer term. So, these are all post treatment in order to see the lasting effect of acupuncture after the treatment is ended. So, strength of evidence is based on age our QS recommendations in our application of grade which I think you were all fairly familiar with at this point. We grade the overall strength of evidence separately for each primary outcome using the domain shown here. So RCTs started high and then the baseline quality of evidence can be downgraded based on concerns around risk of bias, which is based on the individual study, consistency and directness and imprecision across the studies providing evidence again for a specific outcome. For publication bias reporting bias, it's difficult to assess, especially with so few studies so it remains unknown. So, to briefly go over our systematic review process again, we first screen studies for eligibility criteria against our priority inclusion exclusion criteria. Then we look at risk of bias for each studies and each of the individual studies in order to determine the quality and then we provide an overall strength of evidence determination across each primary outcome, uh of high, moderate, low or insufficient, which just talks about how confident we are that the effect we're seeing is true. So, our literature search ran from July 2016 through the middle of November of last year and as has been discussed we identified 3 new RCTs that met our inclusion criteria all in chronic migraine. So, in total, including studies from the 2017 HTA and those from this review, we have nine RCT 's, five in chronic migraine and four in chronic tension type headache. So, this slide just provides an overview by headache type of the studies for each type of comparison. So, for chronic migraine we have three RCTs, two new that compared acupuncture with usual care essentially as well as sham. We have two that compared acupuncture with pharmacologic treatment and one that compared acupuncture with botulinum toxin. There was one, one new, it's just the same study with three Rs for those last two comparisons. Uh for chronic tension type headache again, no new studies were identified and, and the and the previous report, we did look at the results we evaluated him for accuracy and made edits accordingly for consistency with this updated review. There were two RCT 's comparing acupuncture versus sham, one RCT comparing acupuncture with physical training or exercise as well as relaxation, it's another three-arm trial and one comparing acupuncture with physiotherapy, which included a variety of different modalities. So, before I jump into the results, I just wanted to provide a quick overview of the primary outcomes reported by the studies. Again,

these were prioritized via clinical expert input in the prior reports and there are different ways of measuring headache frequency, but most of the studies did focus on the number of headache days or episodes and the change in the frequency of those. We did attempt to look for minimally clinically important differences for all these measures. The prior report used three days, which came from one of the included RCT 's of Botox actually and we did find a newer study that cited four days may be clinically important but again, there are different methods of deriving minimally clinically important differences and you know it's unclear to what extent some of this is, is applicable to the population under study. So, the headache index and a headache score, those are not validated instruments. They were just used by the specific study to measure headache frequency or intensity and for function and disability, those are both validated measures, the MIDAS, the migraine disability assessment, is, is a very common measure and then the SIP, sickness impact profile. Are there any questions before I move on to key question one? OK, great, so for key question one we're looking at the efficacy and effectiveness starting with migraine and these next two slides are going to present some key characteristics across the studies and I just want to point a few of them out. So, this is for acupuncture versus Sham and usual care. Most patients were females in their 40s, approaching 40 in one study. Patient had migraines ranging from 12 to 16 days per month and we'll talk more, I know it's been mentioned medication overuse but in most of these studies, it was either not reported or it wasn't exclusion criteria as here in Vickers. Prior acupuncture patients could not have had prior acupuncture prior to entering the study, or they could not have had it within 6 to 12 months generally. So, the type of acupuncture used in two of these studies was your, traditional Chinese medicine needle acupuncture. Number of treatment sessions in those two studies varied from 12 to 14 across 12 weeks. The study in the middle Habibabadi, which is our one study comparing with a sham, which in this case they used adhesive tape on inactive points of the ears, so this is our uh auricular acupuncture trial, uh they only had two treatment sessions two weeks apart. Again, because these are semi-permanent, kind tack like needles that stay in the ear, and I believe it was about four points. They, they chose the most the four most active points, so co-interventions as well. I want to point out that everybody could continue to take their rescue medication, and, in some cases, patients were prescribed pharmacological treatment, so we don't know the impact that had on the results. So, across our two studies, comparing acupuncture with either pharmacological treatment or botulinum toxin A. So, Yang, the first one here versus topiramate. Little

more similar to the ones we just saw previously primarily female in their upper 40s. Across both of these studies, you can see that the mean number of migraine days per month is much higher ranging from 21 to almost 24 days per month and in Naderinabi, we have a little more of an even, uhm distribution of females and slightly younger patients in this trial. Medication overuse, so this has been this was discussed and I'm sure will come up again, but Yang did have in 3/4 of the population, they did have medication overuse headache and again, we don't know how this you know may have affected the outcomes that we see with this study. So, they define medication overuse as the intake of simple analgesics on more than 15 days per month or the intake of a combination of analgesics opioids or triptans on more than 10 days per month. Um, so I just want to point that out, as we get into the results, the other study excluded medication overuse headache. Again, prior acupuncture patients were not allowed to have had it or within a certain timeframe. Both studies use traditional Chinese medicine with fixed and classic acupuncture points. These, bit higher number of treatment sessions. Here, 24 to 30 over 8 to 12 weeks and again patients could receive medications during the treatment period but in general, I do want to point out, patients were asked to keep whatever medication, they were on a steady and not change anything but few to none of the studies ask patients to completely stop their medications. So, moving on to the results. The next couple slides will be looking at treatment responders or the proportion of patients meeting a specific cutoff for improvement and first let me orient you to how we've organized the plots. So, they're organized by short term, follow up, and then long term follow up and within each of those categories, the studies are listed by earliest to latest follow up and we also have a column for the comparator so you can see what acupuncture is being compared to. So, as you can see from the plot, more acupuncture patients achieved at least a 50% reduction in the mean number of any headache days per month compared with active controls over both the short and the long term. These were considered large effects at both time points. The strength of evidence was low at short term and moderate at long term. Again, Yang is the study that had the high number of patients with medication overuse headache, and I'd also like to point out that Vickers 2004, which will come up, uhm in many places they continued to receive accurate well, a few slight number of patients continued to receive acupuncture after the treatment ended and you know again, we're not sure how that might have of impacted results. Similarly, on this plot, we can see that more acupuncture patients experienced at least a 50% reduction in the number of moderate to

severe intensity headaches over the short term, which at that point we had a large effect in one study compared with topiramate and also at long term smaller effects, compared with Vic sorry compared with the usual care and both of these have low strength of evidence. So, one RCT compared acupuncture with usual care over the longer term, and again found that acupuncture resulted in a greater proportion of patients achieving 50% or more reduction in this time, we're talking mild intensity headaches and a greater than 35% improvement in headache score. Uh strength of evidence was low, and these were considered moderate small to moderate effects. Again, the headaches score was not a validated instrument. So, we're switching now from treatment responders which is a proportion of patients to a mean reduction in headache frequency. So, acupuncture was associated with a greater reduction in the number of headache days per month and pooled estimates across comparators and time points and the results may be clinically significant. Strength of evidence was low at short term and moderate at long term. I would like to point out, we did a few sensitivity analysis. Heterogeneity at both time points was fairly low actually considering what we see in other instances. However, we did exclude the arm looking at sodium valproate at short term since it was a bit of an outlier. Acupuncture stayed statistically favored, although the estimate did attenuate a bit too -2.2. The heterogeneity was completely reduced, however. Uh we also did a sensitivity analysis, pooling just the 2 trials evaluating pharmacologic therapy and of course this resulted in a much larger effect favoring acupuncture of -4.1, but increase the heterogeneity up to 80%, maybe due to the different pharmacological treatments used as well as the follow up periods. So long term, we also did a sensitivity analysis, pooling only the trials evaluating usual care essentially. Again, resulted in a somewhat attenuated estimate that still in favor of acupuncture. That estimate was -2.37 with no heterogeneity. So again, we kind of looked at things a variety of ways and no matter which way we looked acupuncture was superior to the alternate treatments. So, acupuncture was again associated with a greater reduction in the number of moderate to severe headache days per month compared with active controls over the short and the long term and strength of evidence was low at both time points and again, the clinical significance of, of some of these is a little bit unclear. So, one trial again reported the mean reduction in mild headache days per month, finding that acupuncture was favored compared with usual care over the long term, it's low strength of evidence. For mean reduction in headache episodes or attacks per month and this was defined in one of the trials, trial versus usual care waitlisting

usual care as attacks were separated by an entire 24-hour period of freedom from headache as recommended by the guidelines for controlled trials of drug and migraine and the second study did not define what an episode or attack was. The one study versus waitlist found no difference between groups in headache episodes or attacks long term that was low strength of evidence and in the second trial, compared with sham and usual care, the evidence was insufficient to draw conclusions. The study was not well done and had a lot of imprecision. So, disability our last primary outcome, we will be talking about for chronic migraine was measured using the migraine disability assessment. It assesses how severely migraines affect a patient's life that includes questions about frequency and duration of headache as well as whether it affects patients' ability to go to work, day at school or do things around the home. So, acupuncture was associated with a greater reduction in the mean might as score at short term, uhm and but not at long term so its short term is compared to Topiramate, and long term compared with usual care. Strength of evidence was low at both time points and the difference may be clinically important here, it's a pretty large difference. We were unable to find a minimally clinically important difference for this outcome in our population. So, this slide shows a variety of secondary outcomes reported by each of the studies. Again, we don't do strength of evidence on secondary outcomes, but you know, I felt it was important to provide a little bit of overview of these so as you can see with the exception of the two outcomes listed at the bottom there, loss of working days, or social activities and resource use which is visits to doctors essentially, acupuncture was associated with greater improvement versus the alternative comparators in a variety of secondary outcomes considered so such as VAS pain scores, quality of life. We've talked a little bit about medication use previously in our discussions and that that is another outcome that acupuncture did perform better, better on. So, are there any questions on the migraine data before I move onto chronic tension type headache?

Larry Birger: Hi Larry Birger here. Are we supposed to just jump in with questions or when you ask that, do we have to put up the hand function?

Sheila Rege: You know that's a good question Larry and I'm wondering if in the interests of everybody having time, if we could start raising hands and I'm going to let you go first this time because you did jump in and ask and then Tony, you'll be next. Thank you.

Larry Birger: I just had a quick question it, it really stood out to me that there was not a decrease in function and disability but there was a decreased, significantly like a large decrease in number of headaches, headache days and so forth. Was there any discussion, as to what appears to me to be a discrepancy? Because when I was in clinic practice that was a really good way, I thought, that they taught us to distinguish in chronic pain cases or other cases where you know, is it keeping you from work that kind of thing it was a real more objective marker for, uhm severity and improvement.

Erika Brodt: So, or I'm sorry to clarify are you talking about the secondary outcomes here?

Larry Birger: Uh.

Erika Brodt: At the bottom or are you talking about the disability here?

Larry Birger: Correct yeah, no no, the sheet the one that you just had right before this.

Erika Brodt: OK, secondary outcomes.

Larry Birger: Right there. Yeah, no difference in loss of working days, or social activities. Uh and yet we have all this evidence suggesting that there's a you know great big reduction in the amount of headaches essentially.

Erika Brodt: Yeah, I I don't have a good explanation for why, why that might be. Again, these are secondary outcomes, so they didn't play into our strength of evidence. You know one of them was short term, so only eight weeks that I don't know how you know probably can't, I don't know how well you could judge loss of working days over a short time span, we did have two that look longer term, however, yeah, I don't I don't have a good explanation.

Natalia Murinova: I can, I can comment a little bit on this so usually if people have more than four let's say seizures per month, that's considered very disabling for most people, if they have more than let's say seven headache days per month, the most works will not accept you full time because you're just missing way too much work so if the acupuncture in some of the studies, let's say with Vickers, they decreased by 1.8 days per four weeks. You know, so if you go let's say from.15 days per month to decrease it by two to let's say 13 or 12, it's still not enough to get you to having decreased it enough to where you can then be able to function or work. So, I think that's the discrepancy, so the headache days per month have to be significantly. That's how basically look at least at least 50% reduction to make it a very dramatic, but again, it differs for where did you start from

maybe started with 30 days per month and a decrease it by two, you still have 28 days per month mean they're pretty much having headaches every day. If you start with someone who has 12 headache days per month any decrease it by two or three, but again what, what the studies don't show some people would be found in studies. 1/3 of the patients are usually super responders, 1/3 of the people are medium responders and 1/3 are non-responders and so whenever you put all the data together and aggregate it, decreases that ability to see that some people might go from having daily headache to no headaches and some people will stay the same and some people will improve just slightly.

Erika Brodt: Thank you. That was very helpful.

Sheila Rege: Tony is next.

Tony Yen: So, I actually had the exact same question as Larry and thank you for answering it.

Erika Brodt: Great.

Sheila Rege: Janna is next.

Janna Friedly: I I just as a follow up the, the MIDAS, my understanding is, is a you know a, a disability functional measure, but does measure missed school and work and productivity and, and household work. So, there, there, it, it may also reflect just the outcome measure that's used that perhaps that's a better measure of, of looking at that then whatever those secondary measures were, were using. I don't know what scales were used on the ones that didn't show benefit but just to mention that the MIDAS is is measuring the same thing and that did show some effect.

Erika Brodt: Great thank you.

Sheila Rege: Clint, Clint you're next.

Clint Daniels: Alright, thanks I just wanted to clarify on the, the long term, so that's after all treatments withdrawn, correct? So, so the reduced, it's really showing lack of lasting effect as opposed to a plateau effect?

Erika Brodt: Correct. Sure, sure I think that's probably accurate you know, and again if people are going to be getting you know, maybe depending on what the coverage is more than you know, one treatment round of this, you might see something different, yeah.

Clint Daniels: Thank you.

Erika Brodt: OK great, any anything else?

Natalia Murinova: I was just wanted to point out again people can Google but MIDAS, being normal or do not have disability, you have to below 5, so we find that majority of the people with chronic migraines have often severe disability like score 21 plus, you know, so unless we get below 5, you're not normalizing in your disability.

Erika Brodt: Yeah, and yeah, these patients were definitely above 21. So. Yep. Alright any other questions on chronic migraine, which I think is where most of the conversation will be around? OK, great, so moving on to chronic tension type, headache. Again, I wanna reiterate that we found no new trials that met our inclusion criteria after our update search and so we did reevaluate for accuracy, the studies included previously and made edits for consistency with this updated review. So, I'll spend just a minute again going over some population characteristics for the two studies, comparing acupuncture versus sham and I've listed what the sham treatments were here, they were different, one, it didn't actually insert a needle, but just simulated uh puncturing sensation while the other did insert needles but into non acupoints as they call it. So, the studies did differ in the distribution of females and males as well as age. The number of headache days or attacks per month range from 16 up to 28 per month. Medication overuse again was either not reported or in the case of Karst, I believe they excluded rebound analgesic headache syndrome, which I think is what medication over another term for medication overuse or was used previously and this is an older study. Ah, both types of acupuncture were traditional Chinese medicine and they used about 15 to 10 to 15 needles, ah, about 8 to 10 treatment sessions over 5 to 8 weeks. It's a little different than the migraine studies and again analgesics and rescue medications were allowed. So, our other two studies compared acupuncture with active controls either physiotherapy or physical training or relaxation training. As you can see the chronic tension type headaches are all a bit older studies. They're not as well reported, and patients were primarily female in these studies about mid, mid 30s. Prior acupuncture wasn't reported, medication overuse was not reported in one study, but Soderberg did exclude patients who used analgesics or tryptamine greater than 10 days per month. So perhaps patients with medication overuse for excluded or weeded out in that study, it's unclear. The number of treatment sessions for acupuncture rate was variable ranged from anywhere in one study from 4 to 10 sessions. The other study 10 to 12 sessions over two days, weeks and 8 to 12 weeks and again, co-interventions were poorly described in these trials. So only

one RCT which compared acupuncture with sham, this is the needling and non-acupuncture points, reported on treatment responders that is the proportion of patients achieving greater than 33% as well as greater than 50% improvement from baseline on the headache index and although the proportion of patients that experienced improvement here was greater with acupuncture, the difference did not reach statistical significance and that's likely because this was a very small RCT. There were 15 patients in each arm, so they likely did not have enough patients to find a difference and the strength of evidence for this was insufficient. So, we're talking again about a mean reduction in headache episodes, so I mean change in baseline in episodes per month, both at short term across two small RCT 's look at moderately high risk of bias and at long term in one small RCT, there was no difference between groups in the reduction in headache episodes, strength of evidence for both time points was insufficient. So, moving on now to active comparators, we have one RCT that compared acupuncture versus physical training and versus relaxation and across both outcomes, headache free days per week and headache free periods per week, there was no difference between acupuncture and either group at any time point. This is one small RCT at moderately high risk of bias and given the ranges is there, you can see, there's a lot of imprecision so this was rated insufficient. Our second study comparing acupuncture versus physiotherapy, this time over the short to intermediate term, uh, provided very little data. They made statements saying that frequency of headache was reduced, or aspects of the sickness impact profile were better with acupuncture but did not provide data to support these statements so the date, the conclusions are insufficient. So secondary outcomes again for chronic tension type headache for acupuncture versus sham, the only secondary outcome found to be significant favoring acupuncture was a pressure point threshold and this is the minimum force applied which induces pain and honestly the clinical significance of that is really unclear. Otherwise, there was no difference between groups in any of the other outcomes looked at such as VAS headache intensity analgesic consumption or headache index again, not a validated instrument. For acupuncture versus active comparators looking at quality of life and headache intensity scores, the results were very mixed. Again, we didn't do strength of evidence on secondary outcomes. This is just to provide more information. So, are there any questions on chronic tension headache before I move on to safety?

Mika Sinanan: Hi Mika Sinanan, I did have a question on your slide 27 as much a observation. I find that the comparators in these two studies and they're older studies, the sham seems to be a cleaner sham, I mean, it, it uh. I know they're not the same. One is a simulated puncture and the other one is a puncture, but in a non-acupoint site but it, it seems that it as, as compared to usual care or other modes of treatment, uhm, it seemed to be a cleaner comparison, as to whether or not there was a benefit do you have any comments about why these there were these choices of sham for these studies and not for any of the migraine studies? Any idea?

Erika Brodt: I I don't I don't have any idea why that might.

Kathleen Lumiere: I, I could. Sorry, this is a Kathleen Lumiere, the acupuncturist. I, I might be able to answer that question. Sham has fallen out of a favor as a as a research method in acupuncture because it's been well demonstrated that it's a, it's not inactive, it's not inert so it, it is, it's not the, it's not a very good comparator.

Mika Sinanan: Ok and then uh on the 1992 Tavola study, patients were not in a narcotic or analgesics, but were they were then narcotic analgesics withdrawn from them? In other words, were some of the patients on narcotics and they stopped it to become participants in the study in which case they might have a benefit from the medication withdrawal? Do you know?

Erika Brodt: Yeah, go ahead.

Natalia Murinova: So, from what I saw, uh Mika in most of the studies, they exclude patients you know who are on opioids you know for these studies.

Mika Sinanan: But do they accept patients who stopped narcotics to become members of the study, or would anybody do that?

Natalia Murinova: There are no there are no comments on that I've looked at that because it's an area of interest for me, I didn't see but I mean, we can certainly look into that, but I did not see any comments on that.

Mika Sinanan: I mean, the reason I ask that is obviously if medication overuse is you commented earlier as a big part of this, and they withdraw the medications from a large number that might flatten the differences between the treatment and the sham groups and artificially create a different outcome.

Natalia Murinova: Where did my husband told me he just referred someone for acupuncture that the acupuncture is with first refused the patient because they were on opioids and meeting more than 90 because the

acupuncturist told them that it's not effective, you know if you have opioids, you know on board certain level. So maybe our acupuncture, experts you know could comment you know on that.

Kathleen Lumiere: Thank you, yeah, I would love to speak to that. Uh, I supervise in the acute pain service at Harborview or doctoral students who do their rotations, and we treat people who are heavily medicated with opioids a lot. I mean, it does reduce the effectiveness of certain interventions that rely on the MU and Delta opioid receptor sites, but, but there's still a breakthrough effect that can be quite dramatic and we have data on that and uh I, I if if ,if you if that's if that, acute pain service is relevant to your discussion, I'd be happy to talk more about it, but it, it acupuncture is associated with, uh down, a lessening of the use of opioids. It's an approved nonpharmacological intervention in a lot of instances, um so I would say that it's, uh not contraindicated.

Mika Sinanan: Thanks so just a brief follow up question to that regard. Of, of patients who are refusing referred for acupuncture for say these reasons for headache, what proportion decline it because they simply don't believe in the efficacy, do we have any idea?

Natalia Murinova: We usually don't recommend it to patients who are not interested you know, so I think that that's one of the key things that we have done for years is trying to align ourselves with patients beliefs and patients preferences so if we recommend that as an option, if people say no I don't like needles or you know, no it's something I don't believe in you know, I wouldn't go you know recommend. So, about a 1/3 of our patients, we have looked at that out of the 10,000 prefer non medication only options uh at either been so then that will you know include you know currently in headache the big thing is neural modulation devices you know so that's another alternative along with biofeedback cognitive behavioral therapy and acupuncture belongs to the non-medication things that can be used as well.

Mika Sinanan: Thank you. The reason I asked about that, it was the was the issue of the placebo component is certainly going to be stronger and those who believe in the technology, thank you.

Sheila Rege: I would encourage, I would encourage committee members who want to ask questions to do the raise hand because they are like Conor been raised his hand, so you should raise hand if you want to speak in the future everybody, Conor?

Conor Kleweno: Yeah, no worries. I just had the same comment question that Mika did about the sham, sir or not to say surgery, I'm a surgeon, so I would say sham surgery, but this the sham component of comparison. I, I agree that I find that to be a much cleaner comparison and I just I, I think our guest had a comment that there is a uh it's not inert which is actually something I would expect when we talk about placebo effect and, and confounding variables of belief so I, I just wonder if that expert could comment a little bit more for us as we interpret these studies appreciate that, thank you.

Kathleen Lumiere: Yeah, thank you so much for asking. So, there's been a rousing debate in the profession for a long time about sham and the different types of sham. There was, but there's been sham with toothpicks and strike burger needles and um suggestion Capchuck and his team at Harvard have done some really interesting work about, about the placebo a placebo effect. Um, anecdotally, I asked him at a conference once why do you call it the placebo effect instead of mind body medicine and he said, so I can get funding because it's what we're what we're, what we're thinking about what we're looking at is, it is a much bigger question, which is what effect does the mind have on the body and, and I think that in itself is, is, is a, is a is a great line of inquiry. As far as sham in acupuncture goes, this this what the what the committee is looking at right now. Uhm there, they're a varieties of acupuncture that use low or no insertion techniques, Japanese acupuncture, which has been around since the 9th century, and is used by quite a few people. Uhm some types of Korean acupuncture, he's very minimal insertion styles at different points and those, those appear to be quite clinically effective as well as in deeper insertion styles, which are largely Chinese in origin, and produce a do chi effect or oh that which means, oh that's it like, oh, I've got it, that's that's that's the point. Um, so I would say that that's why the profession as a whole has moved away from sham. These are these are older RCT 's uhm as I mentioned early early on just briefly, the Cochrane report included are some newer RCT 's that weren't included for this analysis because it was episodic and chronic headaches together. Uh seven RCT 's in total, four of them, which were mixed. So unfortunately, that's not you don't you don't have those data, uhm, and, and in some of those, uh have, have the, have the the, the new the newer models the newer research models. Uh weightless controls are, are the probably the most common. I'm not sure if that answered your question, but

Conor Kleweno: I, I, I think uh it did address my question, and, and probably I can table the follow up comments until further on in our, our agenda. Thank you very much.

Kathleen Lumiere: Happy to, my pleasure.

Sheila Rege: Alright, Laurie, thank you for raising your hand.

Laurie Mischley: I will also table the conversation until later.

Sheila Rege: Okay back to you, I see no more questions.

Erika Brodt: Ok, thank you and I'm sorry, was there question? Ok and just to circle back to the very first question and to speak to the evidence in this report, I did look up and it's already been mentioned, I looked at whether its studies ask people to stop medications and no they did not but a couple did mention that they had to keep it consistent they couldn't make any major changes to medications and to Tavola specifically did not make people get off their medications but they had to agree to abstain from all other therapies. So, ok so starting again with key question two and safety. So, beginning with migraine and a serious adverse events as you can see, they were very low across two trials. That's all we had that reported either any serious adverse event, not otherwise specified or death, there were no occurrences of either of those as far as adverse events leading to treatment withdrawal. Again, we have some small numbers here primarily and as you can see to topiramate, did result in a bit of an increase in adverse events which I think is to be expected, with some of these drugs, but again without, without understanding what constitutes a serious adverse event as reported by these studies as well as how rare some of them might be. It's unclear if we had sufficient sample size to detect things like death or serious adverse events, so the evidence was considered insufficient. So, regarding any non-serious adverse event for chronic migraine, we do have low strength of evidence that acupuncture has less of a risk of non-serious adverse events over both the long and short and long term across two RCT 's. There's also a third RCT that reported something similar but didn't really give comparative data, but you could infer that adverse events were less with acupuncture, most adverse events that did occur were mild and self-limiting and as was stated I believe by Dr. Transue, primarily related to local insertion of the needles, some local pain, bleeding, paresthesia and hematoma. So non serious adverse events continued for migraine. We did have one RCT that found no difference compared with the usual care in the risk of treatment related headaches. There's low strength of

evidence for that outcome and for the other two outcomes hematoma across two RCT 's and ear related complications in the one RCT of auricular acupuncture, the data for those were both insufficient. There was very little data provided and I do want to mention that the trial of auricular acupuncture, I mentioned previously, it was poor, poor quality. Patients were excluded if they developed redness or infection at the site of the needle implant, so that's really problematic and concerning sort of guard to how that would impact the findings. Moving on to chronic tension type headache and safety none of the trials reported serious adverse events and non-serious adverse events as reported by only one of the RCT 's comparing acupuncture with physiotherapy simply stated that a few patients had a slight vasovagal reaction after the first acupuncture treatment and that that is all that was reported, strength of evidence is insufficient. So, any questions before I move on to key question three differential effectiveness or safety? OK, great, so we had two trials, both in chronic migraine, none in chronic tension type, headache that explored a treatment modification by patient characteristics. Now this RTC compared acupuncture as usual care over the longer term, I think it was out to 30, er 24-36 weeks. Patients with more severe baseline symptoms had greater improvement with acupuncture. No other interactions were observed for different characteristics explored and the evidence is insufficient. In the second trial, comparing acupuncture with topiramate again over the longer term. Patients with more headache days, both any and of moderate severe intensity showed more improvement following acupuncture, compared with topiramate. No other interactions were observed, and the evidence again was insufficient. So, moving on to cost effectiveness. So, one poor to moderate quality cost utility analysis, comparing acupuncture to usual care in patients with chronic migraine suggests that acupuncture may be cost effective for a time horizon of one year at a willingness to pay threshold of 30,000 pounds, which equates to about 40,000 U.S. dollars, a little less than that. Again, this was a 20 or 2004 cost effectiveness reports so I don't know how those numbers would have changed. ICERs ranged from 801 pounds per quality-of-life years up to 12,000 pounds per quality-of-life years and that is if a general practitioner provided the service so we don't know you know how that might relate to what is done here in the United States. Our primary limitations of this study included lack of a more active treatment comparator, limited data beyond one year. They had limited sensitivity analysis around their model inputs and lack of clarity regarding continuation and discontinuation of acupuncture and components of usual care and again, differences

between the UK and US medical system might make generalizability difficult. K so now to move on to our summary. I'd first like to point out that I apologize, there was an error on this slide that from the reduction in mean number of headache days per month, should have been moderate strength of evidence, it was previously listed as low so apologies for that. Uh so, this is for chronic migraine and efficacy and as you can see across all primary outcomes with the exception of reduction in headache episodes or attacks per month towards the bottom of the slide there, acupuncture was associated with improved outcomes across all comparators and time points. The strength of evidence was primarily low except for a reduction in any headache days, both the proportion of patients with a 50% reduction as well as a mean reduction from baseline. Those were both moderate strength of evidence over the long term and some of these differences may be clinically significant. The light green just indicates low strength of evidence and in effect. The dark green, moderate strength of evidence and in effect and then of course, we have our insufficient and evidence and no difference. So, summary for chronic tension type, headache pretty simple here. It's all insufficient across all outcomes and timepoints. These are primarily single trials, contributing to the outcomes small at moderately high risk of bias with some often unknown or serious inconsistency in serious and precision. So, summary for safety across six RCT 's, five in chronic migraine and one in chronic tension type headache that compared acupuncture with SA more active controls provided limited data on adverse events. We did have low strength of evidence that acupuncture resulted in a decreased risk of any side effect compared with primarily pharmacological treatment and Botox. We also have low evidence of no difference for discontinuation due to adverse events or the risk of treatment related headaches. Evidence was insufficient for serious adverse events or deaths, hematoma, ear related complications for auricular acupuncture, and vasovagal reaction. Differential efficacy or harm again only in chronic migraine across two RCTs. Patients with more severe symptoms at baseline and with more headache days at baseline showed greater improvement with acupuncture versus active controls, the evidence was insufficient and for cost effectiveness again suggests acupuncture is likely cost effective compared with usual care. There were limitations however, limited time horizon, limited sensitivity analysis and again, the generalizability from the UK healthcare system to ours. I would also like to mention briefly speaking about different health care systems and none of these included trials were conducted in the United States. There were

four in Europe, two in Iran, one in China and one in Taiwan. So, any questions?

Sheila Rege: Conor had a question.

Conor Kleweno: Uh yes, thank you. One of the categories when we are typically looking at these is risk of bias. I saw that you had one comment on one study, I just didn't know if you had a summative comment on the risk of bias for these studies? obviously without a industry sponsor, uh it's a little bit less common, but not, not without possibility for bias within authorship.

Erika Brodt: Yes, I do, and I apologize I think guys.

Conor Kleweno: And I, I might have totally missed it, I apologize if I did. I just didn't notice it when you presented it. I'm sorry.

Erika Brodt: No, no, I think I think you're right; I think I didn't, I didn't take the time to go over it. So yeah, regarding the overall quality of these included studies so the majority seven of the nine, we graded as moderately high risk of bias, which you could equate to a poor-quality RCT. Uhm there were two in chronic migraine that were rated low risk of bias, I'm sorry, moderately low risk of bias that's Musil 2018 and Yang 2011. So, Musil was weightless versus usual care and Yang was versus topiramate. So some of the common methodological limitations that we found across these trials was unclear randomization and allocation concealment methods and this could just be poor reporting, especially in the older trials that we saw for chronic tension type headaches, you know requirements for reporting and transparency have increased a lot over the past couple decades, so that could that could account for it in part, there was a lot of there was higher often unclear lost to follow up in some of these studies and there were baseline differences as you could see in some across intervention groups and again and then in patients with or, sorry not in patients, in studies where you have the active controls, you know the blind, there's the blinding issue, there. That's just inherent limitation that you don't have with sham so those.

Conor Kleweno: And was there was there a patient exclusion analysis for, for these that that is a part of that rating of low or moderate or high risk of bias that you did include?

Erika Brodt: Yeah, well given, given that seven of the nine were technically moderately, you know, we could go back and look at some of the, the ones that were better quality Musil and Yang but you know overall, they generally were fairly consistent in what they were saying regardless of, of

the quality but yeah, we could you know, we can go back, I could call out just those at moderately low risk of bias, uhm. In the slides if you'd like.

Sheila Rege: I raised my hand to see if Dr. Fotinos, Dr. Charissa Fotinos, who's back with us and I had not allowed her to talk during our time and wanted to take her comments now.

Charissa Fotinos: Oh no, no thank you. Actually, I believe Josh conveyed them around the earlier conversation with how we view things. There's how we view things as it relates to the interpretation of the studies and how we decide what is evidence or you know covered or able to be covered as well as the rules we are bound to in our Washington administrative code about using a hierarchy of evidence to determine medical necessity. So, I think Josh spoke to that and that was all I wanted to say so. Thank you for affording me the opportunity.

Sheila Rege: Thank you. Uh I think next was Mika Sinanan.

Mika Sinanan: Hi thank you. I, I was interested in your re-review of the prior studies where you summarize those and my takeaway from that is that the re review, uh didn't change the strength of the evidence or risk of bias and the conclusions that were based that were that formed, uh the basis for the prior lack of coverage determination, is that correct or do you think the reevaluation actually made something clear or came to a different conclusion?

Erika Brodt: You know that is that is accurate. Yeah, we did we did not change any of the strength of evidence or any of the conclusions. Again, you know, these are all older studies that were identified for chronic tension type, headache and it's you know it's unfortunate that they weren't, there weren't others that that met our inclusion criteria you know, we are limited by the scope were given. So, I think that plays a large part in it, so but no, the conclusions remain the same.

Mika Sinanan: Thank you.

Erika Brodt: Yep.

Sheila Rege: Next is Chris, Christoph.

Christoph Lee: Yeah, hey, great, thanks you may have covered this already, but my question is that for this report, we loosen the inclusion criteria for chronic definition to be greater than equal to 12 headaches per month instead of 15 headache days per month. If you had them more strict inclusion of 15 days per month would some of these RCT 's disappear?

Erika Brodt: Yes.

Christoph Lee: And how many?

Erika Brodt: Yes, they would so I believe the two that would be Habibabadi or auricular acupuncture trial and Musil the 2018 here for chronic migraine and this, this criteria was what was established in the 2017 report. It was decided with clinical expert input at the time to include because of the older studies we were finding that that lower threshold for chronic and it was also decided for this re review not to change any of the scope just for clarification, so that's why we continued to include studies with that cut off, so yes, so these two would go away.

Christoph Lee: Got it OK, so there is some contamination with known chronic migraines here.

Erika Brodt: Yeah, with the pure definition using the, the ICHD 3 criteria, yes, a little bit.

Christoph Lee: OK, thank you.

Sheila Rege: I don't see any more raised hands.

Erika Brodt: K.

Sheila Rege: I'm sorry I do, uh Dr. Transue.

Conor Kleweno: You, you're muted.

Sheila Rege: Uh, Emily lowered her hand so maybe that was just a accident we can go on.

Gary Franklin: I'm sorry, was there a question for me?

Conor Kleweno: I think Emily is still trying to talk.

Sheila Rege: Emily, are you still trying to talk? Yes, the hand is still raised.

Charissa Fotinos: She need to be unmuted by someone.

Kathleen Lumiere: In the chat it says that she needs to be unmuted.

Melanie Golob: Yeah, she's a presenter so she has the ability to unmute unfortunately, it's just not be working. You can try changing your permission momentarily to see if that changes, I'll try that.

Gary Franklin: Emily says it's not on her side.

Melanie Golob: There we go and now it looks like you're unmuted.

Emily Transue: Can you hear me now? OK yeah can you hear me?

Melanie Golob: Yes.

Emily Transue: Excellent sorry so much drama. I'm apologize and so I just had two things, one, I wanted to say we have gotten confirmation, yes, that uh a referral is not needed, uhm for UMP for this and the medical directors would be happy to have that removed from the recommendation if that's what you want to do. So uhm, secondly, I just wanted to clarify with the evidence reviewer there was a question a minute ago about whether the recommendations had overall changed from previously and the answer seems to be just about tension type headaches, rather than both tension and migraine and I just wanted to have the reviewer comment on whether it was, was both or just.

Erika Brodt: Add note, yeah, the question was regarding the re review of the tension type headache evidence since there was nothing new identified and inconsistencies or just make sure that it was accurate, we didn't change any of our strength of evidence or our conclusions.

Emily Transue: Great thank you.

Erika Brodt: Yep.

Sheila Rege: For everybody to know we are seven minutes away from a break if we want to keep it a 10-minute break. So, let's go on.

Erika Brodt: Any other questions or should I go ahead and end my slide show?

Sheila Rege: Oh, are you done Emily?

Erika Brodt: Yes.

Sheila Rege: OK.

Erika Brodt: Yes, I went back to that, but yes, I'm I'm done.

Sheila Rege: Ok great, then we can go ahead and now have time for committee question and answer and please, do the raise hand button for questions on the evidence report or the agency medical directors or, a clinical experts. Laurie, thank you.

Laurie Mischley: Yeah, I just have a question about the methodology. We heard from the Chinese medicine perspective, that the, you know the, the intervention that is actually offered it differs based on pulse and tongue in history and all these paradigms that we don't use in conventional medicine, did any of that get filtered into the research protocol? I mean was the protocol

always written that the acupuncturist has liberty to do their own diagnostic work up within? Like it's a black box of you go do whatever acupuncturist do and we judge outcomes and then in the world of acupuncture, there are really dozens of different interventions happening. Right, is that…

Erika Brodt: Uh-huh, yeah, yeah, so in in these studies, yes, for the most part, the way they were described they would talk about, you know specific acupuncture points that were generally considered. They'd have maybe some that were required and then some that were up to the discretion of the acupuncturist. They would often look at a variety of points and sometimes picked the most active points to treat but there was a lot of discretion on the part of the acupuncturist and again, you know that and that might speak to some of this semi standard, you know if there are certain points they want to include for sure in the protocol but then you know, there are others up to the discretion of the acupuncturist, but it was really variables, the number of sites, you know the number of needles used, so I do think there is a lot of discretion.

Natalia Murinova: And can't comment as follows in time. So what I reviewed in detail like let's say it really differs from study to study a but of Vickers in London, they let the acupuncturist do whatever they wanted and they didn't have any defined like this is how often do you do it, you know these are the points you have to do it just let them do, this is you know you're a professional do you know whatever you want to do we'll just we check in this period of time so they didn't even say like you have to do it once. The frequency was not defined, sides were not defined so completely at discretion of acupuncture is. Let's, let's say that Iran study was only one provider, one neurologist during the ear acupuncture, so and it only on 40 patients, so that's kind of the issue that we don't have any American studies and we don't really have currently from acupuncture like compared to let's say Botox before it was approved as a therapy anyone could do anything. Now we have a standard like you have to do it this off and you have to do these points. This I don't think exists in acupuncture for headache and this time and you know, people can comment.

Laurie Mischley: So essentially some of these studies are asking does point X work while other ones are asking does the experience of going to an acupuncturist once a week work? I mean different studies are actually asking very different questions and we're trying to derive; does it improve outcomes in our model?

Sheila Rege: Uh Dr. Bramhall, John you're next.

John Bramhall: Sure, Laurie you just touched on the sort of thinking that I have. So, I'm, I'm, I'm pretty ignorant about the methodology of acupuncture, I mean, I I know something, but I'm pretty ignorant about it and it, it seems to me that there's likely to be a particular anatomic site in which a needle should be placed in order to get elicit a certain effect. I, I may be wrong there because it may be Laurie, it may be much more holistic than that, but I mean I am an anesthesiologist right, and so I, I can't get hung up on mechanisms because I don't understand the basic mechanisms of what I do every day and yet it works. Sure, it works, but, but so my, my, my sort of question and it's not easy to, to know what the answer where the answer would come from. The, the studies are done, the three trials that we've looked at in particular this morning seemed to suggest a benefit and I would accept that benefit but my question is, if uh if, if in a study I was the person uh doing the acupuncture therapy, would it be expected that I as a untrained personally my sound stupid, I know, but when I get the effect and my question really relates to the accuracy of the placement of the needles and whether that's, that's an element in in the analytic data that should be included. Are we looking at results of a therapy in general, holistically or are we looking sometimes at the skill of individual acupuncturists? And, and I I'm not sure that it makes a difference in terms of the interpretation of the data in its entirety but I, I, I find that an interesting sort of question to ask.

Kathleen Lumiere: I would love to speak to that, if I may.

Sheila Rege: Yeah, and you had your hand raised too, so thank you.

Kathleen Lumiere: Thank you uhm and in answer to Dr. Mischley's question the um and, and one that was alluded to earlier, for certain conditions, there are standard points, it's not standardized but I know if somebody has digestive problems and fatigue almost any acupuncturist is going to use stomach 36, so that's why in a lot of these studies, they'll have the commonly used points and then the variables and that that those core commonly used points are actually more similar than acupuncturists are comfortable with 'cause we pride ourselves on an individual weighted medicine and what we do is pretty standard. Uhm, so and, and in answer to your question Dr. Bramhall, the um one of the one of the findings, one of the, the, the lessons from the sham, the sham study era was that even bad acupuncture is pretty effective so again this is this is humbling for acupuncturists and Masters of acupuncture, who do very precise needling that that even really shotty acupuncture, uh has, has results so I would say that yes, you probably would be effective, though their results.

I would hope would be much better at somebody who's been doing it for decades, but it you know it's still work.

Sheila Rege: Thank you. We are at the time for break, and I would like to go on break, but I would like when we come back people to think about something and that's why I raised my hand. As we discussed terminology just because this is a public meeting, I'd like us to be politically correct and call it acupuncture. I know it originated and we, we kind of talking Stern Western but I I just worry about us using countries and I was, I said Asian too just to kind of try and be politically correct in today's world for the meeting when we come back. Uh we will adjourn for 10 minutes well, 10 minutes or we're going to come back at, uh 11:22. Let's continue with raising our hands for either questions or discussion. I, I had a question for our clinical experts who or anybody with experience in acupuncture, question that came up earlier and I can't remember who asked whether you know, kind of doing something in 12 weeks made sense for acupuncture? Is that standard or how and, and how, how do, how do acupuncture specialists think about this?

Kathleen Lumiere: I'm so glad that you brought that up 'cause sometimes research protocols are very different than clinical practice. Uhm so normally we would, we would see someone for a headache, a standard a standard treatment approach would be somebody comes in for a headache and I'm usually very pleased 'cause I think oh I can probably help you and I would say please come in once a week uh for schedule about four sessions and we expect to see changes within two to three sessions and, and, and some significant relief and at first, uh the effects of acupuncture tend to be short like in an hour or a day or a 48 hour period, but overtime, those results are cumulative so the space between areas of, of, of respite or relief grow longer and longer and longer. So, we would start maybe with four treatments and then extend the treatment time to every two weeks and then extend it to three weeks and then get to the point where they just come in for, for maintenance. So that would be a more typical schedule.

Laurie Mischley: What would maintenance look like?

Kathleen Lumiere: For a migraine sufferer um it would look like, it usually is about once a month or so, maybe once every two to three months if they're, if they're really symptom free. For a tension type headache, it would be, ah, well tension, tension type headaches, correlate, so much to people 's degree of stress and suffering and other parts of their lives, uhm, so that's so it's less actually seems less patterned but ah, I would say once every, you

know six weeks, two months would, would be more typical for maintenance.

Sheila Rege: We uh, Mika Sinanan has raised his hand.

Mika Sinanan: Yes, thank you a question back to you, Kathleen. So, some will get a lot of benefits, some that will get a partial benefits, some won't benefit. For those who don't, are there, is there a way to escalate it or do you say, well it's not working in and now you have to go to medication?

Kathleen Lumiere: Thank you for asking so usually when people come to us, they've already exhausted their, their, their options for medication and that's less true than it used to be, but often we're, we're, we're, uh something that they're trying of last resort. As far as within acupuncture goes, we would start out with a fairly minimalistic technique so fewer needles, uhm if that didn't work, but there was some there's, there's some kind of response, then we might use more needles. We would use other techniques like maybe Gua Sha, which is a uh a scraping technique that, uhm in Biomedicine, the Garston technique if you're familiar with that in PT it breaks up fascia that that originated with the TCM or other East Eastern Asian medicines to Gua Sha of using a tool to scrape. We might do tween now, which is a kind of body work, sort of massage. We would certainly talk about things like, like sleep and diet and exercise. We would teach people about how, how to breathe, how to become aware of how they feel in their bodies so they could relax and we would also say there's a lot of patient education that could go on potentially would go on potentially and then within the technique structure itself, we might do things like Electro acupuncture, which is usually a lot more or maybe the results are the results are, are, are very strong or laser acupuncture, or stimulating acupuncture with acupuncture points with something called moxibustion so that and that's a very partial toolkit but there's a lot of different things that we could do and if within a trying all those things. If within three sessions, we weren't seeing any result, we would certainly say look it looks like, looks, looks like nothing is happening here, uhm, yeah, let's, let's explore other options, so I myself would refer to uh biofeedback, I would refer to nutritionists, I would refer to certainly to MDs uhm and, and we work we work collaboratively anyway, most, most acupuncturists.

Laurie Mischley: Can I just clarify that that paradigm you just laid out is that the same whether you're a licensed acupuncturist or a medical acupuncturist, like if you're an MD doing acupuncture, and what you just described is that different?

Kathleen Lumiere: I'm not surrounded by MD acupuncturists. I know a few of them and most of them refer to licensed acupuncturist 'cause it's not a big part of their practice it's not. Uhm a compensation is so much less, and the training is so much less so they usually are very interested in it and promote it but don't practice it in my in my experience, but I think they would take a similar treatment approach right, but would, they would have less time to spend with people.

Mika Sinanan: So, thank you just to.

Sheila Rege: Why, why, why is this a follow up, because Christoph waiting OK?

Mika Sinanan: It's a yeah, it's a follow up with my prior question so in the referrals that you mentioned you didn't mention referral to a neurologist, what I mean is that deliberate or?

Kathleen Lumiere: I meant that, thank you and that presupposes that they already are in the care of a neurologist. They've already seen a neurologist before they come to us if they haven't, we've certainly would refer to a neurologist if, if they weren't getting results.

Mika Sinanan: OK and, and just so I'm entirely clear, you said within the first three so the paradigm is not do the same thing for 12 sessions and then assess whether there's a benefit, it's do it once and see whether there's a benefit and then change it if it's not working and try something else and if it's not working the second time, try something else the next time so the treatment may be quite different from session to session. One of the reasons I'm asking is the medical director's recommendation about the number of sessions, and what would actually happen during those sessions and are they standardized or not? So...

Kathleen Lumiere: They are not standardized and what I described is it is, it is a pretty aggressive kind of results-oriented model. Uh, not everyone practices that way, but we certainly teach that at Bastyr where I, where I teach and practice. Uhm, not sure if I'm, I'm answering what you're asking.

Mika Sinanan: No, that was helpful, thank you.

Kathleen Lumiere: Yeah.

Sheila Rege: Dr. Lee, Christoph?

Christoph Lee: Yeah, so uh Kathleen again, and then probably a question for you and and other practitioners and I'm just trying to make sense of the amount of sessions over a certain period time and then a maximum of announced sessions for the entire year of coverage, you know, comparing it to say

low back pain in acupuncture for Medicare where the coverage is for 12 sessions over 90 days and if there is no improvement, you go onto an alternative, but there is improvement, they get eight more sessions for the rest of the year so Medicare will cover 20 per year. So, they're saying, you know, 12th or number of sessions, 12 sessions for 90 days maximum 20 per year. What's, what's the parallel for headache and acupuncture, what's reasonable for you know first, several weeks or 90 days? How many sessions to say that it's actually effective and if it is effective, they keep going? What you've described so far is just one acupuncture a different type of acupuncture, let's keep going with acupuncture but for low back pain and acupuncture, it's very much at least for Medicare if it doesn't work, we stop, and you continue if it works. Could you comment on that?

Kathleen Lumiere: Sure, yes, thank you for asking. So, the, the, the, the condition that you all are examining is, is chronic debilitating headaches, uh and what I described was a combination of, of episodic and, and chronic headaches our treatment approach, so, optimally in the beginning, we might see somebody twice a week. So, I wouldn't, I wouldn't want to make any recommendations that would limit someone 's ability to get acupuncture frequently enough to stop that to stop pain signaling and actually turn, turn it around, uhm. Uh so in a in a in a perfect world we probably would see someone, making, making incremental changes and working with other providers actively, probably twice a week for four weeks which would be eight treatments and then and then we would hope to be able to see them once a week for another four weeks and then and then talk about you know, stretching it out so I would think somebody would be able to get substantial relief with 24 visits a year but that's my hypothesis.

Christoph Lee: Great thank you.

Kathleen Lumiere: Thank you.

Sheila Rege: I raise my hand to ask the clinical evidence what, what was the studies what, what was the model in the studies was that described in the methods?

Shelby Kantner: You're muted Erica.

Erika Brodt: Thank you. They you know for the most part, they didn't talk about continuing treatment or referring out or any of these types of things they just, you know, did their X number of treatments over X number of weeks the study was over.

Sheila Rege: Did they describe a protocol? What was kind of a standard protocol?

Erika Brodt: You mean as far as which points were used, and what the active cultures?

Sheila Rege: No how many, how many, like how many times a week. Maybe I'm thinking chemo, you're out, you kind of one, so once a week, twice a week, did they pop up?

Erika Brodt: Yeah, these, yeah, I mean, they primarily would say you know eight sessions over eight weeks, you know, some would say once a week, some would just say 10-12 sessions over 12 weeks, some of them were fairly vague, you could you know, assume maybe once a week if it's 12 sessions over 12 weeks but, yeah, most were not super, super specific in that regard, just this many needles, this many sessions over this many weeks.

Sheila Rege: Janna is next, unless Natalia were you going to help answer that question, you can jump ahead of him if that's so.

Natalia Murinova: Yeah, yes, so when I reviewed it so uh in the Habibabadi study, let's say it was auricular acupuncture, and they did it only two times, so they put it continuously and then retracted in a week. It was just a two-week kind of intervention and the, the Vickers they had many providers, they had, and 186 patients and they just their decision was, however you want to do it, just do it up to 12 times in three months. So, they would leave it to the expertise of their expert and again, they in that one, there was the largest one. They did not go into then specifying like which points again, it was left to having high quality experts, you know that they have through their system in UK and just determining however you want to do it, we limit it to 12 visits at three months. I don't know if that helps.

Sheila Rege: That does, thank you. Janna you're next.

Janna Friedly: Yeah, and I was just gonna similarly comment that these, these were trials. It you know it's a, it's, it's very difficult in a in a clinical trial to, to extend it long enough to be able to really look at long term treatment of a chronic condition like, like this and and be able to study you know what, what's the most impact so all these studies were designed as relatively short interventions, maybe with some longer term follow up but that's, that's the nature of the clinical trials and the funding for clinical trials and how difficult they are to, to, to conduct so I I don't think it's reasonable to expect in a in a clinical trial necessarily that that they would be able to answer the question about how, how many treatments, how long and, and for, for a long, especially in a chronic condition like this so I think

that's something that we're just going to have to grapple, grapple with, with that without the, the, the evidence.

Sheila Rege: Thank you, Conor?

Conor Kleweno: Uh yeah, you know, we had a review in 2017 and had a there was a decision made and then there's been several new studies and I just want to clarify if the committee is just isolating their interpretation based on the new studies or if it's the summation, including some low level, what was considered low level of evidence from the older studies and I just I want to be clear with that 'cause I think actually Mika made the point that there wasn't a difference of interpretation of the older studies based on re-reviews so and if that's true are we are we just isolating out the new studies and should be critiquing them as well as their, their level of evidence or if we should summate what, uh the entire canon of the literature that has been presented today?

Sheila Rege: Would the, would the clinical expert like to take that or I saw Laurie's hand up, was that in response to this question?

Laurie Mischley: Yeah, yeah, I was just gonna say you know, I I've mentioned our review of the 2017 decision on multiple occasions and and you know in the context of what was happening at that meeting, we had Botox with thousands of people enrolled perks study and we had a couple little acupuncture studies with 30 people per arm and it was just with the with the gigantic pharmaceutical you know, we had them flying in reps from all over the country, there were multiple studies with a lot of money behind them and then we had these you know bake sale sponsored acupuncture trials and and it was this kind of the weight of the evidence even there was even a head-to-head study where acupuncture was superior but it was just when you look at how many people had been enrolled in each study, it meant the weight that was played into how we weighted at the evidence and that was one of the frustrations was this philosophical idea that it's not fair to hold you know non industry driven, whole practice ancient paradigms to the standards that were holding pharmaceutical trials to, and and that discussion has led to this re-review so I, I would vote that we interpret all of it together. This isn't just looking at a few new studies, but now that we've had a chance to have a couple years of talking about this and rethinking about it, maybe look at the whole thing from that lens.

Erika Brodt: Well and I would like to just reiterate that all the new trials were in chronic migraine so chronic tension type headache, we have, you know

nothing new, and we did evaluate the chronic migraine studies differently, you know, then then previously because as we started to look across them, you know, we could pull different outcomes that we couldn't pull before or we realized there, really, you know acupuncture was showing superior results, no matter what the comparator was so with very little statistical heterogeneity actually so it just made sense to look across all of them and not you know group them 'cause the more you stratify, sometimes the lower your effort strength of evidence gets right as you start to make the group smaller so, so that that is one way in which the chronic migraine evidence is different. So again, I think a Dr. Kleweno, when you're talking about that again, it's the migraine, we have three new studies for migraine that we added but they have been grouped in with the other ones and looked across all of them, so we didn't just focus on these three new trials. If that makes sense.

Sheila Rege: Doctor Kathleen Lumiere.

Kathleen Lumiere: Thank you, and, and I, I just want to say how much I appreciate the reviewers. I recognized they had a very limited scope and um and the, the review was so precise and so beautifully done and this it, it sounds like this group has can't admit though uh materials that meet the the standards for the the the highest hierarchy of evidence like Cochrane reviews or the VA systematic reviews is that correct or is that not, correct? Are you allowed to look at the Cochrane review on tension type headache or the, the VA systematic review as well?

Josh Morse: Yes, hi this is Josh Morse, so yes, the, the process involves we assigned the process to Erica, to our contractor to identify the best available evidence if that evidence was previously considered if it was part of the prior review it, it's, it's not considered in this review 'cause there, we were asking them to only look forward from the last review essentially building on the last review, and then there are, they apply methodology, which may limit some of these studies being included if they did not meet inclusion criteria for the report so there's nothing that limits the consideration of those except what I just described which would be if it was already part of the prior time period in the prior review, it may be included in the in that previous report or if it didn't meet inclusion criteria for this report.

Sheila Rege: And then Josh, could you if, if anybody disagrees with that at a later time after our meeting can you review the process of how, how come our committee hears back comments if, if it's felt that we've missed some evidence, can you elaborate on that for clarification?

Josh Morse: Yes, would you like me to do that now?

Sheila Rege: Yeah, just, just so in case people are listening.

Josh Morse: Yes, so if, if in the, the search and the work that was done by Aggregate for this report, you know, we did have a draft comment period. The report was published for 30 days, and we hope during that period if not earlier in the review process, that critical studies or important information to consider in the review are identified, and, and we're notified of that, so that we, we catch them before you know the final report is published. In the event that something is missed, though there is a comment period that follows the work today and if there's you know critical studies and somebody says look you know you, you just went through this process, there's important research that wasn't included, it's during that comment period that I would hope that people would make that comment for the committee to consider when they come back to make that final. So, if evidence was missed that's one of the key questions the committee asks itself before they make a final decision. Today's decision would only be draft but before a final decision they ask, uh if somebody has identified information evidence that wasn't considered that it should have been considered.

Kathleen Lumiere: Thank you Josh and, and I understand the, the scope of the, the 2017, uhm, study or review process kind of determined what was, what was looked at in this one as well.

Sheila Rege: Uhm, if you're done and I don't know. Larry, I see your hand is, is does anybody have anything related to this? I see Emily Transue hand and Erica Brodt, are you trying to respond to this question? Both of you? OK, then Larry with your permission, I'm going to let them answer this.

Emily Transue: And we may be saying we may be saying the same thing, I just want to call it in terms of something like a Cochrane review, that the review here is generally focused on primary evidence rather than other assessments that are based, and they also include similar evidence. So, we wouldn't bring in the Cochrane review as a primary source since it wouldn't be a study. Although we do sort of sometimes refer to what's out there. Erica probably has more detail, so I'll let her jump in.

Erika Brodt: Thank you. Yes, I was just gonna say the exact same thing, so the way we generally approach these as we do look at systematic reviews that appear applicable and in rare instances will include them as primary evidence if they meet, you know all the included studies really need our scope and just or right on as far as what we're looking for will sometimes build off

them very rare. So, what we usually do is we use them at to make sure we haven't missed anything and so we'll review all the citations of included trials to see if we can include those as primary evidence in our report. We did do that with the Cochrane reviews and unfortunately you know the populations were all mixed. We will include if the population is at least 80% of one, you know, headache type will include it, but in these it was just too mixed to get at you know what we were tasked to look at which was specifically chronic headaches. These were summarized, though in the prior report under the systematic review, overview section and so they were looked at or possibly considered last time. This time, we mentioned them, and I believe referred back to the report but with the caveat that you know again. It's there's nothing new here and the populations are mixed. So.

Sheila Rege: I say two more questions. Larry, I'm going to let you go and then we'll make a decision as a committee, depending on. At noon, I would like to start kind of getting kind of the straw poll and continued discussion at after that. Larry?

Larry Birger: Thank you. Yes, I just need a, and it may need to come later but the clarification on this idea that we only consider quote new evidence. I don't see how that addresses that the prior comments talking about the, the, the weight before I mean, the, the essential concept of a meta-analysis is that you may have multiple smaller trials that themselves are insufficient to prove a point but by the time you pool with other studies, then now you have an aggregate that, is uh perhaps compelling and directed one way or the other but that effect is lost if the newer studies are only considered and are not considered in aggregate with what previously was insufficient and so I don't know if now is the time to comment on that, but I, I do see that as a, a conceptual question that needs to be addressed and I don't feel like it was addressed by this idea of just, we only look at the new evidence that has come up.

Erika Brodt: Yeah, that that's a good point and when I made the comment about that now we can pull across you know outcomes we couldn't pull across before or we will be able to consider across different comparators and didn't you know break everything up like we did which can reduce the strength of evidence like as you're saying if you have more studies to compare across. So yeah, your point is well taken.

Sheila Rege: Doctor Sinanan.

Mika Sinanan: Thank you. So follow up question Kathleen from some of your prior comments, uhm, you, you I think and Laurie also talked about how this is a different conceptual framework, uh my, my question to you is because the conceptual framework that we're, that we're talking about here and of course, you understand it and we don't but does that require or does it necessitate applying the rules of evidence in a different way or thinking about the evidence in a different way?

Kathleen Lumiere: Uhm, yeah, thank you for that question. So, I think the main problem, uh that we have right now is just the weight of evidence, which is largely financial, that people don't have stand to profit a lot from acupuncture research so it hasn't been done and it also hasn't been done with the kind of specificity that would meet the parameters of this inquiry. Uhm, I'm, I'm, I'm, pleased that there, there, there is some that does, and I think that uh if, if, more research was done the um that, that, that what has been shown so far pretty consistently would, would, continue to play out, which is why these really great reviewers made the recommendations that they did. As far as the way the, the medicine would best be represented in in research that is a big and fascinating topic. Uh I think where as a as a as a medicine, we're headed towards qualitative research and long-term research 'cause that's where it really shines is what happens with all of those nonspecific effects. What happens with the long-term effects that Dr. Birger mentioned, this is this is medicine for health, not just for, for, the short-term remediation of a symptom.

Mika Sinanan: Thank you that is helpful.

Sheila Rege: Conor we will take a question from you and then after that just for staff, if we could get ready to project kind of a straw poll, uh just whether the committee feels that we have evidence. So go ahead Conor.

Conor Kleweno: I'll, I'll defer my question actually 'cause I'd so looks like we're running short on time.

Sheila Rege: No, I think we have noon is when we were going to quit so go ahead.

Conor Kleweno: Uh just the kind of the follow up that, you know, and Kathleen, the question back to you, you described I think of very different model than what we are used to where we are thinking of us, uh specific, specific, treatment for specific diagnosis that can be described and well documented and, and, you describe I think, something a little bit different, and so the question is, are we are we thinking of this in terms of coverage in the right ways? Should it be acupuncture for migraines or should it be treatment for migraines that is uh you know described in it in

a different way, because you know, you did, as, as, we kind of uh articulated you didn't describe 24 sessions of, of, needling you described a very different treatment modality, I think that we all would sort of understand you know you, said mention nutrition and sleep hygiene and and Wellness and and Biomedicine and so just sort of a question to you.

Kathleen Lumiere: Thank you very much. Uhm acupuncture is a catchall for a uh a large set of practices that primarily involved needling, needling is what we bill for so if, if, we bill the state needles were involved, uhm, which is which is a practical answer to your larger philosophical question. I think what would, I mean, my, my, mind is split, I think about all the all the people who, who, suffer from chronic migraines and chronic headaches and if they can get some coverage if they can get some relief from something that works and has very few side effects and it's cost effective, that would be great. Uhm, so, we we do, do acupuncture, we would do acupuncture and acupuncture is bigger than just needles.

Sheila Rege: Last question from Laurie.

Laurie Mischley: This is not yeah that's alright. This is not so much a question but a response to Mika's comment about how we set this study, study, designs up differently and this is where we get into a little bit more of what has already been mentioned with, we're moving away from sham like we don't really care if it is 0.33 and we hit the right spot and get the chi flowing or whether it is the practice of going in once a week and having somebody assess your pulse and give you the impression that there are things that you can do in your life that will change outcomes in the education and the attention. I mean, it's becoming better understood that placebo is not something to be disregarded but something that can be utilized in terms of outcomes, and I don't. So, so, as we move into how best to set up studies that accurately capture what is happening in the acupuncture room, we move into the world of whole practice research in outcomes, research and kind of acknowledged the black box that we don't understand. Let the paradigm be the paradigm and we just look do headaches get better or not right, like that's the proper way to set up a study that gets to what we're trying to answer which is does acupuncture help. From a conventional paradigm, that study rarely gets funded right, like you don't understand it, it doesn't like we already have to sell out the paradigm just to get the study funded like you are funding, a study on migraines so we're gonna call you know like we filter this, we narrow this, we package it in a way that you all can understand to get the study funded. It, it, it is not so much that the data needs to be interpreted

differently or that the bar should be lower but acknowledging that the paradigm that best serves the practice and answers the question, we really want to know is not the research that has historically been done and it's not the research that's easy to get funded.

Mika Sinanan: And just in a response to that, Laurie, I, I really appreciate that I think you've made that point eloquently over many, many sessions. The concern I continue to have is, I don't know that the legislature when they wrote the statute that set this up were thinking in the same way they were thinking I think based on the best advice they had at the time in a more narrow evidence based traditional pathway and so uh we're pushing the boundaries when we start to stretch that and maybe that is again a, a, strategic question to be discussed about how we educate the legislature about how evidence uh based research and decision making needs to evolve in the future because I think that's what you're highlighting here. Thank you.

Sheila Rege: We are going to have thank you that I mean, I think all the comments have been really, really helpful. I'd like to just move us a little forward so we actually finished in time and anybody who wants to, to continue this please type it in the chat box and we will kind of continue but if we can project, uh you know in a roomful we'd be looking at just a discussion on ah key factors in terms of safety outcomes, so we can project that. This would be a straw poll kind of, looking we're looking at safety right now and let's go do it with chronic migraine first. So, kind of a kind of a voting question. No, go, go, back OK, so this is this the side effects. Do are we comfortable with the side effects, uh and, and, did we did we put into that we've adverse effects leading to treatment withdrawal, death, headache, hematoma, ear swelling, pain, serious AES what is that?

Josh Morse: Adverse effects.

Sheila Rege: Right.

Josh Morse: Or events.

Sheila Rege: Is there anything we missed in safety?

Josh Morse: So. Right so we've evolved this, the decision tool for the virtual meeting environment and Melanie has assembled some of the summary information from. Erica 's presentation here and included that in the decision aid and then we have prefilled as we typically do the decision made with the safety outcomes as reported by Aggregate and then we've moved the questions up into the same frame here, so that this is the

discussion of how important were these outcomes to you and did you what did you feel was your confidence in the evidence for these outcomes? Prior to working on your vote here for the sufficiency of the evidence or the technology that's being considered.

Sheila Rege: So, let's, let's, do chronic migraine. Do we as a committee members feel that there was available evidence to, to, kind of do a straw poll kind of like we would do unproven and, and, our bar would be alternative treatments and we've talked about what that would be, be, it for propranolol, topiramate, Botox, nothing, I I've you know, so safety unproven less equivalent and so if Melanie can we just type that into the chat box, would that be OK and you can correlate and this is just for chronic migraine?

Josh Morse: And this is just for committee members, voting committee members is that right, Sheila

Sheila Rege: Oh, so should we

Melanie Golob: Yeah, and then raise hand would probably be a little bit easier just to kind of keep track of.

Sheila Rege: That'd be good. So how many things safety is unproven, raise your hand now.

Melanie Golob: OK, thank you that looks like four, can lower.

Sheila Rege: Maybe you should keep should we lower our hands now?

Melanie Golob: Yeah, I, I get, I get four so I'm gonna go ahead and lower your hand, thank you.

Sheila Rege: How many think that um acupuncture for chronic migraine is less safe for chronic migraine? How many think, in terms of safety profile it is equivalent to alternatives?

Melanie Golob: I see three. You can go and lower your hands.

Sheila Rege: How many think it is more safe for chronic migraine compared to other standard therapy?

Melanie Golob: I see two, oops, three.

Sheila Rege: How many think it is more safe in all patients? I would assume is how that is for chronic migraine in terms of safety only.

Josh Morse: I think that is 10 votes did, we miss count?

Janna Friedly: Sheila can I just clarify what the more in all, I think is more in all of the studies that it's safer.

Sheila Rege: More in all the studies, yeah.

Janna Friedly: They say for in all of the all of the studies.

Sheila Rege: We can, we'll redo it because this is hard ah so let's go back to for chronic migraine is acupuncture safety unproven? Just safety.

Melanie Golob: Yeah, that's four, no five.

Sheila Rege: Going once. OK, lower your hands, please oh did somebody else just raise their hand? Let's do it again on.

Conor Kleweno: No, I just prematurely lowered my hand, sorry.

Sheila Rege: OK. Is it? Are you good Melanie? Did you get?

Melanie Golob: Yeah, so that's five thank you.

Sheila Rege: So, do you, did you did, did you, get uh like we're 11 committee members you got 11 votes?

Josh Morse: Well, I think we're 10 committee members today.

Melanie Golob: Yes.

Josh Morse: Uh. Dr. Hearne is not here doctor, Lumiere are you voting?

Kathleen Lumiere: I'd oh, uh am I able to vote?

Josh Morse: Well, you are technically a nonvoting member on the committee. This is a non-binding vote, so I guess I didn't layout the ground rules at the start. So, Dr. Rege, uh I think actually it's best as a nonvoting member for you to not vote on these aspects that we have, we have two formal votes, really this is the first of the formal voting sessions and then we'll have a final vote. So best for you to not vote, so if you did vote, then that makes you did not? OK, then we're good. We should have 10 total votes, which is what we have from first session of voting.

Kathleen Lumiere: I did not.

Sheila Rege: I'm going to continue on chronic um just on, ah chronic my yeah, let's just do chronic migraine. I going to treat them differently, uh let's do, efficacy, uh effectiveness. So chronic migraine straw poll. Is acupuncture unproven in terms of a meaningful impact on patients and patient care? Is it? So, raise your hand if you think it's unproven.

Melanie Golob: OK, there's two. Thank you, go ahead and all your hands, three.

Sheila Rege: Did you get three?

Melanie Golob: Yeah, three, go ahead and lower your hands, thank you.

Sheila Rege: Do we think that acupuncture in chronic migraine is less effective than alternative therapy, raise your hand? Do we think that acupuncture and chronic migraine, migraine is equivalent to alternative therapy, raise your hand? Next, do we think acupuncture in chronic migraine is more effective in some, based on the studies?

Melanie Golob: OK, I see six. Thank you go ahead and lower your hands.

Sheila Rege: Do we think acupuncture and chronic migraine is more effective in all compared to alternatives? Raising and somebody 's hand did not get lowered always then. Melanie, do we have 10 votes?

Melanie Golob: I think I'm missing one unless there was one that was at the end of more in some, but I don't think anyone voted for more at all unless you.

Sheila Rege: No, so let's go back, let's go back to unproven acupuncture, is unproven in efficacy? Let's raise your hand again, that's two. Let's go to acupuncture is more in some for chronic migraine only.

Melanie Golob: OK, now it looks like seven this time. [pause] Oh, was there eight for a second? I don't think so.

Sheila Rege: Let's, let's say more in some, where we're still on more and some, don't lower your hand yet.

Melanie Golob: OK, that's 8, that will be everyone. Perfect, thank you.

Sheila Rege: Let's lower our hands. Let us now look at just for chronic migraine acupuncture and value, cost effective and cost outcome. So, do we feel acupuncture of chronic migraine and terms of cost effective, cost outcomes or value is unproven raise your hands?

Melanie Golob: There's the five, six, six for this category, maybe was there seven. Did somebody put their hand down? Leave it up for just a moment if you are voting for unproven. Ok, so that is nine for unproven. Thank you, go ahead and move your hands.

Sheila Rege: Acupuncture in terms of cost effectiveness for chronic migraine is less. Laurie was that ok, Dr Mischley, is, OK? So less, anybody for less? I'm going to move on a little faster this time anybody for it.

Melanie Golob: K.

Sheila Rege: Anybody for more in some, so more cost effective, more cost outcomes?

Melanie Golob: So that's one, thank you.

Sheila Rege: And more in all or did we already get 10?

Melanie Golob: That should be 10.

Josh Morse: That is 10.

Sheila Rege: Uhm, let us do, let us do chronic migraine, a kind of a, a, straw poll, uh can you project that on the summary, based on the tool you've developed to help us?

Josh Morse: For safety, backup to safety for chronic tension type?

Sheila Rege: Uh I will actually going to, I know we call it second vote when we talked about trying to make it more efficient, but I just wanted to just have it projected so all of us can see where our totals are for chronic migraine.

Sheila Rege: Let's put up.

Josh Morse: Melanie, do you have the totals in a different sheet?

Melanie Golob: Yeah, I think it got unlinked uhm. The only one that was a little off was the safety for migraines. I think one person had changed their vote because we have more than 10, we will have 11 in total in that one.

Sheila Rege: K let's let's actually.

Josh Morse: I can, I can move the results down and put him all in that table so.

Sheila Rege: That'll be good and then we'll just redo safety and.

Josh Morse: No, I think we, we got it right, I have 10 votes.

Sheila Rege: Alright.

Josh Morse: So, this was the, yeah. So, for safety there were four unproven, three equivalent, three more in some. This is the effectiveness, there were two unproven and eight more in some, and then for cost effectiveness, is nine unproven, one more in some. Oops, I'm putting that in the wrong place at. So, this is the result of what you just voted on here in this table.

Sheila Rege: Yeah, are there any considerations for special outcomes? Why we're looking at these that we need to worry, I think about? I did not see any of the studies, does anybody else think? So, learning OK, so help me out

here, I wanna do chronic migraines. It's interesting to me that we voted that cost was unproven and yet I think it's this committee like Dr. Mischley said voted Botox, which is more expensive is covered. Uhm. What are we leaning towards in a final vote if we if we were to go there on chronic migraines? Janna helped me out here as my, oh, there's Mika, thank you.

Mika Sinanan: You know, I've been thinking about our brief summary that we sometimes do, and I guess that's what you're asking for I, I think that this is a severe illness that affects a substantial number of people variably but both in terms of the severity and in terms of their response to medical therapy, it is a chronic illness that's been poorly studied for financial reasons and because of the issues that that uh number uh have mentioned Janna and Laurie I, uh, it is a difficult to diagnose situation and often incorrectly diagnosed I think we heard that early on, so there is a role for making sure that the diagnosis is appropriate. Of the evidence, we've seen, a there's low to moderate at best strength of evidence with a significant moderate to high risk of bias, uh especially because and this may be part of the treatment benefit but because of the, the issue of placebo there as to whether that's a benefit or a risk, but it is a, it is a confounding factor. I think the patient numbers for the new studies and overall are very small. In the follow up for at least one of the two RCT 's we saw was very short without any standards for the comparators. I think it's very safe, but I also think that the safety profiles are underreported because there is no good incentive system not like for devices and so on to report safety issues so, I bet the majority of safety issues are just never reported, it just seems safe. Uh we talked about the high variability and delivery with the requirement for expert acupuncturist being probably the most important criterion, but then allowing them to do what they think is right based on the patient that presentation their response to prior treatment, they're both with that acupuncturist and by other types of treatment. So, there's no standardized intervention really accept the billing factor for having inserted a needle and I still think that we are being asked or expected to, to, apply a somewhat different way of thinking about this around the level of evidence because of the conceptual framework and I don't know that this is a conceptual framework that fits very well into the standard methodology that we use, so that's a limitation of the methodology and not uh saying that it's a problem necessarily for the treatment but I think it's the way we think about it, it, it puts us um in a bit of a bind. For those reasons, as I went through this, I said that the evidence was insufficient and be at the

evidence for efficacy is insufficient, then you can't say anything about the cost efficiency of it because we don't even know about the efficiently efficacy of it. Having said that I realized that the patients who are looking at this often have been through other treatments and are often desperate and this seems to be a safe thing that's not harmful uhm but from a from opening the floodgates potentially to a large number of patients to receive this, I still have questions about that, so that that's my summary.

Sheila Rege: If, if, we did a straw poll, if you were in you know around the table and you did a straw poll today about not cover, cover unconditionally, cover under certain conditions, uh not that we're, we're, not this is not a vote. Where are you leaning towards just for this based on the comments or you need more information need more discussion?

Mika Sinanan: So, Sheila, are you asking us to like raise our hand for each one of those?

Sheila Rege: No, I'm just, just, chronic migraine, I just, just, on chronic migraine.

Mika Sinanan: No, but ok, so one is, non-cover, who supports that raise their hand?

Sheila Rege: I want I want you to just talk.

Mika Sinanan: OK, we can talk.

Sheila Rege: Just you, personal.

Mika Sinanan: Me? Ok, I don't think we have the data to support coverage.

Sheila Rege: K. Now I would like whoever raised their hand next. I think it was Larry Birger was next. I'm trying to keep track and if I've missed it, I sorry Larry.

Larry Birger: No, that's I, I, think I was up. I would say that in a more broad sense we're suffering from a what I might call a funding bias. Those who can afford to fund the studies, uh have a bias in favor of accepting the studies and I have concerns about that, uhm. That, said, I do agree we're wrestling with a lot of uh issues surrounding this because we just I don't feel like we have a lot to go on. I think, what we have to go on does suggest some benefit. I, I, would agree that this is safe. Uh I'm a little fuzzy as to cost because of the limited amount of data but I guess I would be more inclined to cover with qualifications, but I'd, too couldn't honestly tell you at this point what specific qualifications I would be looking at so.

Sheila Rege: Right, I think Janna was next and forgive me if I'm not doing a good job of keeping track of the order.

Janna Friedly: Great, thanks. So, Mika, thank you for that summary that was that was very thorough and, and I, I, agree completely. I, I, think that the available and as Larry said, I think the available evidence that that that I've seen suggests that there's a uh a benefit so there was there had there was no evidence that really pointed to, to, no difference. So and so I, I, lean towards coverage with, with, conditions but I'm, I'm, I'm struggling quite a bit with all of those details about the definition of, of, chronic migraine and who, who would benefit in that we have so there's so much unknown in terms of how many sessions and over what time period and how you, you, know over, uh you know, how you think about this in a chronic condition sort of perspective when it comes to coverage decisions so I, I, think that there's a lot, that that is unknown unfortunately, and we don't have the evidence to really to really guide us, but because it's because the, the, limited evidence that we have suggest some benefit and, uhm from a safety perspective, although I'm sure we are under reporting and I think it's a relatively safe procedure. I lean towards coverage with conditions and trying to figure out what those conditions are I think is going to be challenging.

Sheila Rege: I think John was next.

John Bramhall: Well again, I echo what was just said about Mika's synopsis. Thank you, Mika, it's a very concise and precise way of looking at it, so my, my, personal take is that I'm pretty convinced about the effectiveness from the in particular from the meta-analysis of the two or three more recent studies. So, I look at the look at the diamond graphs and I'm, I'm, I'm convinced that there's an effect but I'm, I'm, happy in this context and with this topic to look at uh essentially an outcome research. I mean, it's essentially that's what it is. We're not, we're not, we're not prying into the mechanism of action and or rationality for why it might be effective in this, we're looking at purely plus minus do those people who present with chronic migraine, and that's the cohort that I'm looking at do they gain benefits and I'm pretty convinced that they do. I don't know that there are specific circumstances in other words, cover with conditions uhm I at the moment I, I, would personally favor coverage of this modality for anyone presenting with a uh with a clear diagnosis of chronic migraine it seems like that's, that's, that's, the condition and here's the treatment and it seems effective so I may be slipping a little over the surface, but that's my take. Now in terms of cost, so I and my, my vote was for from the cost effectiveness is unproven. I don't I don't see that we have a lot of information about cost and, and here's, here's, something that I worry about if we put in conditions, if we were to say

cover with conditions so sometimes the conditions are the you know all other rational treatments have failed and we see this in some of the surgical interventions and it's not inappropriate, but that we, we see that that people have to go through a series of interventions before they're cleared for example, for certain types of lower back surgery or whatever it may be and it seems to me that if we put conditions of that type like you have to have gone through counseling or you have to have gone through Botox or you have to gone through XYZ and then that that condition adds to the cost of the therapy in the end. If you have to go through two or three interventions that are themselves billable to the agency and themselves fairly expensive than the aggregate cost of ultimately getting to acupuncture, it seems to me logically is, is, increased. So, so, my take is that I would be happy to cover for the disease diagnosis with without a lot of hand waving about other therapies, having been tried first and part of that is not, not, a certainty about the effectiveness of these other interventions but it's to do with the ultimate cost of therapy that's landed on so that's my personal sort of feeling at the moment.

Sheila Rege: Thank you, Conor I think you were next and Clint after that.

Conor Kleweno: Great thank you. So, in terms of safety, my intuition is that it is overall relatively safe. I think that's a, you know equal too, uh, articulate on depending on what you are comparing that to. In terms of cost, I did not see evidence that would make it compelling, uh is that it is more or less cost effective and I don't think I was presented with data on the cost of alternative treatments. In terms of efficacy, I, I, did not see evidence that was compelling to me uh in terms of coverage. I think that a couple of comments you know, and, and, with respect to everyone in the public you know, we, we talked about mechanism, and I did cringe a little bit as people stated that it doesn't matter. I think it, it, does matter and, and, whether or not we understand it yet may be determined and I think that getting things wrong and learning again is a is a symptom of success, not failure and so the fact that we've learned things now that are wrong, they were wrong in medical school is success of inquiry and I would say that we need to be consistent with our other decisions. I remember during SI joint pathology we discussed a lot about mechanism, motion at the SI joint, cartilage stabilization with stainless steel, we talked about mechanism. We also talked about the um the effect of, of, treatment on that and so I think that those are valid things to discuss. During that discussion we also talked about levels of evidence and strength of evidence and there was much discussion on industry funding of trials and

how that was a big concern and I was in agreement with that and so I think risk of bias is still a valid thing and important and how we interpret the, the, evidence one of the public commenters asked us a rhetorical question as to whether we need a randomized placebo controlled trial on every indication and I think our response is, if there is a randomized trial, then it is our responsibility to review those and critique those and, and, create an understanding of the of the level of evidence so I did find and specific review of the articles that were presented. Some critiques and concern of mine that that they had some risk of bias uh and so I would vote to not cover on this condition and I think I would sort of put that in the parentheses of again kind of my last question to the guest expert in that are we are, we covering the right thing and, and, I think we brought up the, the, word placebo and, and, whether that is semantics or should be described as by medicine and I think that if we want to change our, our idea of what we're covering because I think we should be specific about what we're covering right. These are, are, this is the populations money that we're talking about and so if it's more appropriate to say we need a person to see a holistic medicine practitioner for 24 visits, maybe that's more apropos and maybe the effect of going into a quiet and dark room with a with somebody discussing with you and a holistic approach, then so be it but I did not see evidence of acupuncture in specific and well controlled trials that would suggest a coverage decision for it.

Sheila Rege: Thank you, Clint?

Clint Daniels: Thanks, got my, my, mute off there uhm. I mean, I, I think acupuncture is, is very, very safe, particularly in regards to serious adverse events, it's, it's almost nonexistent uh and I think it yeah, even more so when you compare it to the other treatments that already are approved like Botox. From a cost standpoint, I can definitely understand why you know pretty much everyone else went with unproven. I voted at as it being more cost effective because of you know when the state data where they showed how much money is spent on this already and, and, how little of that is, is acupuncture, and then also some of the discussion that I think Dr. Birger brought up on downstream potential cost savings, but I agree that the, the data is still, still, yet to be there on that. As far as effectiveness, in the studies we do have it seems like all of them support it, acupuncture being at least as effective as the usual care if not superior so I'm a little confused by, by, some of that discussion. Although I think there is some risk of bias, you know, potentially there as well but I, I, didn't see a single study that supported the usual care things over acupuncture, all of which are already covered so I I'm going to, or I plan to vote, you know with

conditions and then in in a you know, kind of into comment of what Dr. Bramhall brought up talking about sort of maybe you have to try all these other things before you get to acupuncture, I actually think that's the backwards order. I think it makes more sense to start with acupuncture and if that didn't work, then progressed to pharmacology to Botox to these more escalated services so I think I actually think it should be, you know, maybe Botox should require acupuncture first and not the other way around. My main questions as I think about conditions or where the question of a gatekeeper and whether that's necessary, which I didn't hear, really hear a good argument for and in this state even you know, said they'd be open to not, not, happy, in that and then what the coverage actually means how many visits over how much time frame. I think they initially the state said 24 visits over 12 weeks, that doesn't make a lot of sense to me for a chronic condition like migraine that I don't think yeah, I think you get throw you know 80 visits at them in 12 weeks. I don't think it's gonna cure their migraine. I think it actually makes more sense over the year than it does in a short time period 'cause you know when I think about chronic back pain that we managed a lot, I'm a chiropractor, we, our expectation is not that we're going to cure their chronic back pain and they're, they're, going to have it. It's to reduce their symptoms and improve their function and you know, I would have liked to have seen a little more improvement on the, the function data beyond just the MIDAS, you know migraine scale, but I do think it makes more sense for, for a longer-term coverage than, than the short window. Thank you.

Sheila Rege: I'm gonna ask uh Christoph, Christopher and Laurie to just start with I would say cover under certain conditions and within a minute or less explain so we can get lunch. We're into off 15-minute lunch break right now.

Christoph Lee: Sure, you know, I I I'm in favor of covering under certain conditions. I think that there's enough evidence here to say that it's at least effective as other alternative treatments if not more. The costs at least the overall cost per patient data that was shown among the very small population of Medicaid and others in the UMP plan and it's, it's, tiny so you compare that to any pharmaceutical. You don't have to do a cost effectiveness analysis, you know it's gonna be a dominated strategy. So, I I'm not worried about costs. There's low concern for costs, low concern for safety uh you know, reasonable low to moderate evidence for efficacy. So, I, I, just can't see that you know to be consistent, and that this committee

cannot approve with conditions when we approved Botox, which is a lot more expensive so, that's my vote.

Sheila Rege: 59 seconds. Laurie, Dr. Mischley?

Clint Daniels: You're muted.

Laurie Mischley: I said, I agree with everything that was just said, and I'm inclined to vote to cover with the condition that somebody has a diagnosis of migraine and not put many obstacles above and beyond that on the person. The only thing I have to add that I don't think has been brought up is one of the things that I think through it in risk of abuse overuse uhm things like that and the one thing that I'll just say here is it is so much easier to take a pill than it is to drive to a doctor's visit once or twice a week for a period of time and, and, I don't see this being a therapy that if it doesn't work, I imagine the patient gives up pretty quickly. I don't see that this is something that it's not working, and people are keep using this resource so that's just an angle that I haven't heard brought up in something I think factors into my decision. Let somebody try it, if it works, great, we'd probably save some money with fewer side effects. If it doesn't work, they're likely to move on to something else.

Sheila Rege: Thank you. Who hasn't spoken? Christoph have you spoken?

Christoph Lee: Yes, I have.

Sheila Rege: Christopher spoke too correct? [pause] Christopher Chen? Is it just me then? Let me turn my clock on. I would say, oh, Tony that's what I was missing ok Tony go ahead.

Josh Morse: Is Tony?

Tony Yen: Sure, I would favor covering, and the condition would be chronic migraine, to keep it very simple.

Sheila Rege: Right, and I would go cover and I like what the agency medical director, said chronic migraine with the definition of what chronic migraine means because chronic migraine may mean different things for different people. I personally like a referral from a qualified provider for what Laurie said, you know, avoiding abuse and my only struggle is how many. I mean for I think for chiropractors, we have certain numbers so some number after which there has to be a demonstration of improvement in symptoms that would be my, cover those are the conditions I would want to talk about we should take a break. We are, we were only given 15 minutes for lunch. I am going to make that 10 minutes to try and finish in time and

when we come back, everybody think of the conditions and we will start with the agency medical director of chronic migraines and go from there. I cannot remember what time we were supposed to return.

Melanie Golob: I think it is 12:45.

Sheila Rege: OK, good, that's what I thought too, and so I wanted to make sure. Ah I, I know some people have hard stops right at 1:45 and so uh we, we could go one of two ways. One is to take the final vote and work through chronic migraine right now and then do the same process with a straw poll for chronic tension type headache uh and then chronic daily headache. Is that ok with people given that most of the evidence seemed to be for chronic migraine? Hey uh, let us do a final vote just on chronic migraine. Raise your hand if you want not covered.

Melanie Golob: So, I'm seeing two for not covered.

Sheila Rege: Raise your hand for covered unconditionally for chronic migraine. Covered unconditionally, it's two.

Melanie Golob: Yeah, I see that as well. Thanks.

Larry Birger: Sorry quick question when you say unconditionally you mean assuming a, uh a diagnosis of chronic migraine, that, that would be the only condition. It's just what the other people have mentioned is to have the, the accurate diagnosis?

Sheila Rege: Correct.

Laurie Mischley: And, and does that have a specified number of interventions per year?

Sheila Rege: No

Laurie Mischley: Does that is that a condition that separate?

Sheila Rege: Now it's, yep that's unconditional. You have migraine, you want and acupuncture, you can get an acupuncture any day of the week, 365 days a year.

Larry Birger: No and no limit no limit on the amount?

Sheila Rege: No, it's not it's covered unconditionally.

Larry Birger: Oh.

Laurie Mischley: No, I changed.

Janna Friedly: So, Sheila can you, can you clarify that I'm, I'm, sorry though.

Sheila Rege: That's how I read it unconditional coverage means anytime uh and I don't know I can't remember what the state said, anytime that somebody, there's a bill presented for acupuncture on behalf of a patient, that is covered.

Janna Friedly: Does that include the diagnostic criteria because I think that that, that, to me is one of the sort of critical issues here is and defining chronic migraines. Maybe it's not, maybe it's a moot point if, if, no one is, is, it is voting for coverage unconditionally, but…

Sheila Rege: Uhm, because I, I, think, yeah, I, I, think chronic migraine, what if one person says this person has chronic migraine but it's not, it's 10 times my in my definition, it's 10 times or more per month?

John Bramhall: Well, OK, so if we're treating the definition of a course of therapy as a condition, I lower my hand.

Laurie Mischley: Me too.

Sheila Rege: OK, so that was zero covered on anybody who wants to cover unconditionally raise your hand. Cover under certain conditions raise your hand.

Melanie Golob: And I'm counting 7 for that.

Sheila Rege: So, are we missing one?

Melanie Golob: Yes, then you will not vote.

Conor Kleweno: I I, I got on one minute late when you were discussing cover unconditionally, so perhaps I have not voted. Did you did, you did you?

Sheila Rege: Let's go back, Melanie will you go walk us backwards? Let's everybody lower hands.

Conor Kleweno: No.

Melanie Golob: Yeah, and so we can start again at not covered if you like Shelia.

Sheila Rege: Yeah.

Melanie Golob: So those voting for not covered for chronic migraine, raise your hand otherwise keep your hand lowered please. So, I have three.

Sheila Rege: So that's 10.

Melanie Golob: Yes, so we probably don't need to go back to the others.

Sheila Rege: Correct.

Melanie Golob: Yeah.

Sheila Rege: Uhm, can, we can, we project what the agency medical director had as definition of chronic migraine and the other two conditions that were there and see if anybody is OK with that or would like to suggest you could make that bigger for some of us? So, it says chronic migraine headache, occurring on 15 or more days per month for more than three months at least eight days per month and has the features, we can say clinical features of migraine headache. Everybody OK with that, if everybody is OK with that first definition of what a chronic migraine is, raise your hand.

Melanie Golob: So, it's seven.

Larry Birger: Could you clarify where we're getting that? Uh those parts area 'cause I mean to me; this is highly arbitrary, and I don't know why acupuncture would work if you had eight a month but not if you had six. This I mean, just that doesn't make any sense.

Janna Friedly: Yeah, that's what my question was too.

Sheila Rege: Ah, I assumed that that was a definition of chronic migraine. Uhm Emily are you on the call still can you help us?

Emily Transue: Yep. Yeah, so this.

Natalia Murinova: I'm here, this is Natalia Murinova.

Emily Transue: Sure, this, this comes from or until you can go ahead, but, but the origin of this definition is the um International Headache Society 's definition of chronic migraine, um.

Natalia Murinova: This is a standard as Emily said. This is a standard definition that we accept in the US. It's International Headache Society criteria. That's what we use currently for diagnosis of chronic migraine in US for any insurance isn't for any medical diagnosis. So, it's more than 15 headache days per month of it could be tension type, headache or migraine type, headache, but at least half of those, and have they defy because it's 15 as eight dates per month have to meet criteria of migraine type headache and maybe what we should include because for people who don't know migraine type headache. There is the International Headache Society what migraine is because for people who are not familiar with migraine this might be confusing.

Emily Transue: It if you want, if you wanted us to project that full definition, we could as I think was called out earlier. It's, it's, fairly extensive and we felt as

though it would be too cumbersome to include in a coverage decision but if you'd like me to project.

Sheila Rege: No, I, I, think you can only, you can just say you can put an asterisk and say, excerpted from and either reference so everybody knows that this committee has looked at a definition that we didn't pick out of the blue. Would that be acceptable to the committee in the interest of time?

Mika Sinanan: Sheila, Mika could we just reference the international headache definition and not write it out because it...

Sheila Rege: Right, that's why I said, asterisk, it and on the bottom just say and excerpted from the International, is that?

Janna Friedly: I think I think it's just me, I think it needs to be more clear, though, that that we're using those that it's not, it's not just taken from that based off of that but that that those are the criteria that we that for, for, the diagnosis that that we find acceptable.

Sheila Rege: So, any, any, good wordsmithing here? Right, like we can say must meet criteria ask per but, guideline.

Larry Birger: I would prefer that because what if they changed the guideline definition and we've spelled it out so specifically.

Mika Sinanan: Yeah, I agree.

Janna Friedly: Yeah, makes sense.

Laurie Mischley I just have a quick question about the diagnosis too, do the acupuncturist make diagnosis like this? Is this what an acupuncturist chart note looks like in in terms of justifying the intervention or is the patient come with a diagnosis from conventional medicine, saying and the whole acupuncture thing is just cheese liver stagnation stuff?

Kathleen Lumiere: It's, it's, mixed. It includes a bio medical diagnosis, as well from, from, a primary care provider. There's typically and when we when we bill insurance we would, we would check criteria. When we yeah, when we say uhm for instance, two sessions or 15 minutes of acupuncture to treat chronic migraine then we will look up and say, oh, what is, what is chronic migraine does it fit this and then that has to be in the chart.

Sheila Rege: So just for us, typing by the most recent is at the international classification of headache disorders is that what we're referring to.

Gary Franklin: See International Headache Society.

Sheila Rege: International Headache Society on online. I'm looking at it says ICHD is that what we're talking about.

Gary Franklin: Headache.

Emily Transue: Yeah. And then

Sheila Rege: So.

Emily Transue: I have come. Is it ok for me to talk?

Sheila Rege: Yeah, help us.

Emily Transue: And just so.

Sheila Rege: Re-word, phrase that.

Emily Transue: Yeah, well, one of one of the reasons that we had gone with there, they have a they have a word definition, which was the one that we put in here, but then they also have a criterion based definition, which is many, many pages long and I I guess maybe you don't have to include this in your decision, but in helping us to understand how to implement this, uh I can envision a scenario in which there's a utilization management person with a well, you didn't specify each component of the multipage definition of this, according to the ICHD, I'd assume you would be leaving us some discretion on what degree of documentation, we required around this.

Sheila Rege: So, but I I think we can say by the most recent international classification of headache disorders or where they call it, ICHD or a minimum of and use your what you had previously is that acceptable to people or headache occurring on 15 or more days and, and, you have to say, and has the clinical features of migraine headache on, on, that last. Oh, I'm so I wanna sit down and type here.

Josh Morse: I'm sorry, where do you want me to type?

Sheila Rege: Uh and so just by better English, it would be headache, occurring on 15 or more days, which on at least eight days per month has the clinical, oh that's fine if that's good English, works were good.

Mika Sinanan: So, Sheila where the, the cursor is right now, just back up.

Sheila Rege: Ah. I agree.

Mika Sinanan: Just, just, delete back, then, and put a colon right after the yeah, keep going back a little bit no.

Sheila Rege: That has to be.

Mika Sinanan: Keep going back yeah, put the colon in there.

Sheila Rege: Yeah, but uh call up.

Mika Sinanan: Now, headache, yeah.

Tony Yen: Sheila do we need to spend time on redefining a rewarding what the, this society definition is? Like I, I think let's just use a society definition.

Sheila Rege: No, I wanted to actually Mika or at minimum because the society is only going to get less. I, I, kind of want to give I don't want like Emily said uh agency medical director denying it saying you know you don't fulfill all. Emily, help me out there, I, I, could see what you were saying, I've seen it denied on an interpretation, so I want it really.

Mika Sinanan Tony I think what, what, Emily 's point was that there the definition is, is, multi pages and so the documentation requirement could be interpreted differently by folks who are reading the definitions so to make it more operational, she requested that we include the short version here rather than just refer to the definition 'cause its many pages long with lots of specific criteria.

Larry Birger: And I would agree with that, having heard that when I when I made my prior statement, I didn't realize that I was opening or you know, potentially getting people to enter into that morass having been there myself in the clinic.

Sheila Rege: Laurie, Laurie has that been patiently waiting with our hand raised and sorry I wasn't looking Laurie.

Laurie Mischley: No, no, it was an accidental hand raise but I am laughing to myself that people are going to spend more money getting the correct diagnosis for their headache type then it would cost to do a series of acupuncture treatments and find out if it goes away.

Sheila Rege: Alright.

Laurie Mischley: Like I do think on some level like, I, I am not entirely separating how we're dissecting these headache types. I mean, there is a trend towards even tension type headaches, trending toward improved outcomes with acupuncture, there was lower quality evidence. We voted against it overall in terms of not being that impressed with it but even chronic tension type headaches look to be somewhat improved have some potential for therapeutic benefit with acupuncture and so we're talking

spending a lot of time talking about how to slice headache types, according to a paradigm that acupuncturist don't use to offer the help that they're offering people and it just, this, kind of disrespectful and silly in my mind, I mean, I, I, think we're here to ask might we be able to help people who are suffering with this expensive debilitating condition with a low impact low side effect intervention and I don't strongly favor slicing and dicing all these different headache types that extensively at all. I think these are inexpensive barrier we're placing on patients and practitioners that doesn't really jive with the therapeutic that we're talking about.

Sheila Rege: I hear your concern, and, and I, yeah, but you know, we it's just the, the conundrum is we are, we have, we have charged to be evidence based so let's continue mark chronic migraine.

Laurie Mischley: Do what's their criteria in the studies that we use to review this evidence to what they do, I mean, we should stick with whatever intervention, whatever criteria they used to let people into the studies is what we should stick with here.

Sheila Rege: We can have the experts answer that, but I thought they divided it all up by chronic migraine versus tension type versus daily headaches, that's what I was saying.

Larry Birger: Well, you know, there's one other point to throw in, Sheila that it's in the real world is eminently relevant and that's for every visit that has to be scheduled to qualify a, a diagnosis of migraine chronic migraine rather that is that much less access for somebody else in the health care system.

Sheila Rege: Larry once you are diagnosed with chronic migraine, I don't think you requalify. It's like once you have cancer, once you're pregnant you're pregnant so I, I, don't see that.

Larry Birger: If it's a, it's in numerical definition, I mean? I don't know.

Sheila Rege: How many, how many would vote, let's, let's, go for a vote because I'm just worried where and I know we're going to lose people. People have told me they've hard stops. How many let's do a vote on this wording off the first, just the first not even referral everybody in favor of that to move us forward.

Mika Sinanan: Sheila, Sheila, Mika, a can I just make a, another suggestion here? Some of the data on previous studies were for, for, 12 days as we saw in this in the review some were 12, some were 15. Larry has made the point that it, you know, I cannot it seems to me, that if you have chronic headaches

for 12 days of a month, that's a bad problem and that still keeps you from working and being productive. So, I would suggest if we're going to go with coverage with conditions and there is data to support a benefit at 12 days that we change it from 15 to 12 days.

Sheila Rege: But then you are changing a standard, you're changing an international headache standard.

Mika Sinanan: And that's, that's, the downside, but I'm just saying from the data on the on the basis of the studies that were reported to us some included 12 days.

Larry Birger: Or changing an arbitrary standard. I, I, don't know what the negative consequence of liberalizing it slightly would be except that maybe more people would be helped because I do think that Laurie has, has, made a very important point about a disincentive to abuse of this therapy uh and that's just the logistics of it and including in the face of rising gas prices, especially if you live in a metropolitan area.

Sheila Rege: I, I, guess I was, just as a cancer doc, I struggle because I, I, go for standardization and we are supposed to go by standardize it, you know use a standardized reference. So how many would be in favor, then you'd have to rephrase this to say ‘or’ headache occurring. How many would be in favor of um leaving the all of our guideline referencing international classification? Raise your hand now. I mean, I'm, I'm, just trying to get a sense of the committee. Oh, there's hands raised.

Christoph Lee: Sure.

Sheila Rege: Conor?

Conor Kleweno: Oh no, I was just raising my hand for the vote. Sorry.

Sheila Rege: Ah. Christoph.

Christoph Lee: Yeah, how about because there's this whole 12 versus 15 thing, can we just combine the first two bullet points to say, ‘must meet an official diagnosis of chronic migraine made by a qualified provider’ and that gives a little more wiggle room, but they're gonna have to get an official diagnosis from a qualified provider by whatever definition that provider uses in their clinical notes?

Conor Kleweno: That's a good idea, I like it.

Laurie Mischley: Like it.

Tony Yen: Yes.

Christoph Lee: So, just must be diagnosed with chronic migraines by a qualified provider.

Janna Friedly: I think that's significantly liberalize is this. I mean, so I I that's the, the risk that you.

Christoph Lee: Yeah, but I, I think yeah.

Conor Kleweno: I think also takes out the reality of what you know in in in practice, you know, I think we all realized that perhaps some of the documentation is adjusted to meet criteria so that the patient can get reported and not to be too much of a cynic, but that's probably the reality and this allows the treating provider to do what they do and make a clinical judgment.

Sheila Rege: How many let's, let's, take a vote. How many would be in favor of that phrasing?

Larry Birger: I would agree.

Christoph Lee: Yeah.

Sheila Rege: Uh and then the other choice that'll be, choice A, like going to an optometrist and choice B, would be the most recent international classification, so how many in favor of chronic migraine by a qualified provider, please raise your hand? Did you count that Melanie?

Melanie Golob: Yeah, I see seven.

Sheila Rege: And how many would prefer to have a standardized, that the second one the standardized classification.

Clint Daniels: Is Kathleen on? I, I, have a question and I'm, I'm, curious on if acupuncturist can diagnose migraines or is this outside their scope and in requires another provider to do it for some reason?

Kathleen Lumiere: Thanks for asking yes, in the state of Washington, we would not diagnose. We we, we would use a diagnosis for coding purposes, but we wouldn't we're not, we're not primary care providers in the state so we wouldn’t make the diagnosis.

Clint Daniels: Thank you.

Sheila Rege: OK so that that first so we're going to then remove ‘must meet criteria for chronic migraine’ that whole, yeah and now, now, is the uh, how many sessions are, 24 sessions up to 12 weeks? Uhm, uh Emily would you

tell us how you came up with that? Was that based on claims data or? Uhm.

Emily Transue: No this is based on, uh on, on, the studies that were reviewed in the evidence report and sort of where most of them. There was one that went up to 20 weeks but the majority of them were looking at 12 weeks. I think you've had discussion earlier today around that perhaps being inappropriate in terms of developing a policy so we're, we're open to whatever you decide on this, but that was the origin of it, was looking at the studies.

Sheila Rege: And then if it helps then you go, then, then you start another 12-week time frame, is that what's being envisioned if it's written as is?

Emily Transue: Yeah, that if someone needed another authorization, they would request another authorization.

Sheila Rege: So, we 24 / 12 weeks times, however many they need still maximum I guess would be, yep for the full year.

Emily Transue: But again, we're, we're, open if you want to change that.

Sheila Rege: That's seems fairly liberal, does anybody want to change that? How many would like are, are, ok with it as written let's take a straw vote, straw vote?

Janna Friedly: I'm sorry can I, can I clarify? I'm sorry, so what you just said was that they would get 24 sessions up to 12 weeks but then they could get reauthorized after that, so they'd have to request and is that that part of what we have to decide here in terms of criteria or is not that beyond the scope, that, that's in implementation? Uhm, I'm

Josh Morse: I think that would be an implementation issue that Dr. Transue may have.

Larry Birger: What did Dr. Lumiere say before about the amount of visits and how long it would go in an ideal world I can't remember specifically?

Kathleen Lumiere: I said, I thought the 24 would probably work over the year but, but, yes uh someone comment about the 90 days, wasn't consistent with clinical practice.

Larry Birger: So why are we limiting this to 12 weeks as opposed to a longer period of time with the same amount of sessions?

Sheila Rege: So, so I'm, I'm, here, here's where I'm looking at this, this is actually more liberal because you do your 12 weeks and then if it doesn't, if it's really

helpful, you asked for more and you can go up to 104 in a year. So, in my that's true that is true, I mean in my so, I, I, don't get why were you know, but

Janna Friedly: But then how, how, does who, who, decides or how do you decide whether to authorize that second round? What, what's the criteria for that? Does everybody, if they meet the, the definition of chronic migraine they?

Sheila Rege: And it's helping. I would assume I mean?

Janna Friedly: Well, but that that's not spelled out in this that that there's no criteria that it has to be helping so that that that's where I was confused as to how you would implement that and whether that's part of what we need to think about if it's written this way.

Sheila Rege: Dr. Transue, is that?

Clint Daniels: I, I, think the year makes the most sense, that it strikes me as very over utilization if they were just use it every 12 weeks get a new one and there are people that will do that and, and, both you know, people in practice and patients that will want to get it as much as they can get it covered for.

Sheila Rege: Alright. So, should so are we looking at 24 sessions in a year?

Clint Daniels: I like that.

Laurie Mischley: I think that's reasonable.

Tony Yen: Can we ask her expert for that opinion as well? Like I do not perform acupuncture, but the expert has more experience than us.

Kathleen Lumiere: Thank you, pardon?

Tony Yen: But Dr. Lumiere would that be 24 sessions like over a year be a reasonable super thing because I, I think my hesitancies kind of compressing everything within a very short period of time versus making sure that a person has enough sessions or like a year or some reasonable period of time.

Kathleen Lumiere: Yeah, up to 24 sessions over the course of a year would I think allow for the, the, the differences from person to person and how they present and what helps them manage their care.

Tony Yen: K.

Sheila Rege: So, this is how it looks, does anybody have any more conditions, they wanna add?

John Bramhall: I, I, don't have a condition but I'm just curious now and now I don't remember the data as well as I should but this, this does this quote work if you do it once every two weeks or, or is there an element of intensivity that's required? So, I, I, don't wanna you know, so I don't want to get into this, this is black hole, this this last one here but if you say 24 sessions and you did it in burst over three or four weeks and it worked, and now you're locked out and I just don't, I don't know the data does, does, the does the therapy, is it effective if it's given once every 2 weeks?

Conor Kleweno: Donna said my, my, comment would be, I think these are the side effects of insufficient data. There's a lot of heterogeneity and treatment and, and research methodology and the level of bias and so I, I would say that this challenge we're facing is absolutely a side effect of, of, those limitations.

Mika Sinanan: I agree.

Sheila Rege: John I think those leaves it up to the clinicians and I suspect if it doesn't work with patients not going to come back.

Larry Birger: I, I, would have to defer to Dr. Lumiere or somebody of similar qualification as to you know trying to get something that is sufficient. I think an advantage of putting this over the course of a year is that we've also hopefully helped minimize administrative, uh tangles and that's always at a cost as well.

Sheila Rege: I will accept a motion. Ok, we will hear from the clinical expert and then I will just in the interest of time, since we have 25 more minutes to do the other two, the motion soon to accept language as is.

Kathleen Lumiere: So, Dr. Bramhall makes an excellent point. If somebody has a an extremely severe condition that's well managed by very frequent acupuncture, uh if, if, if there was a uh a proviso, a way for them to petition for, for, for more, but I would think for most cases, almost all cases, the 24 sessions over the course of a year would be sufficient and visits would be more frequent toward the beginning and then start to be spaced out.

Mika Sinanan: Mika Sinanan and based on that suggestion I would make a motion to approve it as written.

Clint Daniels: I just have a quick question.

Sheila Rege: Clint.

Clint Daniels: Do we need a comment about those that don't quite meet the criteria like acute, subacute, episodic that they're outside of the scope does that need to be, that language need to be included or is that just implied?

Sheila Rege: Well, let's, let's, wait because we haven't yet done chronic tension type headaches and this is just migraine, frank migraine.

Clint Daniels: Sure, sure, yeah, I I meant acute migraine, though, acute, subacute episodic, though, so say they have ten days and don't meet the criteria is that outside the scope on whether they would be covered or not or are we saying they're not covered because they didn't quite meet the criteria? I just try to understand that little difference.

Sheila Rege: I think if the primary care physician feels it's chronic migraine they will qualify.

Emily Transue: Can I –

Sheila Rege: Go ahead.

Emily Transue: I think it would be outside of the scope. So, yes, your review didn't include people with episodic migraine so I think you would not be commenting on that one way or another and it would fall to the policy of the carrier outside of this decision if they didn't.

Sheila Rege: Dr. Transue, do you want that clarified so somebody from Regence doesn't ask for it?

Emily Transue: Uhm, so, uh yeah, we could say yes, I think we could say in the in the scope, perhaps expand it, you know it says this decision applies to adult 18 years and older with chronic migraine or tension type headache. I mean, it's good. Oh God don't take that out. So, we're putting it up, ok got it.

Sheila Rege: I got a, a, motion to accept just for chronic migraine the language and I think I got a second. Any more discussion? We will go for a vote of the language just for chronic migraine as is.

Larry Birger: Sorry, one quick conclusion I think, just as a respect point you should put MD comma DO comma, PA.

Laurie Mischley: ND.

Sheila Rege: Deal. Are NDs uh qualified in the state of Washington?

Laurie Mischley: Uh-huh.

Sheila Rege: OK. Anybody we're missing who's qualified because there is an ex-cetera.

Josh Morse: Right or should we just leave it as, as, qualified to diagnose and remove the specifics?

Laurie Mischley: Even better.

Sheila Rege: In case that changes.

Josh Morse: Yeah, that is that OK.

Larry Birger: I think that's a good idea, I, I agree that's a good idea.

Laurie Mischley: Yep.

Sheila Rege: Everybody let's vote, yeah for just a chronic migraine language, the language as is, raise your hand.

Melanie Golob: So, I see all 10.

Sheila Rege: Hey let's go back and so we've got to think about this, we usually have a break, but during that break, we're gonna make all of us work. Let's go back to chronic tension type headache and do a straw poll of ah efficacy, I'm sorry safety first. It'll be the same safety profile.

Melanie Golob: Is that same comparison to?

Sheila Rege: Yeah, whatever the alternative treatments are, and um let's raise our hand for unproven on safety.

Melanie Golob: I see seven.

Sheila Rege: Go ahead and lower your hand please. Uh let's uh on safety ‘less safe’ for chronic tension type headaches. Larry is that you or is that you haven't lowered your hand, I can't remember.

Larry Birger: I'm sorry, no, I, I, uh, one moment. I would say ‘unproven’ I, I apologize.

Sheila Rege: Ok, uhm, ‘equivalent’. I'm going to lower your hand there. One vote for equivalent. ‘More safe’ in, in some. Two for ‘more safe and some’. ‘More safe in all’ or did we already have ten?

Melanie Golob: I think we're at ten, yeah.

Sheila Rege: Yeah, let's move to efficacy on the straw poll and this is for chronic tension type headache. So, acupuncturist compared to other standard

treatments and in terms of efficacy. Uh everybody who believes it's unproven, raise your unproven card.

Melanie Golob: I see nine for that.

Sheila Rege: Yeah, we're lowering. Everybody who thinks it is less in efficacy. Larry was that you or was that uh leftover? Right, I don't see any 'equivalent', 'more in some', one and I think we got that's ten.

Melanie Golob: That's all 10 yeah.

Sheila Rege: OK and now we go to cost effectiveness or value for chronic tension type, headache acupuncture, 'unproven'.

Melanie Golob: Looks like all 10.

Sheila Rege: Right, uh if you will put that into the uh, sorry somebody trying to talk? Did I miss somebody trying to talk? Right. So, we are chronic tension type headache and we're just gonna get our summary and be prepared to do a straw poll on everybody who says it should not be covered. Uh we start raising your hand.

Melanie Golob: I see nine for not covered.

Sheila Rege: Lowering hands. Ah anybody who thinks there should be covered unconditionally, please raise your hand. Anybody who thinks it should be covered under certain conditions for chronic tension type, headache raise your hand.

Melanie Golob: I see one and that's everyone.

Sheila Rege: Ah, any discussion on that for chronic tension type headache, please raise your hand for discussion. I see one hand raised, Dr. Lumiere?

Kathleen Lumiere: Hi yeah, it's a, it's a concern of mine that the, this committee unfortunately didn't have because of the scope didn't have access to the research that was lumped together, because the data are still sound. So, I'd like information about how to provide that after this is over.

Sheila Rege: Yeah, and there is a process and I uh, uh Josh, staff can we help direct others who may also have that question on how to get that submitted?

Josh Morse: We can.

Sheila Rege: Any other discussion? Uh we also have and, and I will ask the committee how to do this uhm in our final a coverage determination, we are also going to have chronic headache, correct, not just chronic tension type

headache? Uhm, can we go back to a coverage decision, what we've typed up? So chronic daily headache, uh how many are comfortable or how many are ok with acupuncture not covered based on the evidence for chronic daily headache, please raise your hand.

Melanie Golob: I see nine.

Sheila Rege: Please lower your hand. How many for chronic daily headache would like it covered with conditions? Mika is that you, are you voting twice? OK, one.

Conor Kleweno: I think he sort of page.

Melanie Golob: One.

Sheila Rege: I, I, see that now. Uh is that 10.

Melanie Golob: Yes, it is.

Sheila Rege: K, uhm, we usually take a coffee break at this point to review this we have that in our recommendation. Uhm, why don't we take a two-minute break and stare at the screen? When we come back at 1:35 and I think we can despite what our processes. So, we'll break till 1:30, two minutes just to kind of conjugate. I uh I do have a question for staff on notes we have from IHS, I thought we deleted that, yeah, ok. Any I'm back, and it's been 2 minutes, any discussion? Will there be any issues about are qualified to diagnose per Washington state would be my question for the agency and Janna has a question too.

Janna Friedly: Yeah, in my mine is related similarly my, my question is, is this consistent with um coverage decision language for other treatments for chronic migraine in terms of the diagnosis of chronic migraine and is that going to, if there's a discrepancy, is that going to be an issue?

Sheila Rege: I mean? Question for Dr. Transue and others, uh do we have to say qualify to diagnose by Washington State Legislature or RCW code or or make it more. It, it, seems a little loosie to me, but maybe it's appropriate.

Emily Transue: Wait, I'm sorry, misstep is a little bit of time to look up the existing um. By agreeing decision I've looked at it before and partly, partly, based are chronic or wording on being consistent with the old ones so I'll, I'll, look at, I'm pulling that up or maybe Josh is as well in terms of what we said before around Botox but what was the other question that had to do with the RCW? I'm sorry.

Sheila Rege: I think they're the same. It just verification.

Janna Friedly: I think Sheila's question was about uh is it sufficient to say qualified by Washington state or does it have to be more specific in terms of what qualified by Washington state means?

Sheila Rege: Like a licensed provider or you know something that? You have to be licensed to.

Emily Transue: Ah, I see, yeah, I think we don't need to be more specific on that or you could say Washington State Department of Health, but I don't think we need more specificity on that. There are a number of different rules that apply to scope of practice, uhm I, I don't think that that is unclear pics are calling this out.

Janna Friedly: Yeah, and I, I, think this this highlights to me when you know the inconsistency and our definition, not using the International Headache Society and then this also brings up the second issue that we, we, we talked about earlier, but we didn't we didn't acknowledge here was medication overuse, which we heard from our experts that if you don't address that, then it's not going to be effective, and which seems like it's the same thing I'm I'm, it's slightly different uhm can, concerns with Botox, but, but, is that something that we need to include in here to be consistent and this also has more specific criteria about ah, the need to show improvement.

Josh Morse: I believe that's based on the labeling.

Janna Friedly: What do you mean?

Josh Morse: For the use of Botox, I think that may be a part of the labeled indication.

Sheila Rege: There must be discontinued as what you're saying Josh.

Josh Morse: Yeah, I think that was specific to the evidence review and possibly the, the label you know.

Janna Friedly: OK.

Sheila Rege: So, Janna are you are you advocating that we consider going back to defined by the International Headache Society versus leaving it up to the licensed practitioner?

Janna Friedly: Well, I, I, think I think we have to acknowledge that we have different, different criteria for two treatments that the same patient maybe uhm considering or you know, and, and, so I, I, think from it, it seems like that

could create, no pun intended, headaches for the agency. Uhm, so, uh in in my mind, I, I, was in favor of including the International Headache Society criteria uh in in the first place, but to me, to me at and it, it, doesn't jive with me to have different criteria.

Sheila Rege: You can make a motion to go back to saying yeah, uh for treatment of chronic migraine as defined by the International Headache Society, to, to put the words back in and see if see if others feel the same way.

Janna Friedly: OK, I'll make a motion to include to change the language back to for the treatment similar to this one to be consistent with this one for the treatment of chronic migraine is defined by the International Headache Society.

Sheila Rege: Can we go back to our wording that we have currently?

Tony Yen: And I just simply second Janna's movement suggestion.

Sheila Rege: OK, thank you for doing that, yeah, I shouldn't have taken it without. So, for discussion where would, you must be diagnosed with chronic migraine and then just add paragraph or hypoth you know as defined by the International Headache Society.

Christoph Lee: Can we actually mirror what we just said for the botulinum toxin? Just because it's not a condition that International Headache Society is mentioned in, it's in the lead up to the conditions for Botox. So, if you go back to the Botox wording.

Sheila Rege: It says limitations it says limitation.

Christoph Lee: It's not. No, for, for, chronic migraine as defined by IHS, it's covered with the following conditions and so the definition is in the lead up to the conditions, the criteria that need to be met, right? So.

Sheila Rege: I don't see that I see it as.

Christoph Lee: For treatment of chronic migraine as defined by age is, it's covered when the following criteria are met, so I adjust as mentioned before the criteria are listed.

Sheila Rege: Janna, what is your motion?

Janna Friedly: Well, do, we if we take that out, do we have criteria, wait, what? When the following criteria, yeah, so, we, we have criteria. So, yeah, I, I, would say let's be, I would be consistent with this language, so I, I, I, I, agree, I think that makes sense to mirror it so that if

Sheila Rege: So, you would, you would add three prior pharmacologic prophylaxis?

Janna Friedly: No, no uh we're just saying uh, for, yes, yeah, so the scope right there, I guess is yeah for, for, chronic migraines as defined by the International Headache Society, acupuncture is covered is a covered benefit with the following conditions and then, uhm.

Josh Morse: So, put it here?

Sheila Rege: Is uh covered is, is, is, covered when the following criteria are met well? Janna, I'll let you dictate where you want it.

Janna Friedly: Yeah, now we're, we're, redundant here, so maybe, maybe.

Josh Morse: Right now, which one do you want? I I'll take out the one you don't want in. I was just putting it in. Want me take out the second one?

Laurie Mischley: Right. I, I, think we're getting close to cover unconditionally for up to 24 sessions for anybody who has been diagnosed with chronic migraine as defined by the International Headache Society. I mean, we're basically saying.

Janna Friedly: Yeah, right, but that's like there's no there's no other conditions other than you have to be diagnosed with chronic migraine by these criteria and it's up to 24 sessions, so that's where I'm struggling it, you know must be diagnosed you, you, you, could say that a criteria is that it, you have to have a diagnosis by a qualified provider I suppose but I'm not sure if that's necessary, but

Conor Kleweno: I'll make a motion, that this looks fine.

Emily Transue: One other piece of language that you have in the other definition is the option for additional visits at agency discretion on that that language was in for additional um Botox and just remembering there had been a question rates briefly about people with more severe headaches and whether you wanted to leave an opening for that. So, I just thought I would toss that in, not to make things even more complicated.

Janna Friedly: I think that makes sense to add that um additional sessions may be considered at the discretion of the agency or, or whatever the same language was for the Botox.

Laurie Mischley: I would support that.

Sheila Rege: Additional treatment cycles, uh do we consistent may be considered at agency discretion. Anything else you want and we'll, we'll, highlight that

so we know that's a change. Anything else we want from, to make it consistent with the Botox, which that but that could be just the labeling discontinued if it is shown inadequate treatment or leave it?

Janna Friedly: I, I, think given that that wasn't, I, I think I would leave it out myself as Josh pointed out that was part of the labeling for, for, Botox and um and, and so I, I, think coming up with criteria that are evidence based, it's there's nothing, nothing, that we had that would guide us about that so. So, I, I, I would, I would say we should leave it as it is I know we're over time.

Sheila Rege: Everybody OK with this? There is an inconsistency which is that you know because we brought it into chronic migraine, The International Headache Society chronic tension type is, who knows who's diagnosing that or daily headaches but I'm OK with them. Uh, any other discussion before we take a vote? Do are we comfortable with accepting both highlighted changes? Please if you are, raise your hand.

Melanie Golob: I see seven.

Sheila Rege: Ah. Please vote if you preferred it without the highlighted, please raise your hand. I'm confused about why we didn't get ten.

Janna Friedly: I think over, we're past 1:45.

Sheila Rege: Uh people left, Josh is not OK, but we still have a quorum.

Josh Morse: You have seven you still have a quorum, yeah, I see. I think you have seven committee members currently present.

Sheila Rege: OK so we're good with that, so this is the language we have accepted. Let's go onto review of Medicare coverage. We've already determined there's no Medicare national coverage determination and in our then we can project it clinical practice guidelines, we've talked about it. Do you want it projected and Josh help me out, am I missing anything?

Josh Morse: I, I'm trying, I'm switching documents here so, uh we, we do need anything to do, have we done the final vote, the formal final vote?

Sheila Rege: Yep.

Josh Morse: OK, Melanie, have that documented can you give me the numbers?

Melanie Golob: Yeah, so uhm. So that was let's see that one was three, zero and seven, so three ‘not covered’, zero ‘covered unconditionally’, seven ‘covered

under certain conditions' and then for chronic tension type, nine 'not covered' and then just one covered 'under certain conditions'.

Josh Morse: And then we did do a vote on chronic daily as well?

Melanie Golob: Yeah, and that was the same as chronic tension type, yeah, nine, zero and one.

Josh Morse: Thank you. So, you want to, these are the guidelines is this what you wanted to see Dr. Regge?

Sheila Rege: Yeah, just for completeness, we needed to make sure that we're still ok after reviewing the guidelines and it's in our package. If everyone is ok, we're going to keep going.

Josh Morse: That is the extent of the guidelines.

Sheila Rege: Then I will, if we're done, I uh Josh will you tell us when our next meeting is and topics and then we will take a motion to adjourn?

Josh Morse: Thank you our next meeting is scheduled for Friday May 20th. It will be to consider these determinations here. We are currently working on the selection of transcranial magnetic stimulation; it will be in a new conditions being considered for that topic. We have not completed the selection process yet, but it is past the first mark is a proposed topic. We had a comment period on that. We have uh at least one signal search in in the works right now for stereotactic body radiation therapy, which we are nearly complete on the signal search in that will inform whether that needs a re- review and the other announcement I have is we are hiring a new program specialist since our program specialist Christine Masters, she did retire at the end of 2021. If you want to talk about any of that or anything else, happy to take those questions and thank you so much for your, your, work today. So, it's going great discussion.

Laurie Mischley: Thank you everybody.

Sheila Rege: Motion to adjourn. And.

Sheila Rege: OK, all right. Thank you, guys, bye thank you.

Christoph Lee: Second.

Josh Morse: Thank you.

John Bramhall: Thank you.

Clint Daniels: Bye everyone,

Kathleen Lumiere: Thanks so much. Bye. Bye.