Washington State Health Care Authority

Washington State Health Technology Clinical Committee Meeting

Vertebroplasty, kyphoplasty, and sacroplasty

January 31, 2025

DISCLAIMER

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

Val Hamann	I think we are still waiting on a couple of members.
Josh Morse	Yeah, we need to have a quorum first. I will just make a, just a cautionary comment. Our agency in a different public meeting recently had a Zoom bombing incident and so we are being extra cautious today about elevating attendees to the panelist level for comment. We will do the best we can, we have no anticipation that will happen or that there will be an attempt, but there was an experience in the agency a week ago with that so, um, they were, it occurred they were using slightly different methods using the same technology when that happened, I just want to forewarn you since we have not had that in our meetings and we hope it doesn't happen here, but unfortunately that is apparently a risk.
Janna Friedly	And Josh, sorry. With that can you explain what, what, what that means exactly and what the protocol is if something like that happens?
Josh Morse	Yeah so when we manage public comment for these meetings, we have panelists as committee members are currently elevated under Zoom as a panelist, so you have access to your camera and your ability to speak and then we have attendees who have less technology access including the chat which is dysfunctioned, dysfunctional, I think for all of us. What we understand occurred was an attendee, not an attendee, but a person, they were not using the same level of control in that moment in that meeting a person with ill intent a person was able to share information visually and orally that was very offensive during a public meeting.
Janna Friedly	Okay
Josh Morse	It's not the first time this has happened, but it is the most recent and it just reminds us about what we need to do. I think if that were to occur, you know, we are just trying to be hypervigilant about that, but if you know, I think if it was something we suddenly needed to control, we would have the quickly end the meeting and or reconvene, I think, but.

Janna Friedly	Okay.
Josh Morse	We will do the best we can, but I just wanted to give you a heads up about that recent experience.
Janna Friedly	Okay.
Josh Morse	Yeah.
Janna Friedly	Okay, so if the meeting is suddenly ends, we should be instructed to rejoin, is that, is that the?
Josh Morse	Yeah, I think yes.
Janna Friedly	If something were to happen like that?
Josh Morse	Yeah.
Janna Friedly	Okay. Great. Well why don't, while we're, while we are waiting for quorum, I'm not sure if we have that yet, I can at least get the meeting started and for those of you that I have not met, I am Janna Friedly, I am chairing the committee today. I just want to thank everybody for joining us today and as a reminder to everyone, this is a public meeting and the purpose of this meeting is to help the state of Washington to ensure that we are, that the health services used and paid for by the State are safe and work as intended, so this is an open process and we are relying on evidence based information today to make decisions about safety, efficacy, and cost-effectiveness, so do we have a quorum today, yet?
Val Hamann	We do.
Janna Friedly	Okay.
Val Hamann	Yes, we have all 10 members that are currently on the committee.
Janna Friedly	Okay. We have a packed agenda today so we are going to try and make sure we stay on time. Tony, can I make you in charge of making sure we stay on time today and prompting me if we are running behind?
Tony Yen	I'll do my best.
Janna Friedly	Thank you Tony, I appreciate it. Okay so I am going to turn it over to Josh then.
Josh Morse	Yeah and I'm going to sort out how to, yeah, okay. So hopefully you are seeing the full screen now of the introductory slide here. Staff will let me know if I have it backwards.
Janna Friedly	Yes.

Washington State Health Care Authority

Josh Morse

Okay, so. Welcome. Let's see if we can move this ahead. It's not cooperating. There we go. Alright, we are recording this meeting. A transcript will be created. Chat is disabled and we ask that you please do not use the raise hand feature unless you are instructed to do so requested to do so, we will be using that for the open public comment portion of the meeting. The Health Technology Assessment program is administered by the Washington State Health Care Authority here in Olympia, Washington. The HTA program brings evidence report to the Health Technology Clinical Committee to make coverage decisions for certain medical procedures and tests based on the evidence that's available for their safety, efficacy and, cost effectiveness. Multiple state agencies participate to identify topics and implement the policy decisions. These include the Health Care Authority's programs for the Uniform Medical Plan and the Apple Health or Medicaid Plan in Washington, the Department of Labor and Industries, and the Department of Corrections also uses these decisions. State agencies implement the determinations from the Health Technology Clinical Committee within their existing statutory frameworks.

The purpose of this program and process is to ensure that medical treatments, devices, and services paid for with state health care dollars are safe and proven to work. The program provides resources for the state agencies that purchase healthcare and develop scientific evidence-based reports on medical devices, procedures, and tests for the Health Technology Clinical Committee and the program supports the committee to make determinations for these selected devices or tests based on the available evidence.

There are multiple ways for people to participate in this process. The link here is to our website on the Health Care Authority webpages. Anyone may sign up for HTA program email updates and provide comment on proposed topics, key questions, draft and final reports, draft decisions from the committee, anyone's welcome to attend these public meetings and present comments directly to the committee and anyone may nominate a health technology for review or rereview. So our agenda today, after I complete this, we'll ask the committee members to introduce themselves and offer any disclosures that need to be made. We will then move into previous meeting business and we have a number of items to go through here. That includes from the September meeting, the chondral defect decision in comments from September, we have meeting minutes from the recent retreat here in January of the committee we have a brief update for the decision aid, and then we have a change to the bylaws resulting from the retreat as well to go through. There will then be a petition review for a topic and then we'll move into the rereview of vertebroplasty, kyphoplasty, and sacroplasty.

There's a limited amount of time available for day of signups. I think there should be plenty of time for that today. Please use the hand raise function when we get to that point to indicate that you would like to comment and we will monitor and limit that time. Yes, people attend, offering comment will be temporarily raised to a panelist and then they'll be returned to the attendee status after that. Staff will monitor the time and will give you a warning and then indicate when that time is up. For those that do provide comment today, we ask you to clearly state your name, declare if you have

any conflicts of interest. This is when we will use this slide during that public comment portion of the meeting. Okay, so after today's meeting, we will publish the approved minutes and other materials from this morning and meeting transcripts and any draft determinations that come from today's meeting. Draft determinations are open for public comment for two weeks. So a draft determination from today will be available for public comment between now and the next public meeting.

Upcoming meetings this year, right now in March, March 21st, hyperbaric oxygen therapy and continuous glucose monitoring are slated for review. And then in May frenectomy. And here's a screen for more information. You can contact me or our team at S-H-T-A-P at hca.wa.gov. You can find this information on our Health Care Authority website. So we will stop the share here and move into that first item, the previous meeting minutes.

Janna Friedly — Great. Thanks, Josh.

Josh Morse — So would you like to do introductions of each committee member and any disclosures. And I'll get the um the materials ready for the next portion.

Janna Friedly — Yeah. Yes, let's go ahead and get started with that. And I've already introduced myself. I'm Janna Friedly. I am a physiatrist at the University of Washington. I'm the chair of the, the committee. I have no financial conflicts to disclose for this topic specifically. The outcomes of the topics that we are discussing today have no bearing on my employment or any finances for myself or my family. So let's go around the committee and include our clinical expert, as well. So I'll just call on folks to make it easier and start with Tony.

Tony Yen — Hi, I'm Tony Yen. I'm one of the panelists. I'm also a practicing hospitalist. I have no financial conflicts of interest.

Janna Friedly — Great. And Jonathan Staloff.

Jonathan Staloff — Hi, I'm Jonathan Staloff. I'm a family physician at Harborview. I do not have any financial conflicts of interest.

Janna Friedly — Great. And Jonathan Sham.

Jonathan Sham — Hi, Jonathan Sham. I'm a surgical oncologist at the Fred Hutch Cancer Center. No conflicts.

Janna Friedly — And Clint.

Clint Daniels — I am Clint Daniels, chiropractic Section Chief and VA Puget Sound. No conflicts.

Janna Friedly — And Chris? Chris, we could not hear you. So is your audio not working?

Washington State Health Care Authority

Chris Hearne	Can you hear me now? Okay. I don't know what that was.
Janna Friedly	We can hear you now. It's a little faint.
Chris Hearne	It's faint. Okay. I'm Chris Hearne. I'm a nurse practitioner at Swedish and I have no conflicts.
Janna Friedly	Great. Thank you, Laurie.
Laurie Mischley	My name is Laurie Mischley. I'm a naturopathic doc at Seattle Integrative Medicine and epidemiologist at Bastyr University and a researcher in radiology at UW.
Janna Friedly	And conflicts?
Laurie Mischley	No conflicts to disclose. Sorry.
Janna Friedly	And John Bramhall.
John Bramhall	I am a professor at the University of Washington, anesthesiologist by trade, training, and I have no conflicts.
Janna Friedly	Great. And did I miss any of our…Oh, Amy, thank you.
Amy Occhino	Good morning. My name is Amy Occhino. I'm a practicing OBGYN at Sacred Heart Medical Center in Spokane, and I have no conflicts of interest.
Janna Friedly	Great. And Evan.
Evan Oakes	Hi, everybody. I'm a panelist. I'm Evan Oakes. I'm with HealthPoint. I'm a family medicine doctor who is the chief health officer here at the organization. I have no conflicts. Thank you.
Janna Friedly	Great. And I think that is everyone on the on the committee and our clinical expert, Sohail.
Sohail Mirza	Hi, good morning, Janna. Sohail Mirza. I'm an orthopedic spine surgeon. I actually trained at University of Washington, was on faculty until 2008. Good to see you, Janna and John and Gary Franklin. Hi, Gary. I'm currently at Dartmouth College. And conflicts are we have some NIH funding for PhD student training and I'm involved with a technology company that's a startup at Dartmouth that's developing a surgical drill based on NIH SBIR funding, small business innovation. There's no marketable products or sales. Thank you.

Janna Friedly	Great. Thank you so much for being here. Really appreciate it. Okay. Okay, so moving on to previous meeting minutes. So this is for, we would like to approve the meeting minutes from our last meeting, which was on September 20th of 2024. And they are projected on the screen. Do we have a motion to approve?
John Bramhall	Yeah, so moved.
Janna Friedly	And a second.
Evan Oakes	Second.
Tony Yen	Second.
Janna Friedly	Any discussion? Questions? Okay. And all those in favor? I'm approving. Same.
Clint Daniels	I.
John Bramhall	I.
Evan Oakes	I.
Tony Yen	I.
Chris Hearne	I.
Jonathan Staloff	I.
Jonathan Sham	I.
Laurie Mischley	I.
Amy Occhino	I.
Janna Friedly	Any opposed? Okay. Okay. So those are approved.
Josh Morse	Minutes are approved. Thank you. Okay.
Janna Friedly	And next, moving on to the chondral defects draft findings and decision. And so as you all know, when we make decisions as a committee, we draft our decisions and then we'll review our draft findings at the next meeting and review any comments that come in for our draft decisions. So Josh, do you want to lead us in that discussion of our draft decisions that we made at our last meeting.

Washington State Health Care Authority

Josh Morse

So at each, when we consider each draft determinations for members who have not been through this process before, we've, you've seen this document in the meeting materials. So this documents all the public comment opportunities and then lists the comments that were received here on the draft determination. So there were three total comments received from two individuals and those individuals are listed here: Ty Jones, Carolyn Garziano and Ty Jones again. From Dr. Jones is from one of our contracted partners, Regence Blue Shield and Carolyn Garziano is with Smith and Nephew. And the comments are here. We've redacted, we do redact contact information to keep that off of the web to the degree that we can.

So the first comment you have in your meeting materials from Dr. Jones suggested clarification and clarification the language of the decision. We have reviewed this and suggest agreeing with this uh that that is all of this is up to the committee based on your review of the comments. The second is from the manufacturer related to a topic that the committee decided to not cover based on, I think, the limited evidence. And the third comment again is from Dr. Jones related to language in the decision, which the recommendation was to, to not make those changes.

And so then we get down to the decision itself And this is the decision, I believe, without the edits. I have the one with the edits open in a different window, I think. Yes. So I turn it back to you, to the committee for discussion about these changes. You have two decisions to make today. One is, does the language meet your intent for your coverage decision? And two, did you miss any evidence that should have been considered? And so the manufacturer did provide information from other published reports, but not information that was not considered in your review. You do not need to reconsider the whole body of evidence in this process. That is not the intent here. The intent here is to capture whether you missed anything that we should have done and would we need to go back and reconsider. Does that make sense?

Janna Friedly

Great. So let's start with the wording changes. And so, I would love to hear comments from the group. Just for context, for the group, as I mentioned earlier, I was not present for this original discussion, so I've reviewed, reviewed the materials and the discussion that happened, but I was not present for that meeting. So I would really appreciate those who were present for the meeting to weigh in on these proposed changes and what your opinions are.

John Bramhall Well, I'll kick off. Happy to kick off, Janna. So in general when the medical directors ask for clarification or suggest language is because an outside person, i.e. Them, is finding either inconsistency or inadequate specificity of our language. The two comments from medical directors, the first and the third comments, I had no problem at all. They're asking for clarity and the clarity that they're asking seems to be consistent with the discussions we had. So that's my opinion of that. The second request is from, from a company representative, fine, and is well supported in terms of the literature that she presents. I personally wasn't convinced that we needed to change a decision. We had looked a significant amount of material in coming to our original decision. There is some additional material presented in her note, but I found it a little, well, not odd, I thought it was very honest that there was uh a sort of component of her submission that included the rationale for her suggestion or her suggestion on the behalf of the company. This has to do with cell free implants. And the sort of rationale that she presents, I'll just quote it. It's the consistent findings from a randomized controlled trial to force small pre-post studies and then They included studies had a narrow patient demographic population, patient-oriented outcomes were self-reported in non-blinded studies, increasing the risk for bias and no studies reported on comparator implants. So I thought this was honest, straightforward, but sort of indicating that even the material that's being presented in this comment is probably something that we would look at with, with caution. And I think that perhaps rather than changing our language in response to or with coverage in response, we found that the cell-free implants were not supported in the literature. And I think the best way forward, just as a gratuitous comment for let's say the company Smith and Nephews just to go forward with a rereview request in due time when the literature is more supportive. So I didn't favor, you can tell, I didn't favor accepting the suggestion to.

Janna Friedly Great. Thank you, John. I appreciate that.

Tony Yen Josh, is there a way to display our recommendations our determination and also those suggestions side by side on the same screen.

Josh Morse There probably is. Yeah, let me see if I can do that.

John Bramhall Josh, I could screen share because that's the way I have it displayed on my own terminal here but.

Josh Morse Yeah, I think. Well, I think what you're seeing here Tony is, let me just go back to the word document this is the edited document with these removing applies to.

Tony Yen Right.

Josh Morse Yeah, so your original had the applies to and this is the. Yeah, based off of the original does that Okay.

Tony Yen — Okay. Yeah, I'm fine with that part, but I was kind of curious about, and I was really listening closely to what John was saying about his comments, but what was that second comment? I'm just trying to keep up brighter things in my head simultaneously.

Josh Morse — Yes. Okay. Yes. So the second comment from Okay. This is the second comment from Dr. Jones.

John Bramhall — Josh, I was referring specifically to the comment from Dr. Graziano that was included in the package. So Dr. Graziano, on my packet it was the second comment And she's a director of reimbursement for Smith and Nephew, I think. Yes, there you go. Yeah, and if you uh just Tony, so that you can see what I was reading. If you scroll up a little. Sorry, I don't want to micromanage this, but scroll up a little further, I think. Yes, there. So that was that little square was what I was quoting from, Tony.

Tony Yen — Okay.

John Bramhall — And I thought it was relevant.

Tony Yen — Okay.

Janna Friedly — So John was suggesting that we not change our coverage decision. But was not addressing the, the suggestion that we add the term unipolar, I think is the is the third, the third change, the suggestion, right? Symptomatic. I think the last suggestion that we haven't addressed is the symptomatic single or multiple full thickness Outerbridge classification or grade three or four unipolar articular cartilage defects. Right?

Josh Morse — Right. So do we want to go back to that third comment?

Janna Friedly — That's the one Tony, I think is the one that you're saying is we haven't seen the change.

Josh Morse — We uh did not. We did not put that change in based on review of your work in September.

Tony Yen — Janna , may I suggest that I think we have to discuss this item as well as like I think, did we review, did we miss any evidence by 8:30? We have three minutes left.
Do we need to take a vote or anything like that?

Janna Friedly — Yeah. Are there any other comments about this? I would like to hear from any other folks on the committee about the this in particular, the unipolar this change. I just haven't heard any comments about this one. Other than the recommendation from the recommendation from the agency medical directors is to not make this change. Were there any dissenting views from the committee? Okay. Then why don't we go ahead and take a vote. Josh, do we need to take a vote on those two separate, two separate issues or is it one vote to make the change uh to the coverage decision with the change.

Josh Morse	You vote to approve.
Janna Friedly	So vote to approve the coverage decision as written with the change taking out applies to in those two lines. So as written on the screen. Do we have a motion to approve?
Tony Yen	I move to approve.
Janna Friedly	Do we have a second?
Clint Daniels	Second.
Janna Friedly	Any further discussion? And all those in favor? Say yes, I.
Clint Daniels	I.
John Bramhall	I.
Evan Oakes	I.
Tony Yen	I.
Chris Hearne	I.
Jonathan Staloff	I.
Laurie Mischley	I.
Janna Friedly	Any opposed? Okay, so this is approved. Great.
Josh Morse	Okay, thank you.
Jonathan Sham	So Janna just um Just for technicality's sake, are we able to abstain if we were not present at the last meeting? Just for documentation's sake.
Janna Friedly	Yes, absolutely.
Jonathan Sham	Just if that could be given as an option during the voting.
Janna Friedly	Thank you for clarifying. Any, anyone wish to abstain from the vote? So Jonathan abstains.
Jonathan Sham	Looks like Amy too is raising her hand.
Janna Friedly	And Amy, how many votes do we need for quorum, Josh? Do we have enough for a quorum? Or. Okay.

Josh Morse	You do. Yeah. Do you have a quorum and then you just need a majority vote.
Jonathan Sham	We still count towards the quorum, right, Josh? Even if we just
Josh Morse	Yep.
Janna Friedly	For a majority vote for this to pass okay. Okay, so this passes.
Josh Morse	Yeah.
Janna Friedly	Great. Okay. So let's move on to the next item on the agenda. And. So the next item on the agenda is to approve the retreat meeting minutes. Do we have a motion to approve? The retreat meeting minutes.
Jonathan Sham	So moved.
Janna Friedly	Second?
Clint Daniels	Second.
Janna Friedly	All those in favor of approving?
Clint Daniels	I.
John Bramhall	I.
Evan Oakes	I.
Tony Yen	I.
Chris Hearne	I.
Jonathan Staloff	I.
Laurie Mischley	I.
Jonathan Sham	I.
Amy Occhino	I.
Janna Friedly	And any abstain? Okay, and that motion passes. Thank you. Okay. And then we did want to review briefly the decision aid language that we discussed at the retreat. And Josh, were you going to project the.
Josh Morse	Yeah, Val, I think, is going to share that document and I will tee up the bylaws which come after that.

Washington State Health Care Authority

Janna Friedly	Okay. And then just for clarification on this, we did have a discussion about just clarifying that the term that we are using the terms that we're using for the decision aid. We wanted to make the change from equivocal to equivalent for less equivalent and more rather than equivocal. And so this is the change that we are making for the straw poll votes and so this would be a change in our bylaws. We don't need a formal motion to approve this. We just need consensus from the group that we want to move forward with these changes as we discussed in the retreat. So I just wanted to make sure that we had consensus from the group about this.
Josh Morse	And can I add a little bit more.
Janna Friedly	Yes, absolutely.
Josh Morse	Yeah, so you had also, had discussed adding another column for the vote here, I think, on effectiveness. And we ran into a technical challenge with adding a fifth column based on the voting technology that we're currently using. We are suggesting not adding that other category right now, we can continue to explore that solution but this at least is a correction of that language issue with equivocal equivalent and we'll continue working on the other recommendations from the retreat here. Thanks.
Janna Friedly	Great. Okay. Any concerns from the group about making this change?
Clint Daniels	I just had a question. So that means going forward, equivalent would mean the evidence is either equal between the two and or conflicting? Because it could be conflicting but not equivalent. Which I think is why we were one of the fifth column. So that's where I'm, I'm just as long as we treat it kind of similar, it shouldn't be an issue.
Janna Friedly	Yes. Yeah. Unfortunately, yeah, because we couldn't get that fifth column. So it's um It's, it would be equivalent or conflicting. Neither less nor more.
Clint Daniels	Thank you.
Janna Friedly	But with some evidence.
Josh Morse	And we can add that to this if you want to, equivalent or conflicting. You can say that in that box if that's what you would like it to say.
Janna Friedly	Yeah, I think, you know, from my perspective, if it just says equivalent, if it's conflicting, then you would have low confidence that it's equivalent even. And so I think you could just have low confidence that it's equivalent. You could have high confidence that it's equivalent if the data is not conflicting. So that's probably how I would interpret it. Is using the confidence as a marker of conflict.

Clint Daniels	I agree. I think that's reasonable too.
Janna Friedly	So I would keep it simple.
Josh Morse	Okay.
Janna Friedly	Okay.
Josh Morse	Yeah, and this is not embodied in the bylaws. This is just a, the committee tools. So if you have agreement on this, I think among everybody as far as how you're going to use this, I think you're good to go.
Janna Friedly	Okay, great. Okay. Okay, Josh, what is next on the agenda?
Josh Morse	Next will be. Let me clear my window here. So here we also discussed bylaw changes at the retreat related to recusal and hopefully you are seeing the right screen here. Yes. Okay. We crafted language based on what you suggested. And.
Jonathan Sham	Sorry, would it be possible just to zoom in a bit?
Josh Morse	Yep.
Jonathan Sham	Thanks so much.
Josh Morse	So the red is the new language. And here I can unstrike this if you want to read how it read before. I can read it out loud. Is just let me know where you would like to start here as far as this language review.
Janna Friedly	Yeah, I think it would be helpful. Can you just quickly read the way it was and then the the new Or.
Josh Morse	Yes.

Janna Friedly	Yeah. Or I can read it. So the previous version was members of the committee must recuse themselves if a material conflict exists related to a matter before the committee, members are required to adhere to the ongoing conflict of interest disclosure requirements a member who has recused him or herself from a health technology topic is considered present for the purposes of establishing a quorum. However, they may not act on the matter before the committee, including participation in discussion or making a motion, a resolution, or voting. And then we've been have, as we discussed, would like to change that to that members must recuse themselves if they have a material conflict related to the matter before the committee. And that a member who has recused themselves from the topic is considered present for the purposes of establishing the quorum. And may at the chair's discretion and based on the nature of the conflict, participate in the discussion but not vote. And that the member who has recused themselves from voting may not make a motion, draft the criteria or vote. And if the chair has recused, it's at the discretion of the vice chair to determine if they may participate in the discussion. So this allows for the person who has been recused to participate in the discussion but not the vote and importantly not participate in crafting the criteria, the draft criteria, which we felt was important and this addressed when the chair has a conflict, which was missing from the prior wording. So I think this, from my perspective, this captures the spirit of the discussion that we had. Any concerns from the group about this change to the bylaws? Do we have consensus about making these changes.
Val Hamann	And Janna, I can go down the list and ask each member to.
Janna Friedly	Sure.
Val Hamann	Okay, we'll start with John Bramhall.
John Bramhall	Yes, I approve.
Val Hamann	Clint Daniels.
Clint Daniels	I approve as well.
Val Hamann	Janna.
Janna Friedly	I approve.
Val Hamann	Chris Hearne. We're not able to hear you, Chris, if you're talking.
Chris Hearne	Can you hear me now?
Val Hamann	Yes.
Chris Hearne	I approve.

Val Hamann	Laurie Mischley.
Laurie Mischley	Approve.
Val Hamann	Evan Oakes.
Evan Oakes	Approve.
Val Hamann	Amy Occhino.
Amy Occhino	Approve.
Val Hamann	Jonathan Sham.
Jonathan Sham	Approve.
Val Hamann	Jonathan Staloff.
Jonathan Staloff	Approve.
Val Hamann	Tony Yen.
Tony Yen	Approve.
Val Hamann	Okay, everyone approved.
Josh Morse	Thank you.
Janna Friedly	Great. Thanks, everyone. Okay. So moving on to the next topic before our primary topic for today, we do have a petition to review hip surgery for femoroacetabular impingement syndrome. And so this is a petition to rereview this topic. I believe Josh has some slides to review the history of this.
Josh Morse	Melanie will share slides and we'll walk you through the process. We did, the committee considered a petition last May as well. This is the second one here in the past 12 months.
Melanie Golob	All right. And hopefully everyone can see my screen.
Janna Friedly	Yes.
Josh Morse	Yep.

Melanie Golob

Okay, great. So yeah, the petition was on femoroacetabular impingement syndrome. And just created a brief timeline of what has happened on this topic. So it's first reviewed in 2011 and it went for rereview in 2019 and both times it was not covered. There was a petition in 2022 and the Director of HCA declined to rereview at that point. We had a signal search done by one of our evidence vendors in 2023. And then there was another petition in 2024 and that was also declined and the petitioner elected to bring it to this group and see if they think if this group thinks that it should be rereviewed. So it was originally slated to be discussed by this group in 2024, but this meeting was rescheduled. It's happening in 2025. So again, that current FAI determination is not covered. So. Yes.

Josh Morse

Can I add just a couple of comments on that we can go back to that. So the literature review that was conducted in 2023 was at the very tail end. So that literature review went up through December. The petition we received, I believe we received it last summer so we were talking six months ago, I think, at this point. I just want to make sure that you know this is not a year between considerations. This is a matter of months. We're trying to be as efficient as we can with keeping these petitions moving. In front of the committee as we recognize it's really important that the requests get considered efficiently so efficiently so It's not 12 months between events here. This has all happened in the past, I'd say 13 months since that time of that literature search. Thanks.

Melanie Golob

Yeah, thanks for that clarification, Josh. So what is being asked of this group is to consider the evidence that is presented in the petition and decide if it could change the previous determination. So this group is essentially deciding if it should be selected for rereview or not. So based on the current petition presented, there were four total references cited. Three of them are randomized control trials. One was a retrospective cohort and I'll get into the next slide, a breakdown. And again, this is my perspective of the evidence. So keep that in mind as we go through this. So these are the four studies. This Kay et al. 2022, that is that retrospective cohort so it doesn't look at efficacy. It's a time to event analysis. So it looks at time to re-operation. The Palmer et al. 2019. So this study, it was published in 2019, but it was actually included in the 2019 HTA review because they pre-published their main outcomes so the main efficacy outcomes were already included in that 2019 HTA rereview. The Griffin et al. 2022, this primary outcome data was also included in the 2019 report. And so the other RCT, again, these last three are the randomized control trials. The Hunter et al. 2021, so this was a study that compared surgery to, I think they called it personalized hip therapy so it's physiotherapist led, led training led, rehabilitation. So the primary outcome of the study was an objective outcome, the MRI of the cartilage. And there was no statistically significant difference between the interventions at one year. They had secondary outcomes that were symptom improvement and so this one was favorable towards the surgery arm so patients reported less symptoms in the surgery arm but the paper also goes on to say that the benefits are not explained by better hip cartilage metabolism.

So again, one group had an intervention, a surgery, and the other group didn't so um that may or may not be affecting these interpretations of symptoms. But so that is kind of the main study that might show effectiveness. And just as a reminder, in order to change the current coverage decision from not coverage to either covered or covered with conditions, we would be likely wanting to consider randomized control trials or good quality observational studies.

So this is just kind of showing the sort of funnel of evidence based on the petition. So there are four articles. All four were primary research. Three looked at efficacy and one is potentially relevant and has the potential to change the conclusions in the in the current evidence reports. So based on this here's, here's a table just kind of showing the study and then what type it is and if it would potentially meet the inclusion criteria, so the original scope of the of the project and if it presents new data and if it looks at efficacy. So again, that Hunter one is the only one that would meet inclusion, present new data and show efficacy. But as I stated before, likely the only objective outcome of this study didn't show improvement and that symptom improvement that was the secondary outcome weren't explained by better hip cartilage metabolism. So it may or may not affect, affect the current decision. So that's the studies. And so typically we just look at the studies that are existing and if it might potentially change the conclusions.

At the request of your chair, of Dr. Friedly, we also included ongoing clinical trials. So looking at clinicaltrials.gov and how many studies they have coming up on femoroacetabular impingement syndrome and these might also be studies that are already published without getting down into it. It's hard to say, I didn't put a date restriction. So this is just kind of an abbreviated Prisma diagram kind of showing the flow of studies that might potentially be relevant to this topic. So some have been withdrawn or terminated or suspended. Among the ones that might potentially work that might be considered for this topic in the future, some were drug interventions, some were radiation and diagnostic tests. So there's 14 potentially relevant clinical trials coming up. And again, down here, the notes are just that it was only recruiting, active, not recruiting, enrolling by invitation, not yet recruiting, or completed. And the relevant records that I looked at for this were surgical interventions only, because that's the scope of the scope of the current topic. So among those 14, six were observational, one was non-randomized, and there were seven randomized studies. And again, without kind of getting into these and, you know, our evidence vendor would likely, you know, look at these and see if they fit and if they would meet the PICO. I know one of these was at least included in the previous, previous rereview. I think a couple of these would likely not be included like this one because it looks at this compartment blocks and drug interventions. So it's surgery compared to surgery and this is as well. So some of these may or may not be relevant, but these ones have likely not been published yet, I know at least one has. But based on that, that's kind of a snapshot of the current studies that are being, being either worked on or published in the area of FAI. So happy to pass this over to Val now to do voting. But before we get to that, are there any questions about any of this, either the evidence presented in the petition or the ongoing clinical trials.

Clint Daniels	It was on the Griffin study from 2022. Can you explain how that was included in the 2019 review?
Melanie Golob	Yeah, so it's part of, so this one was part of a larger trial, the UK FASHIoN trial because they always have their great acronyms for the trials. So this was a secondary analysis so it's not the primary data. So the primary outcome data was published previously and so that was already included in the 2019 report. So this is just kind of like a sub study essentially another analysis.
Clint Daniels	Okay, thank you.
Melanie Golob	Yeah. Any other questions or things that people want to discuss or we can move into voting on whether or not this should be rereviewed?
Jonathan Staloff	Oh, sorry, go ahead.
Josh Morse	I was just going to say, I think on the last slide, the physical therapy study that you referenced was included in the signal search from a year ago. Is that right, Melanie, versus the um rereviewed 2019.
Melanie Golob	This hunter one?
Josh Morse	No, no. On clinicaltrials.gov. That top study, is that the local study from Madigan? I wonder.
Melanie Golob	Ah, yes.
Josh Morse	I think that was captured in the signal search but, but it may not, was that actually captured in the 2019?
Melanie Golob	I think it was.
Josh Morse	Okay.
Melanie Golob	Without our, without our evidence vendors nearby to speak to this, I think this was captured in the previous and I could probably look that up while we're talking because I think I have it pulled up in the background the.
Josh Morse	Okay.
Melanie Golob	The signal search and the previous review.
Josh Morse	Yeah, I don't know that it matters, but yeah.
Melanie Golob	Was there another question?

Jonathan Staloff — Yes, just to clarify, I think is the purpose of sharing the upcoming slash recently completed trials being that If this was not approved for rereview today, these upcoming trials that might have soon to be published literature. Are you suggesting that there might be a better time in the near future to rereview when those studies are officially published?

Melanie Golob — Yeah, and I can definitely let Dr. Friedly speak to this. But looking ahead for the ongoing clinical trials, but that would be the idea. But go ahead, Janna, if you want to.

Janna Friedly — That was my thinking. Whenever I'm thinking about what the right timing is for a rereview of a topic, it's helpful for me to know whether there are clinical trials that are pending that are going to be coming out that might change our decisions. So I wanted to see if there were, there were trials and it looks like there are some that are pending. Any other discussion from the group before we vote?

John Bramhall — I'll just comment. I think that's, so Melanie, thank you for taking us through that, I looked at the four papers that have been suggested in the agenda. And I've actually I mean, the request essentially coming from one of our one of our, one of our experts, I think, as I seem to remember Dr. Hagan from the university was one of our guides through this process a few years ago. I think I'm recollecting correctly. And she presents a very cogent and a very fulsome and a very on the surface of it, a persuasive request for immediate review but the literature that she presents is part of it is in the summary, Melanie, that you've put on there is, is actually not as persuasive as it looks on first sight. My take is that we should be sorry, Josh, this is a little bit outside the scientific scope of things. I think we should be responsive as a committee to requests for rereview as the literature develops and I really think it's rational and reasonable, Josh, that you point out that everything's pretty abbreviated on this one. There's a lot of energy here, a lot of energy and a lot of people are getting this procedure. A lot of people are interested in it and the data is being accumulated. I think that if we can convince the outside world that the committee has got its finger on the pulse and it'll rereview when, when the signal is strong. I think that's what we should do.

Josh Morse — I'll offer. Thank you, Dr. Bramhall. I think sharing the clinicaltrials.gov information and just recognizing whatever decision you make today, if you were to select this today for rereview, it would not come before you for some time given the scheduling challenges that we face right now so you know this it would, it would take a little bit of time to get to you. I think that's another factor to consider today if you're if you feel that these clinical trials that are pending could influence a selection decision. I think we wanted to make sure we enriched the per Janna's suggestion, the information that was available beyond the petition.

Jonathan Staloff — Apologies. Oh, sorry. Go ahead.

Janna Friedly And well, I guess with that, Josh, I did want to clarify, though, is there a way Is there a way to, to qualify that we would review when there is new data, when there's new clinical trial data or this is a Yes, we will review now or no, we're not going to review now.

Josh Morse I.

Janna Friedly But there is an opportunity to rereview again, petition later when the clinical trial data is published.

Josh Morse Yeah, I think, yeah, I don't, yeah, I don't, I probably created some murkiness there. No, I think what we can do is definitely be as responsive as possible to new publications when we become aware of it or when it's petitioned, it doesn't have to be a petition. If we become aware of a relevant study, we can expedite a selection as needed. I think we're definitely poised to do that given you know the energy around this particular subject. We want to do the right thing when it comes to rereviews. So yeah, it's probably best not to select if you don't feel that the evidence can change your policy.

Janna Friedly Right. Yeah.

Josh Morse Right now. But we could definitely expedite a selection and um a review should something emerge.

Janna Friedly Yeah. Okay, because I actually, from my perspective, I think in doing it would potentially be doing, my concern is that without this additional data that perhaps we would rereview it now without much additional data and come to the same conclusion when there is pending data that might actually alter potentially, the decision, maybe not, depending on the outcome of those studies. But that we would have much more complete data after the completion of those trials. So from my perspective, I would prefer to wait and make a much more informed decision after those trials are completed is my is the way that I'm looking at it. Any other discussion or questions? Before we vote.

Evan Oakes I appreciated that explanation there, Janna. That seems to resonate with how I'm feeling about the situation right now. Thanks.

Jonathan Staloff	Just to share, I guess, speak some of the thoughts I've been having aloud. I was a little bit more struck by the conclusions of the Hunter 2021 paper. My feeling is that probably what matters more to patients is whether their symptoms are improved rather than the intricacies of their cartilage metabolism. Obviously surgery versus physical therapy is a comparison of what the treatment options are out there, but this is not a comparison of surgery to sham surgery, which would probably capture better whether this is placebo or the specific surgery itself, which I think lends itself to the cartilage metabolism. But I was struck by the fact that probably the most patient relevant outcome is symptoms and that there was improvement with the surgery. Having double clicked a little bit more on that paper, there's only like 50 something total participants, 20 something for each arm. So I just thought I just, if you hadn't had an opportunity to see the study, just let you know there's 20-ish patients per each arm.
Janna Friedly	Well, why don't we go ahead and take a vote?
Val Hamann	Great, yes. So if I am seeing five connections right now, so if everybody wants the voting members of the committee want to go to ttpoll.com. You were sent a session ID this morning. Please do not share that session ID. But that email should help to outline how to log in. I know we do have a couple of new members. So once I see 10 connections I will launch that poll. It looks like we just need two more so you should just be seeing a pretty blank page right now while we wait for those two connections. And just a reminder, stay in the Zoom meeting and open ttpoll in a separate browser or on your phone. And it looks like we're waiting for one more connection. We're still waiting on one more. Happy to kind of talk anyone through that to assist so If you feel comfortable identifying.
Janna Friedly	Is anyone having trouble getting on?
John Bramhall	Yeah, I'm having trouble getting on. Can you, I think it's me that's not, I'm not logged on anyway um Can you, can you resend the information? Do you mind? Are you going to send it as an email?
Val Hamann	Yes. Yeah, no problem. Yep. I, I just re-sent that to you.
John Bramhall	Okay, thank you. Sorry. Sorry to be a. Thank you. Sorry, guys, I'm slowing everything down but I apologize.
Janna Friedly	That's okay. We are, actually, not too far behind schedule. We, we had until nine o'clock for this discussion, we made up a few minutes, so we're just a few minutes.
Val Hamann	Okay, I see that connection so.
John Bramhall	I look better.
Val Hamann	Okay, that poll is open now.

Josh Morse	And Val, will you share that from your screen when you have it?
Val Hamann	Yeah, we're waiting on one more response.
Josh Morse	Okay.
Evan Oakes	I am getting a, it might be me. It's stuck or something so hold on.
Laurie Mischley	There's no enter button, right? Once you make your selection you just hold steady.
Val Hamann	Yes.
Janna Friedly	And it was a little odd to not press enter.
Jonathan Staloff	I was wondering the same thing, so thank you.
Janna Friedly	We're conditioned to I have to press enter after you make your selection.
Evan Oakes	There we go.
Val Hamann	There we go. And I will show the results. So we have nine no's and one yes.
Evan Oakes	Oh.
Janna Friedly	Great. Okay. Thank you.
Evan Oakes	That might be my mistake. Sorry about that i was. Could the evidence for that change them? Oh, yeah. Sorry. Can I change my vote somehow?
Val Hamann	I can definitely, I can relaunch.
Josh Morse	You can, yeah. Sorry.
Evan Oakes	My mistake. Can I just.
Janna Friedly	Should we re, re um relaunch the vote is that. Okay, let's do that one more time.
Val Hamann	Yeah, definitely. Okay.
Josh Morse	Yeah, we typically have to vote a question in front of you as you see it now so that you know what you're voting on.
Janna Friedly	That was a.
Evan Oakes	My apologies. I was flustered by the flustered.

Janna Friedly That's okay. It's a good practice. Practice vote for the afternoon or the rest of the day session. So that we can get used to the polling technology.

Val Hamann And we're waiting on one more.

Evan Oakes No. Thank you.

Josh Morse And you're seeing this question, is that right? I don't know your view. You do see the question. Okay, great. Yeah.

Janna Friedly Yeah, yeah.

Josh Morse Yeah. Okay. Okay.

Val Hamann So yes, now we have 10 for no.

Janna Friedly And then, Josh, just for clarification, with these rereview petition requests, do you communicate back directly to Dr. Hagan, the person who's made the request and the rationale and as we discussed today with explanation about the process going forward and how we will be responsive when there's new evidence that comes out and obviously this is public, you know, so she's able to see the rationale for the decision, but that we're taking into consideration the upcoming evidence.

Josh Morse Yes, we will do that. And thank you. For explaining that.

Janna Friedly Okay, great.

Josh Morse And I will say just for those that are new to this software, so we went through a very careful process two years ago to identify software that would work in this way that would meet the committee's needs and the Open Public Meeting Act needs so we do have a record of how people voted through a process like this. It is not anonymous. There is a record available for documentation purposes. So anyway, so that's what happens here this is uh If you don't see the vote happening on the screen, it doesn't mean there's not a record kept.

Janna Friedly Great. Okay. Well, thank you everybody for getting through our previous business. So next on the agenda is to move to our topic for today. We do have a scheduled break for 10 minutes. I think we should take, we're a little bit behind schedule, but I think we should take a 10-minute break and reconvene in maybe slightly less than 10 minute break, reconvene at 9:15 and get started.

Jonathan Staloff Janna, I might be a minute or two behind. I have to take care of a baby related issue, but I will return.

Janna Friedly Okay, 9:17, we will, 9:17.

Washington State Health Care Authority

Jonathan Staloff	Thank you.
Azadeh Farokhi	Val, is it okay if I just get my presentation up so we're ready to go.
Val Hamann	Yes, no problem. Yep.
Azadeh Farokhi	Okay. Make sure it works.
Val Hamann	And I am going to step away for just a little bit but.
Azadeh Farokhi	Okay.
Janna Friedly	Welcome back, everybody. Do we have everyone? Back and ready to go.
Val Hamann	It looks like we may have a couple of members not quite back yet.
Janna Friedly	Okay, if you could, when you're back, turn on your camera so we know you're I know you're here and then we'll get started as we have a Busy day today.
Val Hamann	Okay, I think we are good to go.
Janna Friedly	Okay, great. Let's go ahead and get started.
Azadeh Farokhi	All right, just to confirm you guys are able to see my full slide. Okay, perfect..
Janna Friedly	Yep.
Azadeh Farokhi	All right, then we can get started. So good morning, everyone. My name is Azadeh Farokhi. I'm Associate Medical Director at Labor and Industries, and I will be presenting on behalf of the agency medical directors on VKS. So just to start with a little bit of background vertebral compression fractures, as you probably know, are a pretty significant health burden. There's about over 700,000 Vertebral compression fractures that occur annually in the US as a result of osteoporotic disease. These account for approximately 66,000 physician office visits and anywhere from 45 to 70,000 hospitalizations each year and as we know, the risk of fracture increases with age. So worldwide, there are approximately 9 million fractures per year as a result of osteoporosis. One in three females and one in five males over the age of 50 will have an osteoporotic fracture. And of course, this can lead considerable pain, loss of function, and decreased quality of life. So when we consider treatment, the goals of treatment really include pain relief, restoration of function, and prevention of future fractures. Now, when we consider or talk about conservative management, these really involve use of opioids or analgesics for pain control, bracing, physical therapy, and maybe the use of some nerve root blocks. Now, VKS, vertebroplasty, kyphoplasty, and sacroplasty are minimally invasive surgical procedures that are used to treat spinal pain that's believed to be caused by the fracture in the vertebrae or sacrum and these techniques are intended to stabilize the fractured bone, but the mechanism of pain

relief is not quite clear. So just to kind of uh go over what each of these actually mean. So when we talk about vertebroplasty, this involves injection of bone cement directly into a partially collapsed vertebral body and this is typically done under CT or fluoroscopic guidance. Now with kyphoplasty, this is a modification of vertebroplasty and where what you're actually doing is first expanding the partially collapsed vertebral body, typically using some sort of expansion device like an inflatable balloon before actually injecting the bone cement. And then sacroplasty is just an extension of vertebroplasty. It's just injection of bone cement into the sacrum to repair a sacral insufficiency fracture.
So this is the first time that VKS was reviewed was back in 2010 and at that time it was determined to be not a covered benefit. Since then, there has been multiple literature reviews in 2016, 2017, and 2020 and the technology at that point was not selected for rereview. At this time, we have substantial new evidence that's available for this update compared to 2010. So just to give you an idea, in 2010 we had about seven total RCTs and we now have 32 RCTs with majority 31 of those being on specifically osteoporotic fractures and only one on fractures due to malignancy. Okay, in terms of the agency medical director group concerns, in the past, the concern for safety, efficacy, and cost were all medium. I would say that at this time after this review, our concern for safety and efficacy are on the higher side and you'll kind of see where I'm going with this. Okay, so just current state agency policy. So again, this is currently not covered. It's not a covered procedure. And unfortunately, due to the low volume of claims, we're unable to really report any cost and utilization data, but we did pull this data. This is from the Healthcare Blue Book which is a healthcare price resource online and really just to give you guys an idea of what the cost of these procedures might be. So don't focus on the fair price, we don't really know what that actually means, but really just to give you an idea or range of the prices and you can see that kyphoplasty is more expensive than vertebroplasty, so just an idea of price point.

Okay, so I'm going to jump in. I'm going to not spend a ton of time on the evidence because I know you guys will hear quite a lot of that, but just to kind of give you an idea of how I got to the recommendation that I did. So this is pretty high level. This table shows a summary of effectiveness evidence for vertebroplasty versus usual care and majority of these are all going to be, what we're going to talk about is osteoporotic vertebral compression fractures because that's where majority of the data is on. So you can see when we compare it to usual care that in terms of pain scores and function scores we see that, yes, vertebroplasty is favored, there's better pain, better function scores. However, when we start looking at vertebroplasty with sham-controlled studies, we sort of don't see that significant difference as much, both again in terms of pain scores and function scores you see that they're really more similar. I wanted to kind of bring this study to your attention for a couple reasons. So first, this is a Firanescu study, it came out of the Netherlands, it is an industry funded study by Stryker and really what I wanted you guys to take from this is that this was a really well-blinded study and that 80% of the participants in the sham group actually believed they had received the treatment. This is really great graphic and as you can see, both groups have improvement in pain at one month and at 12 months, but really no significant difference between the sham and the vertebroplasty group. So I think

one of the key differences in this study is that all the participants received not only a local anesthetic in the subcutaneous space but they also received the anesthetic into the periosteum so there was periosteal infiltration. And this is really important in my opinion, because you will see when the evidence report is presented to you guys in the forest plots, you will see that there's one particular study, it's the Clark study, and this is an outlier from the other studies and it consistently at every timeframe shows that vertebroplasty is favored. However, the key difference between the Clark study and this Firanescu study is that in the Clark study the anesthetic in the sham group was only in the subcutaneous tissue and not down into the periosteum, whereas this study the anesthetic was in both of those areas. And so I think one of the things to kind of think about with this study is, does this suggest that, you know, periosteal infiltration alone, especially in early phase, is that enough to provide the pain relief without really the need for cementation. All right. And then just to kind of take this a little bit further, this table shows a summary of effectiveness evidence for vertebroplasty versus medial branch nerve or facet blocks. And again, we kind of see that, you know, later on after two weeks, the scores for pain and function were pretty similar again. Not a ton of studies here, but again, suggesting you know maybe cementoplasty is not necessary.

Now, just switching to talking about kyphoplasty here. This is kyphoplasty versus usual care. Again, pain scores and function scores, we see a difference. So when we compare these treatments with usual care, we do see a difference. Unfortunately, we don't have any studies that compare kyphoplasty with sham. But we do have some studies that compared vertebroplasty and kyphoplasty and in general, again, really no difference between the two. So one isn't favored over the other, they're pretty similar in terms of pain and function scores. So just to kind of summarize that, again vertebroplasty and kyphoplasty both when we compare them to usual care, we do see some effect. For vertebroplasty, when we compared it to sham, we don't really see much of a difference anymore when we compared it to medial branch nerve or facet blocks again, no difference. I think one of the interesting things to also consider, some of the studies looked at secondary outcomes and specifically opioid use and it was found that the proportion of patients that were using strong opioids and weaker opioids was actually pretty similar between patients that received vertebroplasty and those that receive the sham treatment. And another study of vertebroplasty was actually associated with a large increase in the likelihood of using major opioids at 12 months compared with usual care so just something to also consider. And again, with kyphoplasty, no sham studies to compare, but we didn't see any difference when we compared kyphoplasty with vertebroplasty. Okay, so really briefly, fractures due to tumors or malignancy. So, kyphoplasty versus usual care, there was pretty limited evidence there's only one RCT and again, just like our previous studies we see that, yes, there is a large improvement in pain and function when it's compared to usual care. This study had a pretty high crossover rate at one month and then with vertebroplasty and kyphoplasty comparison really, this evidence base was pretty sparse and insufficient. All right.

So briefly talking about safety considerations for vertebroplasty and kyphoplasty. So I will say that the harms were pretty variably defined and inconsistently reported

throughout the studies overall, the risk of mortality, new vertebral fractures, and serious adverse events were similar across the comparators. However, cement leakage is very, very common and I think this is the one thing that there's concern about. So following vertebroplasty, the range across RCTs was anywhere from 40 to 91% of treated levels so very, very common. Now, cement leakage can cause damage to the intravertebral disc, the paravertebral soft tissue, and the spinal cord. And if you have venous leakage into the epidural and spinal veins, this can result in cardiac and pulmonary embolization, cement embolization. So although the studies all report that leaks are asymptomatic, I would say that these studies are still pretty short term and we don't really know the long-term effect. So there is a case study in an individual who had a cement pulmonary embolism and this was three years after vertebroplasty. So even though people might be asymptomatic initially, these studies go on for maybe up to a year, and we don't really know what the outcome might be following that you can have the embolization's anytime. And then I just kind of wanted to share this, this is from the evidence report the cement leakage following vertebroplasty and RCTs of VP versus sham. So again, just to give you an idea of how common cement leakage is, you know, this study, 70%. This is the Firanescu study that I mentioned earlier. This had 91% of treated levels and they kind of go further to kind of type you know, give a type and kind of sort of the location and what percent of treated levels and you can see that perivertebral veins, you know, almost half, so 39%, almost half of those will reach the perivertebral vein you know, 7% pulmonary, 8% spinal canal. So, again, just to kind of make you aware that we don't necessarily know the long-term effects of what cement leakage might lead to. Okay. Okay, so in terms of sacroplasty for sacral insufficiency fractures or malignancy, the evidence base here for both the effectiveness and safety is pretty sparse and insufficient. So for this, there was only a total of six studies and these were considered pretty poor quality due to serious confounding. So not, we don't have a whole lot of information here on sacroplasty.

In terms of cost effectiveness, there were six full economic studies that were relevant to populations with osteoporotic vertebral compression fractures and one that was relevant to cancer-related compression fractures. Of those six, only two were US-based studies, and both of those were industry funded and they relied heavily in part on Medicare claims data for mortality. So you know, as we know, there's pretty well-known limitations of using this type of administrative database, such as selection bias, inability to control confounding, missing data, or misclassified data, so really a causal inference for mortality benefit is not possible. In general, the evidence report stated that most of the economic studies do suggest that vertebral augmentation may be cost effective. However, I would also state that there's differences in healthcare system and reimbursement policies between the US and other countries so generalizability of these findings from studies outside of the US is unclear. Interestingly, the evidence report also noted that some of the large database studies that reported a statistically significant mortality benefit were industry funded.

All right. So in terms of selected other payers as policies, so CMS does not have a national coverage determination on VKS, but there is a local coverage decision and it is covered with conditions. I will say that the majority of the private payers do cover

vertebroplasty and kyphoplasty, however, sacroplasty is considered experimental. And then in terms of the clinical practice guidelines, the evidence report actually had several pages of guidelines, so there's lots of groups that have some guidelines on this. I just picked a handful here. In general, most of them do recommend it. I will say that the American Academy of Orthopedic Surgeons most recently updated their guideline in 2023 for vertebroplasty, they do not recommend it, so it's not recommended for osteoporotic spinal compression fractures without neurological impairment and the strength of recommendation here is pretty strong. For kyphoplasty, it is an option for osteoporotic spinal fractures, benefits in pain and function up to six months, and strength of recommendation here is limited. So the other groups really didn't have any reporting on their strength of recommendation based on any evidence besides the American Academy of Orthopedic Surgeons. Again, most are recommending it, most of these groups are recommending it.

All right. And then finally, so our agency medical director group recommends a non-covered decision for vertebroplasty, kyphoplasty, and sacroplasty for vertebral fractures and sacral insufficiency fractures secondary to osteoporosis or tumors and malignancy. And this again is really due to the lack of evidence for effectiveness, especially sham RCTs showing no difference. And then the safety concerns that I brought up in terms of cement leakage. And that is all I have for you guys today.

Janna Friedly Great. Thank you very much. Any questions from the committee?

Azadeh Farokhi Questions?

Jonathan Sham Maybe I could ask, I'm not sure if it's an appropriate time to address our expert on this, but on the one sham trial that was presented. If you just pull up that slide, it'd be helpful.

Azadeh Farokhi Yep, you got it. Yes.

Jonathan Sham I'm just interested, is there any reasonable, reasonable kind of pathophysiologic conclusion or pathway that could be made to link just injection of local anesthetic or needling into the periosteum with an improvement in long-term pain. I'm just trying to, I'm just trying to really evaluate what the sham, if the sham intervention had any therapeutic effect as opposed to just a subcutaneous injection. And I don't know much about bones. I'll just throw that out there.

Sohail Mirza Is that a question for me? Sohail Mirza. Yeah, so, you know.

Azadeh Farokhi Yes.

Jonathan Sham I think so.

Janna Friedly I think so.

Sohail Mirza — So you know, the way, at least from an orthopedic surgery point, the way we think of bone is most of the innervation is in the periosteum. So for fractures and for other treatments most of the sensory nerves end in the periosteum. We don't think there are that many inside the mineralized location of bone. So, from what I understand, and I think the evidence that's been presented very nicely with this assessment is there's short-term pain relief, particularly in the first week. So if you use a long-term anesthetic I think for a day or two the patients might notice a dramatic difference in pain from the fracture. And that may mobilize them better, maybe condition them so that they're, they feel like they're getting better and they might be able to get out of bed and start moving faster. So I think there is some physiological basis for thinking some kind of a causal pathway for short-term pain relief for the local anesthetic injection in the periosteum.

Jonathan Sham — What about after one month and 12 months?

Sohail Mirza — I can't think of any reason for that, other than maybe these patients just subjectively know that the pain can get better and then start moving faster. I don't know any reason. But I think from the data that I've seen, the effects are so small at one month in three months that other than, you know, by then physiologically, the fractures are already more than 50% strength in terms of bone formation. So biologically, it wouldn't make sense that the benefits would last that long from an injection.

Jonathan Sham — Thanks so much.

John Bramhall — Jonathan, I'll just comment that there's no data we're presenting with today, but it's a similar kind of observation has been made with things like epidural steroid injections, different mechanism different pathology, but I think you will know that you know in some of the studies that have been done have been done quite well the injection of local anesthetic appears to have a long-term effect, appears to have a long-term effect when sham studies have been done with no for example, no steroid included. So it's an observation that's been made in other settings as well. It's a little confounding but It's a robust observation, I think.

Janna Friedly — Okay.

Evan Oakes — Could I ask for some comment from members that have been on longer and might be more I don't know, used to this. What is exactly the disconnect it seems to me from the recommendations from these professional organizations and what we're talking about right now, the recommendation being not to cover this. Does that come from exactly? I mean, I saw, I think the point was that the, I don't have it in front of me, the osteopathic group or the um yeah saying there was strong evidence and they recommend vertebroplasty for compression fractures, I thought is what it said there as long as there's neurologic impairment. Yeah, thank you. Comments? I mean, they're just trying to learn myself but what to think of those.

Josh Morse — Yeah, is Dr. Friedly?

Janna Friedly	Yeah, I mean, I'm happy to weigh in with my perspective. I think the reality is that each organization has different processes and guidelines for how they come up with their recommendations and there's also different biases and different, different motivations and perspectives that they bring into it. And so I think you have to look at what the organizations are to understand why they may come up with very different conclusions. And then also the timing of when they, when they come up with the recommendations may vary as well. So you do have to sort of weigh all of those different, different things when looking at these different guidelines.
Josh Morse	And we do have public comment coming up. We're actually into the public comment period time right now.
Evan Oakes	I appreciate that.
Josh Morse	I think there's ample time. We have the evidence vendor ready to present after that and then after that plenty of time for committee discussion around these topics, I think, afterwards.
Evan Oakes	Okay, sorry, Josh. Nice.
Josh Morse	That's okay. I'm just looking at the agenda. Thank you.
Azadeh Farokhi	So I'll just, I'll stop sharing. Thank you.
Josh Morse	Yeah, I don't mean to cut short your conversation about questions for the agency medical directors, that's not my intent but.
Janna Friedly	Nope. Great. Thanks for keeping us on track. So let's move into open public comment.
Josh Morse	Yeah, we'll turn this to Val. We have commenters who are signed up and then we will see if there are commenters on the day of. Thank you.
Val Hamann	Yeah, I'm currently seeing four of the five previously signed up public commenters and we will start with Douglas Beal today. For those present, please be aware you will be promoted to a panelist, once you accept that, you will then have access to your camera and audio you can also We have a number of individuals who do have slides today. Feel free to either share those or I can share those. And everybody will have four minutes today as we do have a pretty packed public comment session. So I will give you a heads up at the two minute mark and the 30 second mark. And then once we get to the end of that four minutes, you will be, we will be moving on to the next presenter and then you will be moved back to an attendee. So we can get started with Dr. Beal. I can present those or you can. What would you prefer?
Doug Beal	I can do that, Val.
Val Hamann	Perfect.

Washington State Health Care Authority

Janna Friedly: And just as a reminder to all of the speakers, if you could please start with any financial conflicts of interest and if you were paid to present today.

Doug Beall: So I'm Doug Beall. I'm an interventional radiologist from Oklahoma City and I'm not paid to present today of no financial conflicts and in presenting this. I did author the vertebral augmentation guidebook. I treat patients for non-surgical management all the way through all forms of vertebral augmentation and if I could get my slides to go. So one of the things that I'll give you more complete examination of the literature, hopefully. You know, the choices of either treating with augmentation or bracing when the patient's acutely painful, we tend to ignore the evidence for the bracing and based on Kim and Bailey, hard brace, soft brace, no brace or brace plus or minus for acute fractures, there's no difference in either of these. Rzewuska did a meta-analysis studying optimal pain management, and I quote that from their paper and I also quote from the conclusion of their paper, these are five articles and did a meta-analysis, said there's insufficient recommendation for optimal pain management for osteoporotic vertebral compression fractures. And a little bit more on the literature there's a lot of literature here. So there's Papanastassiou meta-analysis included 27 level one, level two trials. The one that we did, I'll show you in a second, included 25 and the bottom line is there is a difference here. If you include all the best literature in the world ever produced, vertebroplasty versus kyphoplasty does have a difference. Vertebroplasty is not as good as kyphoplasty in terms of pain and quality of life and also mortality. And all of these are available by the way. This is a meta-analysis previously that showed that kyphoplasty had better reduction the non-surgical management. And there's about 250 manuscripts produced a year so these are, these are 52 level one and level two articles that have been produced since 2010. And there's quite a bit of data coming out all the time. And I color coded these.

Val Hamann: Two minutes remaining.

Washington State Health Care Authority

Doug Beall	And one of the color coding means it's equivocal. I notice you quoted Vertas 4 problem with that study is you compare a difference between means, you'd have to have something at 6.25 points or over to, to get a significant advantage as we know, nothing does that. And also the, there's M. Wang, David Wilson as level one trial showing that facet injections are an active treatment and do reduce fracture pain. Bill Clark's vapor trial was mentioned, but the VOPE trial and Paul Lawley's Vertas 5 that showed a statistically significant improvement of vertebroplasty versus sham were not mentioned. And so these are the unequivocal trials that showed an advantage for vertebroplasty. In addition, real world data, there's a thousand patients, we have complete records and over 700 people with vertebral augmentation. And it's interesting the median pain score goes from a nine to a zero in a profound Roland Morris improvement in function and there was zero persistent adverse events. And so I kind of take a little bit of issue with the cement extravasation rate. Here was 24, but it was completely asymptomatic and didn't cause any adverse events or significant adverse events, certainly no persistent SAEs. And then the sacroplasty registry this was published last year, JBIR, this is the interim analysis showed a very strong 6.9 point reduction in pain all the way out to six months. The median pain score in both of these registries went from a nine to a zero.
Val Hamann	30 seconds remaining.
Doug Beal	And prominent improvement in Roland Morris function. Last, there are four measured endpoints and five measured secondary endpoints showing statistically significant improvement in pain, function, and quality of life all the way throughout the EVOLVE trial, which was the largest trial ever done on kyphoplasty. So the bottom line is the real world evidence shows a lot of improvement as compared to some of these equivocal trials that I think have been cherry picked from a while back. There's a lot more in this industry. Very strong.
Val Hamann	And that concludes your four minutes.
Doug Beal	Thank you.
Val Hamann	Yes, we appreciate you coming today. We will next move on to Emily Panteli. And promoting her.
Emily Panteli	Hi, Val, can you hear me okay?
Val Hamann	Yes, we can. Would you like to present your slides or would you like me to?
Emily	I can share my slides. It's no problem.

Washington State Health Care Authority

Val Hamann	Sounds great. Feel free to start when you are ready. And sorry, actually as the chair said, if you have any conflicts, please let us know.
Emily Panteli	Of course. Can you see my slides?
Val Hamann	Yes.
Emily Panteli	Excellent. Good morning. On behalf of Medical Technology Innovators in vertebral augmentation, Stryker, Medtronic and Merit Medical. My name is Emily Panteli. I have no financial conflicts of interest to disclose. I am a clinical evaluation specialist for Stryker Interventional Spine. As a qualified physician and researcher with experience at the Irish National Spinal Injury Unit, I appreciate the opportunity to speak today regarding our stance on coverage of surgical treatment for osteoporotic and malignant vertebral compression fractures. Since the committee's first review, substantial new evidence supports surgical intervention for VCFs over non-surgical management. Regarding the sham controlled vertebroplasty trials which question the efficacy of surgical treatment, we urge the committee to evaluate the use of local anesthetic in these studies which does provide pain relief for sham patients, potentially influencing outcomes. We urge the committee to consider placing more weight on evidence from vertebroplasty versus usual care trials. Next, we appreciate the inclusion of retrospective claims studies, offering long-term insights of up to 10 years. These studies consistently show a correlation between surgical treatment and reduced mortality observed globally, not just in US data. Next, we recommend inclusion of the RAND UCLA Care Pathway as a source of reasonable coverage criteria. This was a multi-specialty consensus and was cited in all CMS local coverage determination revisions in 2019 to 2021. This was also an important factor in Medicare coverage determinations on the appropriate patient population. Furthermore, given that three of the four balloon kyphoplasty versus usual care trials were rated a poor due to unclear blinding, randomization, etc, we suggest that the committee evaluate outcomes from the EVOLVE study, the largest single arm study of kyphoplasty efficacy. Lastly, while the report identified one Medicare LCD, there are in fact seven LCDs available to reference.
Val Hamann	Two minutes remaining.

Washington State Health Care Authority

Emily Panteli	When evaluation coverage policy for Washington State. Each followed their own independent review and all seven cover vertebroplasty and kyphoplasty for osteoporotic VCFs. Five explicitly cover vertebroplasty and kyphoplasty for VCFs secondary to osteolytic metastatic disease and myeloma. In summary, the report correctly highlights the strong evidence supporting surgical treatment of osteoporotic VCFs. While evidence for malignant ECFs is less robust, timely access remains essential due to severe quality of life implications. We also agree that sacroplasty evidence is still evolving. We respectfully request the committee consider coverage of surgical treatment for osteoporotic and malignant VCFs, which would align with all national and commercial payers and each of the Medicare administrative contractors. Thank you for your time. Please contact me or any of the other listed contacts mentioned for any questions, I now defer any remaining time to physicians or societies who have registered to present.
Val Hamann	Thank you for your presentation today. We'll move on to Scott Kreiner.
Scott Kreiner	Good morning. Can you all see me? Yes. Okay. So I did not prepare a PowerPoint presentation. I'm here as the president of the North American Spine Society. I practice interventional spine at Barrow Neurologic Institute in Phoenix. I do perform kyphoplasty's as a small part of my practice. You know I, I appreciate um doctor the, the prior evidence from Dr. Beal. And, you know, I think that while I am in agreement that some of the studies that we have looked at so far that you have looked at had some at least the colonies and buck binder study are looking at patients four and five months out on average from their initial presentation of a fracture, which is probably not the ideal time to be treating these patients and many of the newer studies look at treating fractures more acutely when they're probably more symptomatic. But I think that the reason that everybody kind of supports this is probably not because everybody, you know, all the societies in CMS are biased towards the treatment, but because I think in general, most of us see the evidence a little bit differently than it was presented a moment ago. And so I think that, you know, in general you know, I think the quality of the evidence here is high and we've developed coverage policy recommendations as well as everybody else at the North American Spine Society in support of this after extensive evidentiary review as well. I'm going to leave it at that and let somebody else take the rest of the time.
Val Hamann	Thank you. We will move onto Dr. Shonnard. I've just promoted you.
Neal Shonnard	Can you hear me?
Val Hamann	Yes, we can. You are wanting me to present your slides, correct?
Neal Shonnard	Yes, and Val, I want to say that I have no conflicts of interest and I am not paid for any of this.
Val Hamann	Great. Thank you so much.

Washington State Health Care Authority

Neal Shonnard

And Val, if you would run the slides, we could first start off. I want to tell you that I'm going to tell you three things. I'm going to show you something that's never been seen before, and that's the ability to predict surgical outcomes of lumbar spine surgeries before you operate on the patient. I'm going to show you the world's largest cement augmentation registry, and I'm going to show you the data that changed national Medicare health care authorization policies for cement augmentation. First slide, please. And what these studies show, this first is from SpineScope, it's housed at the Foundation of Healthcare Quality. It's surgeons across Washington state who developed the ability to predict lumbar spine surgery outcomes before any of the patients are operated on. The editors of the Journal of the American Medical Association designated this as an original investigation because it's never been seen before. All of the authors on that list are from the state of Washington and represent the University of Washington, MultiCare, Proliance Surgeons, and Swedish. The lead author, Sarah Khor, remember her name, you will see her again, and the anchor author, David Flum, are from the Surgical Outcome Research Center at the University of Washington. Next slide, please. The next slide is also a powerful prospective observational registry study housed in Seattle, built by physicians in Washington state If you look at the author list, I'm from Puyallup, Evert Verschuyl is from Providence - St. Pete, and Olympia. Justine Norwitz is from Seattle to Nell Shonnard from Tacoma, Sarah Khor was the lead author on the predictive analytics paper, she did the analytics on this. This is the world's largest vertebral compression fracture registry measuring the benefits, safety, and outcome of cement augmentation. There were five out of 1,094 patients. Five had adverse events, none of the adverse events were related to the cement. So the cement discussion you heard earlier is not relevant to safety. The reliability of the treatment outcomes, however, next slide, is dramatic. And what you see here is profound, profound improvement of pain, profound improvement of disability, the pain and the disability disappear after these treatments and sustain for six months. Next slide, please. This is what the registry tool looks like. And notice you were asking questions about balloon kyphoplasty and vertebroplasty, and they are two of the four columns There are other issues that are important, but you're not asking about them. But two of the four columns were exactly studied and look under each of the columns, you'll see the name of every company that manufactures that implement or device and they are all measured by the same yardstick. The reason that Washington state registries.

Val Hamann

Two minutes remaining.

Neal Shonnard	Are so profoundly beneficial is they're properly built to embrace heterogeneity. Heterogeneity of the treating clinicians, every kind of clinician, no matter your training. Who does this procedure gets measured in every type of treatment gets measured by the same yardstick. Next slide, please. This is the slide that changed Medicare policy. Notice that if you treat this patient two days after diagnosis, the cost is $6,000. If you treat them six months after diagnosis, the episode of care cost triples. Next slide. Notice that if you treat them right away, their pain and their disability disappear for six months. If you delay treatment the disability score triples. The pain score triples. So you're going to end up with chronic disability and chronic pain. That's very important for L&I. You have to lower disability and lower opioid use and you do that by prompt treatment. Next slide. This has all been published. Next slide. Thank you for listening. If there are any questions you have the experts on this matter are here and available. We'll help in any way we can. Thank you.
Val Hamann	Thank you for your time today. Now the last public commenter that we had signed up ahead of time I do not see Ray Jensen. If you could either raise your hand. I did reach out to him a little earlier this morning when I did not see Dr. Jensen, and I have not heard back. Okay, we do have, Peter Thurlow.
Peter Thurlow	All right. Sorry. I'm actually at the Society of Interventional Oncology national meeting right now. Can you hear me?
Val Hamann	Yes, we can. And are you taking Ray Jensen's place or?
Peter Thurlow	Yeah, Dr. Jensen, I think had got some last minute add-ons and asked me to sign in.
Val Hamann	Okay.
Peter Thurlow	And I didn't hear the earlier comments, so I apologize for that. I was in some meetings but I can share his slides.
Val Hamann	Okay.
Janna Friedly	And before you get started, could you please state if you have any financial conflicts of interest or were paid to be here today.
Peter Thurlow	I do not have any financial conflicts of interest. I've received training from Stryker and Medtronic. But no payments or anything like that.
Val Hamann	Great. And you will have four minutes today. So I will give you a heads up at two minutes and then again at 30 seconds.

Washington State Health Care Authority

Peter Thurlow	Okay, I'll be brief. These are Dr. Jensen slides. I presume most of this data was shared earlier. I think these are the studies we really focus on showing mortality outcomes with vertebral augmentation and the really profoundly low number needed to treat to save lives. And just the impact that these fractures have on these patients is also just as profound and morbidity is incredibly high when we don't treat them. And we send them into this catabolic crisis And this is really a struggle. I work at Harborview and at University of Washington, I'm a musculoskeletal radiologist that does percutaneous intervention and ablation. I'll add on the ablation in a second. But we have this coverage by all these other providers but our patients on Medicaid can't be treated in Washington state. I see patients at Fred Hutch as well and it's particularly in tumor ablation and augmentation, we can't ablate tumor for either pain control or oligometastatic disease control if we can't augment their spine. Because we'll just cause further collapse and we're subjecting them to huge surgeries as an alternative. I see that every day. And it's at a huge cost and incredible morbidity of these patients. So that's all Dr. Jensen wanted to present and I would just add on my oncology side as well. And that's all I have.
Val Hamann	Great. Great. Thank you for being here today. That was our last pre-scheduled presenter today, do we have any others in the audience if you could please raise your hand. Okay, we have Dr. Jones. We are unable to hear you, Dr. Jones.
Ty Jones	How about now?
Val Hamann	We can hear you.

Washington State Health Care Authority

Ty Jones	Oh, excellent. Oh, thank you. All right. Well, good morning, HTCC. I'm Ty Jones, and I'm a senior medical director at Regence. The health plan that administers HTCC determinations on behalf of the Health Care Authority for around 450,000 of its members. And in my role, I specifically support the HCA's account with Regence. I have no financial conflicts of interest. The HCA's insurance plan is self-funded and I'm not being paid to speak today. So for HCA members, we apply a Regence medical and surgical policies to their preauthorization requests unless there is an HTCC that specifically addresses the requested service, then the HTCC are viewed instead of the Regence policy. So I wanted to speak briefly to supplement the local health plan landscape. I didn't see Regence's own policy within the review, so I'd like to share that Regence does have a policy that provides medical necessity conditions for both vertebroplasty and kyphoplasty. So at present, Regence supplies this policy to approve requests for vertebroplasty and kyphoplasty for its commercial members with the exception of HCA members, because the current HTCC lists these procedures as non-covered. So essentially, the Regence policy does not provide coverage as an alternative to usual care for a vertebral fracture, but does when usual care is not effective, such in the setting of a failure pain or functional impairment to respond to six weeks of conservative treatment or sooner like Kaiser's coverage is specifically a vertebral compression fracture requires hospitalization or prevents a member from ambulating or transferring without assistance in spite of conservative efforts, bar of course, unsafe contraindications. Also, Regence's policies find sacroplasty investigational under all circumstances. So I hope this information is helpful in your deliberations. Thank you.
Val Hamann	Thank you. Do we have any other individuals who would like to present comments today, please raise your hand. I'm not seeing any other raised hands for today.
Josh Morse	All right. Thank you, Val.
Janna Friedly	Great. So I think we are scheduled for a break until we're scheduled for a break until 10, 10:20, we're a few minutes ahead of schedule. We could come back at 10:15 if we want to start a few minutes early is that sound okay to everyone since we're a few minutes ahead of schedule Does that sound okay, Josh?
Josh Morse	That's fine. Yeah.
Janna Friedly	Okay, why don't we take a short break and come back at 10:15 to get started with the evidence report?
Val Hamann	Janna, I believe Josh had to step away for a minute, so I think you can take over and start.
Janna Friedly	Okay, great. And do we have everyone back? That needs to be back. It looks like we're still waiting for Amy? Okay, great. Thank you. Okay, so it looks like we have everyone back so we can move to start the evidence report.

Washington State Health Care Authority

Andrea Skelly

Okie dokie. So Erika will be sharing our slides and. Yeah, I want to thank you for the opportunity to present the evidence report. And I do want to thank our team members for the work that they did on putting this report together. In addition to the team that you see the report being prepared by, I'd like to thank Dr. Roger Chou who served as an internal methods review and clinical reviewer, as well as our clinical experts who provided information along the way when we had questions about the clinical aspects and provided peer review. If we go to the next slide we, as you know, had done a report in 2010 where the evidence base was substantially smaller than what we have for our report today and you can see the conclusions that were reached at that point. And some of these are very similar to many of the conclusions that we reached as a result of our current report that the vertebroplasty was no more effective than sham for pain or function, at least at that time and that vertebroplasty was better than usual care for pain and function. And that there was sparse data for sacroplasty and in malignant fractures as well. And safety, again, we noted that there was substantial opportunity for cement leakage, but most of it was asymptomatic and that the risk of serious adverse events was considered to be fairly low. If we go to the next slide. In addition to the report in 2010, I believe Dr. Farokhi indicated that there were some signal updates that were done and just by way of review, a signal update is not intended to be a comprehensive review of the subject, but we look for specific signals, if you will, in terms of new randomized trials that may be pivotal or systematic reviews that provide data That would be consistent with our prior report and provide new insights from new trials, randomized control trials that might change the decisions from the prior review. If we go to the next slide, several of these were performed. The most recent was in 2020. And again, our methodology is to look at high quality evidence, systematic reviews, new pivotal high quality randomized control trials that might change conclusions to the prior technology assessment. And at the time of the 2020 review, we found additional RCTs that went from seven in 2010 to 24 in 2020. And with regards to the decision related to efficacy, we found that there were no changes to the prior conclusions, although we did notice that there was a change in statistical significance with regard to the pain response that favored vertebroplasty versus sham for osteoporotic vertebral compression fractures and that the new evidence might impact our strength of evidence determinations for some outcomes and comparisons. With regard to safety, we did not find that there were any changes to the conclusions. And with regard to differential effectiveness or safety, there was no new evidence. And cost effectiveness, there were new data so that the section could be updated, but that is not usually a criterion for suggesting a rereview. And just for information purposes, any relevant primary studies that we identified during the signal updates are carried forward into the rereview if they meet the inclusion criteria. If we go to the next slide, the rationale for the rereview is that there obviously is a lot of additional evidence and there were technological advances since the time of the 2010 review. And in terms of the topic refinement process, public comment was reviewed based on the public posting of the draft key questions. We considered the public comment and discussed them with the Health Technology Assessment Program in conjunction with information clinical experts and questions we had asked them. This was all prior to the finalization of the key questions and the scope that we finalized. We also did review public comment to the draft report and the response to the public comments is on the website together

with the report and all of its permutations. As always, we do look at suggested citations and they were evaluated against our final PCOTS inclusion and if there were relevant studies, we did include them in the final report. We did obtain clinical input throughout the period of the systematic review development to assure that we were representing things accurately.

If we go to the next slide, by way of background, I'll just keep this brief because you've heard from both the public commenters and Dr. Farokhi that this is an important topic from the standpoint that osteoporotic fractures are very common and that metastatic bone disease and fractures related to metastatic bone disease are a problem as well. And as was mentioned initially, there may be non-operative treatment being done using bracing, rest medications, and various supplementation opportunities. Augmentation is usually considered for symptomatic vertebral compression fractures that may not respond to non-operative treatments and that the surgical procedures, of course, are more involved. If we go to the next slide, again, you've heard uh what that vertebroplasty, kyphoplasty, and sacroplasty are types of cement augmentation. Polymethyl methacrylate is the usual cement that's being used to treat these things and of course, it's done under either IV sedation or general anesthetic and is guided image, used done during guided imaging and of course, the goal is to reduce and relieve pain, improve mobility and functionality and prevent further vertebral collapse. And since the last report, there are new devices that have come on board. If we go to the next slide, we have a visual representation of what is done. We have a fractured vertebra and the cement in vertebroplasty is injected directly into that fractured vertebra and then we kyphoplasty, you have the opportunity to reestablish some height within the vertebral body before you inject cement and therefore maybe improve functionality, improve the stability of the fracture. And then sacroplasty is again just the injection of cement into an insufficiency fracture within the sacrum.

If we go to the next slide, you know, the indications I think have been pretty well covered looking the most common indicators being vertebral compression fractures due to osteoporosis. There are contraindications asymptomatic fractures and high energy trauma fractures are some of those contraindications and if there's a substantial loss in vertebral body height pr damage to the pedicles or facets or tumors invading the spinal canal, those are some contraindications as well. If we go to the next slide, we'll talk about the complications in more detail related to the evidence but there are always potential for procedural, excuse me, periprocedural complications as mentioned, cement linkage is very common and the leak to the venous structures and cause of leakage for as a pulmonary embolism or through other mechanisms is considered to be fairly small. New vertebral fractures or refracture can occur and there may be procedural trauma related and also potential adverse events related to any allergy to materials that might be used.

If we go to the next slide. The questions and scope I think have been covered. Again, we're looking at the effectiveness, safety, and differential effectiveness or safety of these methodologies, techniques for vertebral compression fractures, and looking at the cost effectiveness. If we go to the next slide, the PICOTS, again, it's fairly

straightforward and has been discussed, we're looking at patients who have symptomatic vertebral compression fractures secondary to osteoporosis or malignancy. We've discussed the interventions and then the comparators included sham procedure or placebo, conservative or conventional care, and also other minimally invasive procedures such as nerve block, as well as surgical procedures and then we did compare vertebroplasty with kyphoplasty. For evaluating our certainty of the evidence, we focused on functional outcomes, pain relief, and harms and complications. We did also in the full report describe data that we found related to quality of life, measures of disability, opioid use and other secondary outcomes. For cost effectiveness, we looked at cost utility studies as well as other cost effectiveness studies and looked at the incremental cost effectiveness ratio as a metric for that. If we go to the next slide, we did focus on best evidence, looking at comparative clinical studies with the least potential for bias, which are usually RCTs. We did look at non-randomized studies with concurrent controls if they controlled for confounding and there was no evidence from RCTs available to answer the question of effectiveness or efficacy. For safety, we did look at RCTs and non-randomized studies, and those are non-randomized studies needed to control for confounding. And then for key question three, the differential effectiveness or safety we looked only at RCT evidence and then we looked at formal economic studies for key question four. And you can see for publications, we looked at the peer-reviewed journal literature that was published in English, we looked at other technology assessments or publicly available FDA reports, and again, full economic studies that were published after the prior HTA.

We go to the next thing just as a reminder of methods. We use a very rigorous standard for our systematic review process following the precepts of the Agency for Healthcare Research and Quality Institute of Medicine, which is now the NASEM and Cochrane review methodology so as to make an objective evaluation based on criteria established a priori for the selection and reporting of studies. And we've talked a little bit about the topic refinement process. And then our clinical experts, like I said, we ask questions of them throughout the process. All of that led to a formal search of the literature. Not only did we look at the information from electronic databases, we also searched by hand the bibliographies of studies that appeared to be relevant and were included for our review and there was dual review at all steps of the process to lead to inclusion and final exclusion of studies. Excluded articles are documented and the reason for exclusion at full text in the appendices. We go to the next slide. We use predefined criteria to assess individual studies with regards to their internal validity related to their methods for selection, inclusion, and allocation of patients to treatment and come to a determination based on those predefined criteria as to whether the study is good, fair, or poor, or in other words, at low risk of bias, moderate risk of bias, or high risk of bias. And I would point out that a large number of studies generally fall in the category of a fair study where the study may be susceptible to some bias but not enough to potentially necessarily invalidate the results. And if we go to the next slide, just by way of review, these are the common criteria that we use for assessing risk of bias in randomized control trials. These are based on the Cochrane low back pain criteria. We go to the next slide. We also have criteria for risk of bias for non-randomized studies of intervention or observational studies and I would point out that pay series do not

answer the question of comparative effectiveness or safety so pre-post or single arm studies are considered at high risk of bias. And let's go to the next slide. So the individual studies are rated in terms of their internal validity and then it's not the same thing as the strength of evidence. The strength of evidence looks at the overall body of evidence for a primary outcome and we use the risk of bias as only one metric for determining the overall strength of evidence. We look at the consistency across studies with regard to the degree to which the estimates across studies for a specific outcome are similar in terms of their range and variability. Directness is not an issue here since we're talking about direct patient outcomes. Precision is of concern that looks at the level of certainty surrounding an effect estimate. And publication bias and reporting bias are difficult to assess but we do try to assess that as well. If we go to the next slide, it sort of summarizes the overall process and if we click on the next bit there, we see that we looked at studies using established criteria for inclusion, we rate those studies, and then we come to an overall strength of evidence determination. Again, looking across studies for specific outcomes and determine whether our confidence in that evidence is high, moderate, low, or insufficient and again, so this is across studies. And you can see that for different outcomes, the strength of evidence could be different based on the outcome and the studies that are included. As a note, we do note separately whether there were no included studies, we listed as no evidence versus rating it as insufficient.

If we go to the next slide. It's important to understand that our summary includes information related to the magnitude of effects that were observed and we use this paradigm to determine whether the change between groups for continuous scores or we've got information on risk ratios down below. But looking at the magnitude of effect as being small, moderate, or substantial. And you can see that on a zero to 10 scale for a numerical rating of pain, we considered a slight or small improvement of 0.5 to 1 points on a zero to 10 scale, 1 to 2 for moderate, and over 2 for a large substantial improvement. For function, ODI and RDQ were the most commonly reported functional measures and you can see how we determined slight, moderate, or substantial, and then we did do some pain or function mostly for function standardized mean differences and for risk ratios or odds ratios, you can see the range here. I do want to note that for small effects that what we have used here and we've used this for our AHRQ reports and other reports over the years, the small effects may be below what thresholds may be published for clinically meaningful events or clinical meaning of meaningful effects. But for some patients, those small improvements in pain or function may be important. I would also like to note that we did consider that if an effect size was below the threshold for a small effect, we categorized it as no effect or being similar.

If we go to the next slide. Where we are, we get to the results. And as you can see, as mentioned, there's substantial increase in the available evidence particularly in terms of RCTs compared to our 2010 report. And you can see that most of them have been in the usual care for vertebroplasty versus usual care. We do have some new sham control trials and we do have some new kyphoplasty trials versus usual care, as well as new comparative trials for vertebroplasty versus kyphoplasty. If we go to the next slide. As

we get into the overview of evidence, I wanted to point out a couple of things. First of all, our focus is on RCTs for effectiveness or efficacy as, quote, best evidence. Observational studies are more susceptible to bias and confounding, especially when we're looking at outcomes that are more subjective, such as patient reported pain and function. Observational studies are subject to selection bias including confounding by indication wherein patients who may have more severe disease may be treated differently than those with less severe disease. There may be residual confounding even after adjustment. So selection bias is a potential concern about observational studies. Historically, especially in this topic, they may overestimate the effects and other factors may impact the outcome, such as disease severity and comorbidities. So for those reasons, we focused on the RCTs. Non-randomized studies were included for safety. The quality of studies did vary, we'll get into that as we go into the specific comparators and there was a lot of heterogeneity across studies Including related to the patient populations, the pain duration, and the criteria for the pain duration for inclusion criteria across them varied. With regard to procedures, there were differences in the techniques and amounts of cement that were used and other factors. And for the comparators, the sham and placebo methods differed across included studies. And for usual care, usual care was not usually well specified. Across the randomized control studies, as pointed out, the adverse events were variably and sparsely reported. And the serious adverse events were variably defined and studies generally did not indicate whether they were procedure related or not, but most indicated when they did that they were not procedure related, procedurally related.

If we go to the next slide. This is just intended as a brief overview. We will get into more of the data to discuss, to discuss these various points. But the major point is that the vertebroplasty and, and kyphoplasty, both may improve pain and function. For vertebroplasty, there was inconsistent association over time versus sham and then versus usual care. There were differences in the level and size of the effects, but also inconsistencies and whether an association was seen or not. And vertebroplasty may improve pain and function, even looking at processing consistency, same thing with kyphoplasty versus usual care. For sacroplasty, the evidence still is sparse and remains insufficient. We can take a look at the next slide, which takes a look at the safety for both osteoporotic fractures, for both vertebroplasty and kyphoplasty, there seems to be similar risk of mortality and new fractures across comparators. As mentioned previously, cement leakage was common with vertebroplasty, but few studies reported on symptomatic leakage. And for vertebroplasty and kyphoplasty, the risks for cement leakage appears to be similar. For kyphoplasty, the osteoporotic fractures, again mortality and new fractures appear to be similar in compared to usual care. And for malignancy, again, the evidence is very sparse, but it appears that there were similarities for serious adverse events and new symptomatic fractures and mortality. Again, we'll get to more of the data as we go, go further on.

Let's go to the next slide. In terms of differential effectiveness or safety, the analyses are very limited and our confidence in these data are very low. Differential effectiveness related to whether or not specific subgroups or aspects of the patient population or technique may impact the outcomes is difficult to assess. And we have very limited

data, but there was no apparent modification of the treatment effect or differential effectiveness for either pain or function based on sex or prior fracture and that was based on one randomized controlled trial, which provided no detailed data on that. Looking at subgroup analyses across randomized controlled trials and those trials that did look at subgroups related to fracture age or pain duration, there was no evidence that those factors differentially affected outcomes. And with regards to some of the other aspects, again, stratified analyses across RCTs, PMMA volume did not appear to affect treatment outcome. And the study enrollment requirement of whether or not the MRI findings of bone marrow edema were present for inclusion criteria did not modify the effect as well. There really is very limited information on vertebroplasty versus kyphoplasty and no data were provided. Only a statement that there was no impact of sex, age or perioperative pain scores.

If we go to the next slide. Cost effectiveness is already mentioned. There were two U.S.-based studies that suggests that vertebral augmentation is cost effective versus non-operative management but those effectiveness studies stated that there was sensitivity varying the degree of assumed mortality differences did impact the outcome. There was a comprehensive cost utility analysis done by the UK National Institutes for Health and Research and they did notice that cost effectiveness for both vertebroplasty and kyphoplasty was influenced by mortality assumptions that were based on administrative data and also whether or not the comparison was blinded or unblinded trials. For malignant vertebral compression fractures, a Canda, a Canadian study suggested that it was cost-effective, vertebroplasty and kyphoplasty may be cost effective versus non-surgical management. So that's sort of the big picture overview. I won't spend a lot of time on the data. It will probably go fairly quickly.

Starting with the next slide, we'll focus on first presenting the fractures information related to fractures due to osteoporosis in terms of effectiveness and safety. If we go to the next slide. We take a look at the effectiveness. And we can see that there were six RCTs, a fairly small number of studies, but six RCTs. And again, a variety of places for heterogeneity in terms of pain duration and the patient population. Four studies reported pain duration of less than nine weeks and then we had ranges up to 26 weeks so later on, maybe in the course of their in their disease process. Three of the trials required evidence of bone marrow edema and the interventions were single level in most cases and the RCTs that reported that and we can see that there's a broad range in the volume cement that was used in those patients. The sham procedures were variable. The attempts were made to mimic the procedural language and cues, physical and verbal cues with the PMMA injection, including the smell of the cement and talking about things and maybe even having some physical sensation related to, to the procedure. As mentioned previously, local anesthetic injection was used in 4 of the RCTs that include the periosteal injection, 1 into the vertebral body and then 1 was subcutaneous only, so there was variability across those studies.

If we go to the next slide, as we look at the results, it's important to kind of remember that conceptually a treatment response is more than just related to a surgical or other procedure, that there are a variety of things that contribute to response, some of which

may not necessarily be attributed to a specific treatment. And so you can see that natural history, the effect of a placebo response, the effect of a comparator all need to be considered when we take a look at whether or not a specific intervention may improve a function or pain score compared to a comparator. And if we go to the next slide, again, just a reminder that the placebo response also is a very complex thing. There are incidental effects that may contribute to the overall placebo response, which is the sum total of the placebo effect and these incidental effects. And so, again, just as a reminder, a patient reported outcomes in particular, if the studies are not blinded need to be considered in terms of the magnitude of response in at least some instances. Let's go on to the next, next slide. I want to orient you briefly to the meta-analyses, the forest plots for some who may not be as familiar, that we have the studies, the timeframes on the left-sided column. We did include information on the duration of pain that was required for the inclusion criteria and where it was reported, we put the information on the duration of pain and then also whether bone marrow edema was required for an entry criteria into the study and the volume of PMMA that was injected, dichotomized into whether it was greater or less than five milliliters.

And then the outcomes that were reported for the measures that were used. So in this slide, we're looking at pain response in other words, whether or not patients achieved at least a 30% improvement from baseline in their scores. And we see that vertebroplasty was associated with a greater likelihood of achieving a pain response at most time points, with the exception of the one to two week timeframe. And we can see that it was large or moderate at most timeframes that did report a difference, but it was smaller later on. And as was pointed out previously, there was a study, Clark study, which is impacting the findings really at all the times and they had a higher likelihood of put a response basically across time frames in this trial. It differed from the other trials in a couple of ways. First of all, the mean fracture duration was less than three weeks in 79% of the patients. Again, local anesthetic was confined to subcutaneous infiltration periosteal numbing and they also used a higher volume of PMMA compared to the other trials. It's unclear whether or not these differences may have impacted the heterogeneity but nonetheless, the heterogeneity is the clinical heterogeneity is there.

Let's go on to the next slide. If we look at pain scores, it's a little different story. There was similar improvement at the earliest and the latest timeframes in pain scores and small improvement was noted then as sort of at those intermediate time frames as marked here. And the vertebroplasty was, of course, favored with those small improvements at those intermediate time frames. And again, just noting that there were some there was some heterogeneity, but not a lot, as we might have expected. A point that I would like to make is that for a small improvement in pain according to the scale we described, a 0.5 to 1.5 difference constitute a small improvement and we can see that the improvement here is sort of barely over that threshold for a small improvement.

So let's go on to the next slide. If we turn our attention now to function using the scores, uh we see that vertebroplasty was associated with small improvements in function at two timeframes, but it was similar at all of the other time frames. And our

strength of evidence was low for most of the timeframes. The small improvement at the intermediate time frame, we did consider to be a moderate strength of evidence for the function scores here. And again, we see that the Clark study is a bit of an outlier and again, mentioning that there is some clinical heterogeneity with regard to the procedures and the population. If we go to the next slide, we see that secondary outcomes again we didn't do strength of evidence on these that basically they're a similar quality of evidence scores and opioid use at all time points based on the available evidence. And there's more detail in the report on the secondary outcomes.

So if we move on to the next comparator for patients with osteoporotic fractures, we're looking at vertebroplasty versus usual care. And again, we see some heterogeneity in terms of the demographics, but also pain duration. Evidence of bone marrow edema being required for entry into the study. And the PMMA volumes less variable than what we saw with the sham studies, but still variability. I would like to point out that although we have new studies, a number of the new studies were considered to be very poor, in other words, at high risk of bias. And again, usual care consisted of a variety of things, including analgesics, physical therapy, maybe graded activity, braces or walking aids but most of the studies did not really provide specifics of what conservative care entailed. If we move on to the next slide, again, we see that vertebroplasty was associated with a large or moderate pain improvement at most time points, again, these are based on scores, average scores. And in contrast to the sham control trials, patients can't be blinded and so the larger effect sizes, maybe partially explained by that lack of ability to blind compared to what we saw with the sham studies, the effect sizes were smaller with the sham studies. If we take a look at the one to two weeks, we did exclude one outlier. The graph here, the meta-analysis shows that it was maybe not statistically significant, but when we take Blasco out as an outlier, the results did become statistically significant and again, showing a moderate improvement in pain score.

Moving on to the next slide, if we take a look at functional scores. Again, vertebroplasty was associated with a small improvement. But again, it was barely above the threshold for a small improvement based on the standardized mean difference of 0.2 to 0.2 to 0.5. And then there was moderate strength of evidence at all time points, except for that earliest time point. If we go on then to the secondary outcomes. Again, it looks that with regard to quality of life, there really wasn't a lot of difference across studies in terms of finding similar quality of life and most measured for the qual FO In the report, we talk about vertebroplasty being associated with better quality of life based on EQ5D, but it was similar for SF36 measures and that was in one randomized control trial. One study, Ms. Blasco, did not define what major or minor opioids were, how those were defined, but there was a similar likelihood of their use at all time points.

Moving on to the next slide then. If we take a look at the two studies that we have for RCTs for nerve block. There was also one non-randomized study that was considered poor quality, high risk of bias and again, we have sort of limited information and um not super good reporting and again, between the two RCTs, the PMMA volume was variable. If we go to the next slide to take a look at the results for the nerve block, we do see that vertebroplasty was associated with moderate improvement at the earliest

timeframes but similar improvement at the later time frames. And that improvement at the later, similar improvement at the later timeframes is based on larger fair quality trial which, you know, kind of looks like an outlier. This is one of the concerns about looking at only few studies and a meta-analysis that you may have more discrepancy in results so we focused on the highest quality larger study for that determination. If we take a look at the next slide looking at nerve block and functional scores, again moderate to large improvement in function occurred at the earliest timeframes, but at the later timeframes, there was similar improvement in those functional scores.

Then moving on to the comparison of vertebroplasty versus kyphoplasty, I think the main point again is that we see heterogeneity across the studies that were included both in terms of population and as well as the intervention. I would also like to point out that although we have a lot of new studies, many of them were considered to be at high risk of bias, over half of them were considered to be poor quality trials. Moving on to the next slide, getting into the results for pain, pain improvement was similar across vertebroplasty and kyphoplasty groups for all the time frames for which there was sufficient evidence to assess this. As a note, we, if there only were poor quality high risk of bias studies for any given outcome, we considered the evidence to be insufficient. Continuing on to the next slide, looking at the functional scores, again, we see that there was similar improvement in various functional scores based on the standardized mean difference. We do again see some heterogeneity but again, there was similar improvement when you look across the aggregate across the studies for which we felt that there was at least one or more fair quality trial. Moving on to then the secondary outcomes, again, quality of life was similar across measures for these trials, you can see the breakdown here and opioid use was similar at 6 and 24 months, but that was confined to a single RCT.

If we switch gears now and now talk about kyphoplasty versus usual care. We see again some similar patterns, differences in patient demographics, differences in the numbers of levels treated studies basically did not tell us how much PMMA they were using again only one study was considered fair quality, three were considered poor quality, and many of them were due to poor reporting on methodological factors that would allow us to assess internal validity. If we go to the next slide, looking at the pain scores, I want to point out that primarily there was a single large randomized control trial, the Wardlaw FREE, FREE trial was a fair quality RCT. And we can see that although, yeah, there are a couple of other trials, but a lot of the information that we have is from the FREE trial and we can see that there was large to moderate improvement at all time frames, except for the earliest time frame when we only had one poor quality trial available so again, improvement with kyphoplasty over usual care. If we go to the next slide and look at functional scores. Again, kyphoplasty was associated with moderate functional improvement at the two intermediate timeframes and only a small improvement at the later timeframe in terms of the functional scores. Turning our attention into the next slide again based on the FREE trial quality of life was associated that was an association between kyphoplasty with a small to moderate improvement in quality of life versus usual care up to six months, but it depended a bit on the measure.

Opioid use was associated with a moderate increase in the likelihood of less opioid, but again, this is a single trial and these are the secondary outcomes.

Okay, if we then look, we're still osteoporotic fractures and we're going to look at safety of vertebroplasty versus kyphoplasty. And when we go to the next slide, we can see that in terms of mortality looking across randomized controlled trials for both vertebroplasty versus sham and vertebroplasty versus usual care, there were no differences, the risk was similar across those studies. And it's important to note that the randomized control trials may be underpowered to detect rare events such as mortality and that the effect sizes from randomized controlled trials and the administrative data studies that are reported in the full report were reasonably consistent, but there was a lot of heterogeneity, a lot, or not of a lot of imprecision around the estimates. So we'll talk a little bit more about the non-randomized studies in just a moment. The next slide talks about mortality for VP versus KP and vertebroplasty versus kyphoplasty, and again, we can see that there was a similar risk of mortality in the studies that reported it at the various timeframes. And for nerve block versus vertebroplasty, they did not report on that. But again, there's a small number of RCTs which are likely underpowered to detect rare events. Looking at mortality, we did include in the full report summary across administrative database studies, because those were brought up in the public comment to the draft report. We considered the strength of evidence to be insufficient in due to the, sort of some of the bias related issues, methodological issues related to those studies but also related to the fact that there was not consistently an association seen between, an association between vertebral augmentation and mortality. And I won't discuss all of the studies in detail, they are in the report, but 30-day mortality, again, it was not consistently an association seen between mortality and the vertebral augmentation also a longer term mortality, an association between augmentation and mortality wasn't consistently seen and most of these studies relied on administrative data, particularly Medicare data for two of the largest studies but even across those studies that use Medicare data, there was inconsistency when there were other aspects of the Medicare data that were sampled in another study. Anyway, the bottom line is that there's inconsistency across administrative data studies looking at mortality and the impact of the augmentation. Yeah, and as a reminder, observational studies may show an association, but it doesn't connote causality and we need to put these findings in the context of the limitations of administrative data studies. Most of these studies while they did control for confounding usually via a propensity score matching, there, there are other concerns that one might have, and those are discussed actually in the full report.

If we go to the next slide. If we look at new fractures, the risk of a new fracture, if we look at vertebroplasty versus sham and the cumulative numbers of new fractures, they were similar between those comparators. If we look at vertebroplasty versus usual care new symptomatic fractures by time, again, were similar across time frames in studies, again, there's some heterogeneity. And if we look at vertebroplasty versus usual care, again, in the full report, there were similarities for any new fracture between all groups at all times. And, um, yeah, so again, similar fractures when we look at the various comparators and the various timeframes. If we look at the next slide and we look at

new fractures comparing vertebroplasty and kyphoplasty or vertebroplasty versus facet block again, there was a similar risk for new fractures across those comparators for both new adjacent as well as new symptomatic fractures. But for new symptomatic fractures we considered the evidence to be insufficient. Moving on then to looking at serious adverse events.

Tony Yen Andrea?

Andrea Skelly Again, serious adverse events were poorly reported and were not consistently defined, so the RCT evidence really is sparse. The trials may be underpowered to detect rare events.

Tony Yen Hey, Andrea.

Andrea Skelly Most of the serious adverse events were considered not to be procedure related. Was someone asking a question or I'm sorry?

Tony Yen Yes, that was me I don't.

Andrea Skelly Hi, Tony.

Tony Yen Yeah. Hey, Andrea, regarding the new fractures you mentioned across all time frames for vertebroplasties and kyphoplasties. Can you tell me what those timeframes are?

Andrea Skelly I believe we have them in the full report but they would have been early on. We tried to segregate things by you know early uh like within the first couple of weeks middle timeframes. I would have to go back and look at the full report, Tony, and we can do that.

Tony Yen Okay, great. Thank you.

Andrea Skelly To do that. Yeah, the one the slide that Erika has up here, the routine plastic versus usual care, we can see that we looked at them to one to two weeks basically and then you can see the breakdown of the timeframes here. And we tried to do similar things to that for, for the other for the other where we had the data.

Tony Yen Okay. Okay, thank you.

Andrea Skelly Okay, thanks. Alrighty then. So where were we? We were talking about serious adverse events and we could see that based on the data that we have the risks were similar but the effect sizes are but hugging the null, but there's a lot of imprecision and again, this may be due to the power to detect serious adverse events, many of them which would be rare. With regards to vertebral plastic versus usual care, there were similar rates of

reoperation and we can see that when we had detail for things like DVT and thrombophlebitis, the risks were similar. And um again, very sparsely reported across the studies. So I think we can move on. As mentioned previously, looking at cement leakage is very common across studies reporting for vertebroplasty, we don't have data for kyphoplasty specifically. And it appears to be that the symptomatic cement leakage is rare for both vertebroplasty and kyphoplasty. And it's important to note that across the studies they were not good about telling us whether there was symptomatic or asymptomatic leakage and I think that's an important thing to consider. We do have it detailed as you see here for vertebroplasty versus sham up to 90% of treated levels again, not a lot of detail about symptomatic or sequelae related to the leakage for vertebroplasty versus usual care. Symptomatic cement leakage was fairly uncommon, zero to one percent across the seven RCTs that we looked at. Asymptomatic cement leakage was more common across the studies that we looked at. And then for vertebroplasty versus sham, again, symptomatic was fairly uncommon but similar across the two treatment groups. And embolism from symptomatic embolism from symptomatic extrusion was fairly rare but again, we've only got one RCT that reported on that and we can see that the estimates are very imprecise based on the one RCT which is listed there. And then one RCT reported that vertebroplasty versus sham, it was a little bit greater versus, excuse me, a little bit greater versus there was one patient, so again, we're dealing with small numbers for some, of some of these studies. If we go on to the next study, there are a number of adverse events for which we felt evidence was insufficient, including serious adverse events, refracture or worsening of a fracture and this is for vertebroplasty versus kyphoplasty and device or procedure related serious adverse events, they just generally were not defined or well reported and then re-operation for any new or repeat fracture. If we go to the next slide, I'm looking at vertebroplasty versus usual, excuse me, kyphoplasty versus usual care. Again, we see similar risk of adverse events across a variety of different outcomes, including mortality. Serious adverse events, treatment related serious adverse events, those were at 30 days and at 12 months. There are only two serious adverse events that were attributed to the kyphoplasty specifically and those are delineated in the report. Withdrawals due to adverse events were fairly low, again, similar. New clinical or asymptomatic or new clinical or symptomatic vertebral fractures again, we're similar across treatment groups in two randomized control trials. And evidence of new radiographic vertebral fracture again no difference really between treatment groups and then re-operation for a new symptomatic fracture was reported in one trial and again, fairly similar across treatment groups.

If we go to then now leaving the osteoporotic fractures and return now to looking at augmentation for fractures due to malignancy, we do have a new randomized control trial compared to the last review, the CAFE trial, which looked at kyphoplasty versus usual care. It was a fair quality study. Important to note that they had a high crossover rate at one month, after one month where 59% of the patients from usual care did get kyphoplasty we're not really be able to provide information on comparative effectiveness. You can see that the demographics here and the most common previous treatments that should be noted are that they receive, patients received chemotherapy of some sort, surgery, steroids, or radiation therapy. It's important to note that at

baseline, more patients that were randomized to the kyphoplasty versus the usual care had three fractures. And there were some differences in the previous treatments between the groups. It's unclear to what extent those could impact the findings. If we go to the next slide. I think the bottom line is that kyphoplasty was associated with large improvements and likelihood of improvement in terms of pain and function for all the outcomes that they report at one month. The exception would be the Karnofsky performance score which, again, was a moderate improvement. But the strength of evidence really is low across these outcomes based on the single fair quality trial. We didn't do SOE for looking at secondary outcomes, but there may be some evidence to suggest that there is an improvement in SF36 mental and physical component scores. Moving on to the next slide and looking at the summary of the safety results, when we look at things the differences between treatments were not statistically significant, but for some things kyphoplasty tended to have an increased risk for things like mortality especially when you looked at the as treated, in other words, as the crossover but also serious adverse events and, so it's just something to consider, but again, the strength of evidence is low and statistically they are similar. Just wanted to point out that they tended to have higher risk for things like even symptomatic fractures, of course, are going to be only, were only in the kyphoplasty group as well and some of these tend to be very rare adverse events. I would also like to point out that some of the patient population characteristics suggest that these are patients who are already at high risk of mortality, comorbidities, and adverse events from a variety of perspectives. If we go to the next slide. If we look at the studies that were non-randomized, we had 3 retrospective comparative non-randomized studies looking at vertebroplasty versus kyphoplasty. Again, because of the high risk of bias and some inconsistency across studies, we felt that the data were insufficient to draw firm conclusions. That said, there was similar improvement in pain for the two augmentation procedures across the comparative non-randomized studies. There were some outcomes that we did report from case series that, again, suggests significant improvement from baseline in those studies and the incidence of adverse events was low and occurred with similar frequency in the comparative studies. But again, it's hard to draw firm conclusions and we felt that the data were insufficient to draw conclusions.

Moving on to then sacral insufficiency fractures and the use of augmentation. Again, we felt that the evidence was insufficient from poor quality non-randomized studies the registry that was mentioned in the public comments, we did include information from that registry in here. The summoned substances for pain and function, the results did vary a bit by comparator. Again, these are very messy studies. And sacroplasty was included, was associated with a greater improvement versus usual care across these studies again the safety, the decreased risk of mortality and for, with sacroplasty versus usual care with similar risk. The data, again, are very messy and it's difficult to draw firm conclusions about it. They are detailed in the report, and we can go into them, if necessary.

If we look at differential effectiveness and safety, as I already pointed out that the analysis of these factors was very limited by the study sample sizes, the numbers of trials that looked at such factors, and the way in which they looked at the factors. We

reported on trials that provided tests for interaction, as well as the AHRQ systematic review by Chou et al. that did stratified analysis across the randomized control trials to look for evidence of differential effectiveness and safety. And the bottom line is that our confidence is really very low in the findings and the estimates are imprecise. For vertebroplasty versus sham or usual care, none of the factors that were evaluated appeared to modify the effect of treatment and you can see them listed here and we talked about them previously. And again, as mentioned previously for vertebroplasty versus kyphoplasty, the only study that we have available really did not provide data or even p-values for interaction. If we go to cost effectiveness, again, the next thing again has been already discussed. One cost utility analysis from Canada suggests that vertebroplasty and kyphoplasty may be cost effective versus non-surgical treatment. We mentioned the comparative analysis done by the UK group that noted cost effectiveness for vertebroplasty and kyphoplasty was influenced by the assumptions about differential mortality for augmentation versus usual care and again, those modeling pieces were based on administrative data and again, they cautioned that causal inference regarding mortality isn't plausible from administrative data and they also found that the cost effectiveness was influenced on whether or not the comparisons used in modeling were blinded trials or unblinded trials. And as previously mentioned, there were two studies in the US that suggest that augmentation is cost effective versus non-operative management but again, the varying, varying the degree of assumed mortality differences did impact the outcome for cost effectiveness and Medicare claims data were used extensively in most of those models.

So then moving on to the summary, I'll keep it very brief. Let me explain our color coding system here. So where we felt there was high strength of evidence, we've color coded it in green, moderate is yellow and low strength of evidence is in the coral. And I think the bottom line is that there is some evidence that there is a moderately, a moderate increase in the likelihood of a pain response versus sham for vertebroplasty at some timeframes, it's a smaller likelihood at later time frames based on one randomized controlled trial. If we look at pain scores, we can see that the pattern's a little different, that the similar there was similar improvement in some time frames and the small improvement was noted across trials at the intermediate timeframes, while the strength of evidence is high I would note again that the magnitude of effect was just sort of barely above the threshold for a small effect. And for function scores, again, when there was a small effect, the effect was small, but mostly the strength of evidence for function was low strength of evidence. Again, similar mortality, new vertebral fractures, new fractures that were symptomatic with evidence of bone edema, serious adverse events, all of these things were similar and then again, cement leakage is fairly common across the randomized control trials. If we go to the next slide.

Tony Yen Andrea.

Andrea Skelly Yeah.

Tony Yen On that prior page.

Andrea Skelly	Yeah.
Tony Yen	That in the upper left hand corner one RCT that shows less than one week with the N of 113, is that the Clark study?
Andrea Skelly	No, this, I believe, is the Farinescu study, are, um, the only one that, only one that only one that reported response.
Tony Yen	Okay.
Andrea Skelly	We could go back. We can go back to the slide showing response if that would be helpful.
Tony Yen	Okay.
Andrea Skelly	Or maybe it was the Clark study I apologize. Let's go back to that responder, just responder slide. So yes, you're right, Tony. I was wrong. It is the Clark study is the one that showed the greater likelihood. I apologize.
Tony Yen	Yeah. Yeah. Okay. No worries. I just want to make sure that as you're showing these summaries that I have a more clear representation in my head about which studies were kind of outliers in the first place and how they're represented over here in the summary slide.

Andrea Skelly

Yeah. No, I understand. Thank you for pointing that out and apologize for misspeaking. Okay, then I think we can maybe go on to the vertebroplasty versus usual care and again there was improvement at most time frames for most vertebroplasty versus usual care. Again, I would note that the effect sizes were larger for the usual care than the effect sizes that we saw versus sham and again, the strength of evidence was low for many time points moderate for some time points And again, with regard to adverse events, we see a pattern of things being very similar between the two treatment groups. Cement leakage was rare that was symptomatic across the studies that we were able to get information on symptomatic leakage and again, asymptomatic leakage was common across studies with vertebroplasty. Yeah, I think we can move on. And then in terms of summary, looking at vertebroplasty versus kyphoplasty, again, similar, similar effectiveness, similar information across studies for effects related to mortality, fracture, cement leakage, and serious adverse events were insufficient, but again, you can see low strength of evidence for cement leakage and cement embolism in these studies that reported that. Moving on then to the next, looking at medial branch block again. Early on, vertebroplasty appeared to confer moderate improvement in pain and function, later on, however, the effects were similar. And not much reported with regard to adverse events, new vertebral fractures were similar across the two groups. And then next, looking at kyphoplasty versus usual care. Again, patients are not blinded, we see that there was large improvement or moderate improvement across primarily one randomized controlled trial for this set of outcomes, so there was moderate improvement in pain and function at most time frames, but the strength of evidence was low. We can see that, again, strength of evidence was low for similarity across all of the safety outcomes. Against symptomatic cement leakage was symptomatic was, was again not uncommon. I think that that may have been a typo, we'll check on that. But leakage was not uncommon, but in terms of symptomatic, I, there were no differences. If we move on to the next slide, kyphoplasty versus usual care. Again, we see that there were large effect sizes for patients who had tumors or malignancy, but again, this is based on one randomized control trial, which had a high crossover rate after one month and so that's why we say that there's no evidence at the later time frames. And again, mortality, serious adverse events and new symptomatic fractures were similar the one month time frame there was a greater risk of new symptomatic fracture with the kyphoplasty when we looked at the timeframe after the crossover and again, symptomatic cement leakage was rare. And I think that if we go on again, vertebroplasty versus kyphoplasty the evidence base is insufficient based on three retrospective studies. So the evidence remains sparse and insufficient in patients with tumors or malignancy for that comparison of vertebroplasty versus kyphoplasty. And then related to sacroplasty again there is basically a very poor evidence base from poor quality non-randomized studies. And again, we felt it was insufficient to draw conclusions. Moving on then for differential effectiveness, again, very limited information, no modifiers that were identified, modified the impact of on the outcomes for the treatments. And then again, cost effectiveness, we've talked about the two studies in the US and um noting again that the cost effectiveness may be influenced by assumptions related to mortality, differences between vertebral augmentation and usual care, and whether or not the studies or the modeling is based on blinded or

unblinded trials. And again, many of the studies that are in the report are in non-US systems and so their applicability to the US situation needs to be considered.

Finally, a few things to consider. Again, we have a higher, higher number of higher quality studies than we did for the 2010 report. We still have no evidence for kyphoplasty versus sham. And the malignant fractures and sacroplasty literature remains sparse or an insufficient. Again, I would note that there is substantial heterogeneity across trials of vertebroplasty with related to, relation to patient selection, procedure protocols, and regarding to the comparators as well, including variations in the sham procedures and inability to really understand what usual care entailed in those studies. Adverse events were variably defined and inconsistently reported across studies. Again, the full report has appendices with a lot of information from non-randomized studies that was considered insufficient. I think one of the questions that remained are, you know, there are still questions that remain whether periosteal infiltration with local anesthetic without the administration of the PMMA is associated with an independent persistent therapeutic effect and to what extent the impact of those different placebo procedures may impact the differences we saw in effect sizes between vertebroplasty and sham, and vertebroplasty versus usual care. I think the reasons are unclear, some of them may be due to the nonspecific effects that we talked about earlier, um, and use of the local anesthetic has been proposed as it might provide the therapeutic effect, it's unclear whether that would be something that would persist into longer term. There's just a lot of questions that make it unclear. The impact of pain duration and pain severity and the timing of treatment based on the evidence that we have presented also is unclear and it's unclear whether or not that would impact the findings and the effect sizes that we've seen. So the next slide, again, RCTs may be underpowered to detect rare events for the adverse events and again, there's insufficient evidence to really draw from conclusions about modification of treatment by the factors that we've discussed. And the studies may have lost statistical power and the estimates are very imprecise. So let me stop there and see if there are questions. Thank you for your attention.

Janna Friedly — Questions from the committee? I, I, I have a question, but If anybody else has one they want to start with. You can defer.

Laurie Mischley — This is Laurie. I just had a question about whether or not any of these studies looked at the long-term, long-term, like over time, the alternative of not treating and the effect of chronic, you know, three years out I'm just worried about everything from lung function to chronic pain to some of these downstream consequences of untreated. Just wondering if any studies looked at that. Everything I saw seemed to be just 12 months was the end point.

Andrea Skelly — Most of the studies do not give us long-term follow-up, we reported what we could within those time frames. We can go back and look at some of the things that we've not represented into the slides, but by and large, there has not been long-term follow-up from the randomized control trials. Some of the non-randomized trials, again, we focused on harms. We did not look at effectiveness over the long term because most of these studies are from registries or databases. And again, given that concerns regarding the quality of observational studies for patient-related outcomes and we did not use non-randomized studies to look at effectiveness. There are some appendix slides related to harms for non-randomized studies and they are detailed to the best of our ability with what we had in the full report.

Janna Friedly — My question, Andrea, for you or maybe for Dr. Mirza is um related to the Clark study, the Vapor trial and I just, I'm trying to uh I'm trying to, as you pointed out, there's um heterogeneity in the results and some outliers and some differences and results and I'm just trying to understand what those what those differences are. That some of it, the differences in study designs are related to acute fractures less than six weeks and beyond but I'm curious if there's additional insight that I missed maybe in the report or in the, in the discussion about that Clark trial in particular and why. What's different about that trial or what's playing into that?

Andrea Skelly — I think there are a number of differences in the trial. One of the differences we've mentioned is that they used only subcutaneous infiltration uh for the for the local anesthetic versus extending it into the periosteum which is, is what other studies did. I think a couple of other things that might be noted is that the mean fracture duration in the Clark study was shorter, almost 80% of the patient population, the fracture duration was less than three weeks. That potentially could impact, but it's unclear whether that how much that would impact. They also used a higher volume.

Janna Friedly — But that wasn't differential, right? That was not that was.

Andrea Skelly — Yeah. Yeah. The differential effectiveness information did not show a consistent result. I mean, there was no impact on the duration of the acuity of the fracture, the duration of pain. But again, we have limited amounts of data from the RCTs and
the numbers of RCTs for the meta regression reported in the AHRQ review. The estimates are imprecise, but we did not see evidence of effect modification. That doesn't mean that it's not there, but we don't have, have sufficient information to talk about that. The other thing that makes the Clark study different is that they did use higher volume of PMMA compared to the other trials. And Dr. Mirza probably is better able to speak to the potential impact of those factors on the results, but those were the things that we thought of in terms of why there may be heterogeneity.
In this particular study, it was a well done study.

Janna Friedly — Mm-hmm.

Sohail Mirza — So.

Janna Friedly Yeah, I'd be curious to hear from your perspective because it does the, the thing that does come up quite a bit in my mind and what I hear is the technique of the procedure. So I'm curious to hear your thoughts on that.

Sohail Mirza Janna, my, I think the earlier treatment makes a big difference because the natural history, at least from what I've seen clinically is that the pain improves very quickly, particularly in the first month.

Janna Friedly Mm-hmm.

Sohail Mirza So it makes sense that if you're catching patients within the first three weeks or so, that you'll see a benefit in the short-term relief, no matter what the procedure was as long as there's anesthetic injected into the fracture area or anything injected into the fracture area it would be expected to have a short-term effect. But once the bone starts healing, which is really four to six weeks and longer, I think the effects would be diminished. That's my sense.

John Bramhall Dr. Mirza.

Janna Friedly And so is the thought then that, that early potentially one explanation is that the early benefit to a procedure, whether it's the local anesthetic or whichever procedure is that that early pain relief allows for a faster recovery that potentially could improve mobility and recovery in some of those consequences that you get from that cascade of lack of movement and, and, and pain sequelae that causes longer term consequences.

Sohail Mirza That's my interpretation from a clinical perspective. Also, I think most patients, if you don't if you treat them non-surgically, are off pain medications by a month. So that's pretty common the first two, three weeks is when they're requiring some medication, even simple analgesics but they don't really need that much longer than that. In fact, they also resume activity so you have to kind of tell them to still be cautious with activity and lifting because they're feeling so much better that they're feeling better go back to lawn mowing and other stuff that you may not want them to doing in the first few weeks after a fracture. And edema, you know, other studies have tried to get at this from MRI edema. Edema on an MRI takes much longer to resolve than fracture healing. Fractures can be healed and still show edema on MRI.

Janna Friedly Great. Thank you. Other questions for Andrea?

Clint Daniels Well.

John Bramhall Andrea, I had a question about the Clark study as well. Sorry, this one keeps on coming up but was it you did a close reading of the report. Is it your impression that the authors in that Clark report went out of their way to be very concrete about it being a subq, subcutaneous injection of local anesthetic versus periosteal? Do they go out of their way to make that distinction? Sohail, I know what you think, but it's, you know, they're driving a needle into fractured vertebral body and I,t It seems like a human thing to do would be to give generous local anesthetic in that area to still have the patient tolerate, you know a needle or trocar actually going into the bone and so I'm just wondering, Andrea, did they explicitly want to do sub-Q and make that the, the comparator to arm or it was this a throwaway line, do you think?

Andrea Skelly That was their intention.

John Bramhall Yeah, yeah.

Andrea Skelly Was to go subcutaneously I'm not a clinician, but it seemed to me that they did, did intend to avoid periosteal numbing and Erika has pulled up the study for us. Thank you. And again, I'm not a clinician, but it sounds like they did try to do due diligence to assure that it was just the skin the subcutaneous aspect for the infiltration.

John Bramhall Okay.

Janna Friedly And, and in the protocol, John, I'm just looking at the protocol paper they specifically said that they made the incision four millimeter incision, skin incisions made and light tapping on the skin will be made to simulate the vertebroplasty needle advance conversation regarding cement mixing and injection will be made by the operator to suggest a vertebroplasty is being performed.

John Bramhall Right. Right.

Janna Friedly After the subcutaneous tissues were injected with a local anesthetic. So it was very intentional, this subcutaneous injection.

John Bramhall Okay. Thank you. Thank you.

Sohail Mirza So John, to answer your question about periosteal injection, it's been a long time since, long time since I've put in a distal femoral pin for femur fractures, but as a resident, we did it basically every day. You really have to numb up the periosteum in addition to the subqueue before you can drive and you know a distal femoral pin for femur fractures is three millimeters big, much bigger than an 18 gauge needle or 16 gauge needle. But the patients don't tolerate it unless you really numb up the periosteum. But once you numb up the periosteum, how far you drive the pin, doesn't really affect them.

John Bramhall Because it's a mechanical expansion of the area that puts stress onto the periosteum and that's the innervated region, right? I mean.

Washington State Health Care Authority

Sohail Mirza	For the pin tip touching the periosteum is very painful.
John Bramhall	Exquisitely painful.
Sohail Mirza	But once you go past the periosteum, you can drive the pin as far as you want. It'll cause microfractures or whatever. It doesn't hurt. The internal architecture of the bone, we don't think has enough innervation to be very painful.
Janna Friedly	So do people ever do for this, rather than injecting cement, do they ever do just periosteal lidocaine injections? Like the sham procedures.
Sohail Mirza	I think, the procedures that have 0.4 mils of cement are respectively just periosteal anesthetic injections. I don't think there's, no, I haven't heard of it. It is tough to get an anesthesiologist to do a thoracic nerve root block because of the risk of pneumothorax. So I wouldn't think they would do it unless there was really a compelling reason.
Clint Daniels	A question about one of the comparators of the medial branch block. Is that separate from usual care or is that sometimes part of usual care? I thought it was interesting that the medial branch block after the very short term was very similar to the augmentation whereas the augmentation seemed to outperform the usual care at more time points. So I was curious Is that a common treatment for this, or maybe this is a question for Dr. Mirza?
Sohail Mirza	I really haven't understood that comparison. Medial branch blocks are used in chronic low back pain a lot. I don't think I've ever seen a thoracic pain patient get that. So I don't know why that was chosen as a comparison treatment. I don't think it's common, at least not in my experience for patients to get medial branch for vertebral compression fractures.
Jonathan Staloff	Piggyback question on that. Do we know if medial branch blocks are a covered service by the HCA for vertebral compression fractures?
Sohail Mirza	My sense is they probably are covered no matter what the underlying indication. I'm not sure.
Janna Friedly	We should check that. My suspicion is they are not, but is that, but uh we, we should, we should verify.
Sohail Mirza	Yeah, sorry. I thought you were asking a general question for procedure coverage, not the HT. I wouldn't know that.

Janna Friedly Yeah, let's, let's get verification about that because there's, there's also diagnostic blocks and therapeutic blocks, so there's a difference between those but and they're So I would doubt that they are covered for, for this indication. But we should get them to weigh in on this. So we'll come back to that, we'll get an answer to that question.

Jonathan Sham Dr. Mirza, I was hoping you could provide some context. It was reported earlier that the AOS, I think it was one of the only professional societies that did not endorse this unless there was nerve impingement as a relatively recent guideline released, I think 2023. Can you give us any context? Was that in response, was that a change to their previous recommendations? I'm just seeing all the other professional societies kind of are a bit more bullish on, on the technique. Do you know if that is a change from previous and if it was a response to maybe some of this new data that we're looking at right now?

Sohail Mirza I actually don't know exactly what the process was for the W, the AOS guidelines. I can tell you that they have taken fairly bold positions on guidelines-based care. Particularly with regards to total knee replacement and then, you know, particular injections for CINVISC and other stuff. They took positions that were very unpopular with their membership, so I'm not sure what's going on, but I don't have any insight on this specific guideline by the Academy of Orthopedic Surgeons. I think they are trying to be more science driven in general.

Jonathan Sham That's helpful. Thank you.

Janna Friedly Other questions for Andrea about the evidence report? Okay, hearing. Yeah.

Josh Morse Could I. Yeah, just doing some investigation, you know, the clinical committee did look at spinal injections I believe it was last in 2016. I'm not answering for the agencies right now because I think I'm just going to say that vertebral compression fractures were an exclusion from that decision, so you did non-cover therapeutic medial branch blocks at that time but compression fractures were not part of that scope. That doesn't help answer the question about agency coverage, I'm just letting you know that's the first place I looked.

Janna Friedly No. Okay.

Josh Morse And we can work with the agencies to find out. I have a feeling it's there may not be a policy at least for apple health that this would be a separate request.

Janna Friedly Okay. Okay. Thank you for looking into that.

Josh Morse Thank you. I'm sorry if that's a minutia question. My rationale for asking it is since this informs coverage decisions, it would be good to know which studies are most relevant to our existing sort of ecosystem for vertebral compression fracture care.

Janna Friedly	Yeah, it's always helpful to know when we are weighing alternatives to the treatments that we are considering, what's covered and what's not covered. So I think it's a good question to ask. We are scheduled to have a lunch break currently. So we are scheduled to come back at 12:30. So unless there are any other questions, we will adjourn until 12:30. Great, thank you everybody.
Janna Friedly	Straw poll process.
Josh Morse	We do, yeah. Melanie and Val will, when you're ready, bring up those slides to guide discussion as you want to do that. And then I'll have to do a word document when you get to place when you're ready to start talking about draft criteria.
Janna Friedly	Great.
Josh Morse	Or coverage criteria, coverage decision you know that's um so we'll switch back and forth on that., so.
Janna Friedly	Okay, great.
Val Hamann	And I think we're just waiting on Amy and Jonathan Staloff.
Amy Occhino	This is Amy. I'm here. I'm just coming in from a quick walk with my dog, so I am available.
Val Hamann	Sounds good.
Janna Friedly	Okay. Let's give it.
Val Hamann	And Andrea, I see your hand is raised.
Andrea Skelly	Yeah, I just wanted to say that with regard to Tony's question about the fractures and the timing of fractures. The appendices have a lot of plots that we did not put in the full report that detail what we have for the timing of fractures and then there are some additional tables in the report if any of those would be helpful to you. And then to Laurie's question regarding some of the longer term follow-up, particularly on harms. Again, the report has a number of tables related to harms some of them go up to 36 months and same thing for the fractures, I think the longest we had was two years, one was 49 months. So just as in terms of follow up on those two questions, it depends by the comparator. And so if there's if there's additional detail needed, we can look that up.

Janna Friedly

Okay, great. Thank you for that. Do we have Jonathan back yet? Oh, there we are. Great. Okay. Looks like we have everyone, everyone back. So now is our time to continue our discussion and come to a coverage decision. So, I would like to open it up again for any additional questions, either for our vendor or our clinical expert, if folks have reflected over the lunch break and have any additional questions before we, we sort of take a straw poll vote based on what we have heard and read and digested. Okay. Doesn't look like there's any other outstanding questions. Should we move to showing the slides and showing the slides. And again, I want to acknowledge this is my first meeting, going through this decision-making process completely on my own as chair. So I will lean on Josh to make sure that we are following all of the rules in terms of the process. Let's walk through this coverage decision-making process.

Melanie Golob

Yeah, Janna, and I'm happy to walk through this. So just as a reminder for the group, I think in the past we've used like a Word document to guide the group through as a decision aid and I believe the decision aid is still in the packet, but just for simplicity and to help to help with the overall process, we've put it into some, some PowerPoint slides to help with making the decision. So Val, if you wouldn't mind going on to the next slide. Just as a reminder, this is where we are in the process. We've already done the first four, so the presentation, the public comment, the evidence report, the committee questions and answers. And so now we're getting into the discussion and the development of the draft determination and some straw poll voting.

So this is what the group should consider when thinking about coverage or not for vertebroplasty, kyphoplasty, and sacroplasty. The safety, so the evidence of effect looking at morbidity, mortality, and non-fatal outcomes, short versus long-term complications. Again, that's all in terms of safety. And then efficacy, so if there's a benefit and what those important health outcomes are through either direct or surrogate measures. So looking at the short or long-term effects that this group was discussing. And then also the magnitude of effect and quality of life and as well as pain and functional restoration and disease management. And then lastly, costs. So whether costs are more, less, or the same compared to management without use of the technology. So, and then other considerations. Again, the idea is to result in overall health benefit for patients. And looking at those three areas of safety, efficacy, and cost, deciding on the availability of evidence, your confidence in that evidence and then the applicability to the decision. So there might be plenty of evidence, but it doesn't apply to the, this particular decision, so just kind of thinking through those aspects of this. And then these are also considerations to think of when making these decisions, the nature or source of the evidence, the characteristics of the study and if they apply to these populations, consistency across studies, so if you have very disparate studies, it might be tougher to make a decision, the recency, relevance, and bias of that evidence and also those unique populations based on sex, age, ethnicity, race, or disability. And the idea is to, again, give the greatest weight to the valid and reliable evidence.

And this is just kind of the big takeaway is the ideas to essentially pay for what works for what works. So, get patients better health outcomes by paying for those health technologies that work. And that funnel is just to kind of show the considerations that go into the decision, so not just the safety, efficacy and cost from the reports, though that is a big one and the main one, but also what other alternatives there are or comparisons to alternatives, including information from the Director, the advisory groups, and the public comment process and all those go into the determination. So I think in the past we've done this as kind of a table, but we thought it might be easier for discussion to think about. So the list that you see in front of you for the safety outcomes, mortality, new fractures, serious adverse events, cement leakage and re-operation, those were the ones that were listed in the studies that were presented, but we also want the group to consider, are these the important safety outcomes? So sometimes studies might not give you the outcomes that you would need to make a decision. So we want to make sure that as you consider these outcomes that are presented, are there any others that would be useful for you in making your decision that might not be reported in this study. So this is kind of a discussion point right here.

Janna Friedly — I think for me these, these cover the important safety outcomes that come to mind. I don't know if, does anyone have any other safety outcomes that are not included here that we should add to the list?

Sohail Mirza — And I don't think it's reported very often, but deformity like kyphosis is a concern in compression fractures and some people think kyphoplasty corrects it or prevents it. I'm not sure that's proven. But I don't know if that's a major safety outcome but deformity could be disabling. I would put parentheses kyphosis in particular. S-i-s.

Melanie Golob — I'm not hearing any other safety outcomes that people would want to consider. We could definitely move on to the efficacy outcomes that were reported.

Evan Oakes — What about pain? Or I'm not sure if it's captured there. Isn't that an adverse outcome, like added pain? Or is that under serious adverse events? What is that? Is that just an outcome measure? I'm just bringing that up.

Sohail Mirza — I personally would consider pain and function in the outcomes category.

Evan Oakes — Okay.

Sohail Mirza — But one other kind of rare event and I would be like neurological deficit, anything to do with spine risk of paralysis. I don't know if pain would fit in this list of safety outcomes, but neurological deficit, I think. Could be a consideration.

Janna Friedly — And are there related to, to, cement leakage um or is there are there any other Things to.

Sohail Mirza Deficit. Sorry, Janna. F-i-c-i-t.

Janna Friedly Oh, sorry. D-i-c-i.

Val Hamann Okay, sorry, one at a time.

Sohail Mirza D-e-f-i-c-i-t. And I would, while we're on this, sorry, I should have thought of these earlier when infection, infection. I have seen some patients come back with osteomyelitis after a kyphoplasty and it's catastrophic, usually is associated with deformity and paralysis. Sorry, go ahead, Janna.

Janna Friedly Oh, I was just going to ask, it sounds like from the data that the vast majority of the time that cement leakage is asymptomatic, but the concern with cement leakage, there are reports of, of embolism or, you know, um migration of the cement um is that, is that the case or is that and is that captured in cement leakage as an outcome or is that something?

Sohail Mirza That I personally had a case and we reported it in spine of catastrophic cement emboli. It was a very small embolus but through the venous circulation, this unfortunate patient had a patent for M&O Valley and it went across the heart to the heart arterial circulation and block the middle cerebral artery. So the patient had a major stroke. And she expired like a month because family withdrew care after a while. But other than manifesting as mortality or neurological deficit, asymptomatic cement emboli are usually not a concern.

Janna Friedly Great. Thank you.

Melanie Golob Okay, I think we can move on to efficacy which, Dr. Oakes, to your point about pain, I think they were, yeah, using them to measure how effective the procedures are. So the efficacy outcomes, pain response, pain score, and function score, but are there any others this group would think of to look at efficacy that might not be here?

Jonathan Sham Just because I think this is kind of central to the discussion, maybe Dr. Mirza could give us some context on really the difference between pain response and pain score. I know pain response was defined as like greater than 30% VAS reduction from baseline versus obviously the pain score just being the actual number is one use more regularly in these types of studies? Is there an MCID, a minimally clinically important difference that we should be thinking about? Because I think a lot of my thoughts hinge upon this.

Sohail Mirza: So I was actually going to ask about that difference. I'm not sure. I don't think patients understand either one. I don't know if any back pain patient who'd be content with understanding 30% improvement, like going from a score of nine to six or something like that would necessarily, I don't think most patients would necessarily consider that a big change. My sense is from a patient's point of view, they ask for successful like what's your success rate and my sense is their perception is that their pain is going to be gone. So if you are going to have two different outcomes one is, one important one patients might be looking for is complete pain and as small a percentage as that may be that may be something patients want to consider. I don't know if a pain score by itself is very meaningful to patients.

Janna Friedly: And this is something I can speak to this from a research perspective and a pain research perspective. There's typically, when people are reporting on pain, 30% pain reduction is often considered to be a moderate pain reduction and 50% is more significant pain reduction. And so those are common 30% or 50% are commonly used as cutoffs when you're looking at responder analyses. And there is a lot of debate about whether you use mean pain scores when you're comparing two treatments mean reduction in mean scores versus what percentage of people reach that certain threshold, either 30% or 50% improvement. And oftentimes the thought is that there's going to be a subset of patients that respond with any of these pain treatments, a subset of patients that respond and a subset of patients that don't respond or a subset of patients that get worse. And so if you look at the mean scores that you may not see any difference because the mean scores will be the same but if you look at a responder analysis, that there will be a subset of patients that respond and so you'll, you'll see a percentage of patients that respond. So you might get a different answer if you look at the responders versus the percent that respond versus a mean score, if that makes sense. So there's a lot of debate about which way that you should look at pain. So there's, there's no pain, in my opinion, there's, there's necessarily right or wrong answer with that. I don't know if Andrea wants to weigh in from her perspective from the evidence standpoint.

Jonathan Sham: That's super helpful.

Andrea Skelly: No, I think your comments are spot on. The average pain score may or may not represent what a patient may achieve and some folks have suggested that the pain response is more meaningful because you have at least some assurance what the likelihood of a set of patients achieving that response, but no, nothing to add. Nice. Thank you.

Sohail Mirza: But I want to clarify, Andrea and Janna. I thought you were talking about pain responses like percent improvement versus responders, like how many the number of patients or proportion of patients that achieve that degree of improvement?

Janna Friedly: Yes. Well, so there's the percent of the percent, percentage of patients that achieve a 30% improvement or a percentage of patients that achieve a 50% improvement.

Sohail Mirza	Okay. That's what you mean by pain response?
Andrea Skelly	Yes.
Sohail Mirza	Okay.
Janna Friedly	Yes. And some of these, many of these sites. So I think that the Clark study, for example, used a 30% improvement was their primary outcome. What percentage of patients achieved a 30% improvement was their primary outcome is what they were looking at the difference between those two groups, between the two treatments. Correct? Is that just as an example, I think that's I understand.
Andrea Skelly	Yeah, I think some studies also did report 50%, but because the majority focused on 30%, that's what we presented, but they should be in the report.
Erika Brodt	Yeah, it looks like at least from the plots Clark use pain less than four. So you had to have a score of three. Or lower. It wasn't a percentage. Necessarily. They didn't put in those terms anyway. But I can.
Jonathan Sham	But for inclusion in that study, you had to start with greater than 7, right? Am I recalling that correctly? So then there would be a, a 50% reduction.
Erika Brodt	Say that again, sorry.
Jonathan Sham	The inclusion criteria in that study, didn't you have to have a baseline pain score of at least seven? I may be misremembering.
Erika Brodt	That's correct. Yep. Seven or more.
Jonathan Sham	So then that's actually a 50% reduction or more than 50% reduction.
Erika Brodt	Yes, if you were to look at it that way. Yep, exactly.
Janna Friedly	Okay, so I misspoke then. It was not a what percentage had a 30% reduction. It was what percentage achieved less than 30%.
Jonathan Sham	Yeah.
Janna Friedly	Or less than four. Okay. My apologies.
Erika Brodt	A score less than four, yeah, out of a yeah,
Jonathan Sham	Much. Yeah, and it was grouped together in the vendor slides in the pain response 30%. But it's just slightly, slightly different criteria

Andrea Skelly	I think the point is that patients had to meet a specific threshold for having improved pain over baseline.
Laurie Mischley	The other efficacy measure that should probably be on here is reduction of opioid use was reported in at least a couple.
Janna Friedly	Great. Any other outcomes that we should Include. Otherwise, I think we can move on.
Melanie Golob	Okay, yeah, and the last one is cost which those are a little more straightforward, cost and cost effectiveness. But if there are other important cost outcomes that people are thinking of, we can add them to the list as well.
Janna Friedly	I think that looks good.
Melanie Golob	Well, then we can go ahead and move on to straw vote and Val, I can let you take it.
Val Hamann	And. Yeah, and just how we had decided to do these is to do kyphoplasty. Sorry, vertebroplasty, then kyphoplasty, then sacroplasty. So we'll run through all three votes for safety, efficacy, cost effectiveness, like on vertebroplasty, then we'll start back at the top for kyphoplasty with safety and so on. So if you all would jump back over to ttpoll and when I see 10 connections the next slide will be the first voting slide on safety for vertebroplasty. Just waiting on one more connection. And if anybody is comfortable identifying if they're having issues so we're still waiting on one more connection.
Janna Friedly	Oh, it's me. I apologize. I'm having issues. It is.
Val Hamann	Okay.
Janna Friedly	It logged me out and um but I am almost there.
Val Hamann	Yeah. No problem.
Janna Friedly	Okay, I am back in.
Val Hamann	Perfect. Okay. Waiting on two more responses.
Janna Friedly	Oops, are you able to go back to, yeah, thank you. Okay, so. So looks like we have quite a spread here between low, high, I can't, oh, sorry. So it looks like we have five. Well, six. Six total low but then one uh too moderate and too hot too high. So kind of a spread across the spectrum, but the majority low, low in terms of safety. Okay.
Val Hamann	The next will be efficacy. Waiting on one more.
Janna Friedly	Okay. Oops, sorry. Okay.
Val Hamann	Then again, we'll start back at the top for safety for kyphoplasty.

Janna Friedly	Okay. And efficacy. Okay. And cost effectiveness. Okay.
Val Hamann	And then we will start back up again for sacroplasty. Waiting on one more response.
Janna Friedly	Okay.
Val Hamann	Efficacy.
Janna Friedly	Okay.
Val Hamann	And cost.
Janna Friedly	Great. Well, there was one that we all agree on. So that's good. Is there a way I guess, too, we can't see these all together, but we can sort of go, go back to go back them individually, I suppose.
Josh Morse	I think there is a way to do that. Is there not, Val? To review?
Val Hamann	I don't believe so.
Josh Morse	So we can't put this. Okay, so it takes some manipulation to get it into a spreadsheet to show it all.
Janna Friedly	Sort of visually say at least each one together.
Val Hamann	Well.
Josh Morse	That's fine. Yeah, that's okay if you can't do it. I thought. Maybe I'm thinking three this technology.
Val Hamann	Yeah, I would have to get out of this and then save it and it.
Janna Friedly	It takes some work. That's fine. I think we can probably, if we could just go back perhaps to the, maybe just start with vertebroplasty and just look at those. So I think that the bottom, bottom line is there is a spread in each of these different questions, there is a spread, although there is one answer that seems to have more of a majority. So for safety, 6 out of 10 rated it as low, sort of safe with low to medium confidence, although 2 rated it as moderate and 2 high. Is there any, and I think the same was true for kyphoplasty, if I recall. So we might talk about those safety considerations sort of together Yeah, there's a little bit more, it looks like concern about safety with kyphoplasty than with vertebroplasty it looks like from these answers. Does anyone from the committee want to discuss anything related to safety? Given that there's some differences of opinion about safety. Does anyone want to share what they're?

Washington State Health Care Authority

Tony Yen	Janna, can I start?
Janna Friedly	Sure.
Tony Yen	So I voted, let's see, moderate low confidence I've been practicing for quite some time as a hospitalist and often in the past were quite a few vertebroplasties or kyphoplasties before. So I'm speaking just from personal experience. And what I found useful is reflecting that personal experience upon the available literature, which is really informative to me. And also listening to our clinical expert, Dr. Mirza, really appreciate your input about the safety about all of this particularly given that you're a spine expert you've seen probably way more cases than I have. I've ordered this procedure quite a bit for typically for vertebral compression fractures. And just on my just small number of cases that I've ordered personally and seen throughout their hospitalization, seems like there aren't a whole lot of complications. And this is even in light of coming to the realization that there is cement embolization. What I did not know and what the literature didn't reflect for us and this is where I appreciate Dr. Mirza's input is there could be adverse outcomes behind this, but I think in aggregate, this is just my take on it, is that I personally haven't seen that many problems from this.
Janna Friedly	Great.
Sohail Mirza	Can I comment on that or are we good? So I agree, I think complications are rare. So in a handful of cases, you're unlikely to see mortality or embolism or infection or anything like that. So I think it's common for hospitalists and primary care physicians to order this. I've actually, I get consulted for consulted older patients, most of the time even older than 80 with asymptomatic diagnosed on a chest CT for other reasons or sometimes symptomatic Following a fall rarely fall can they not be managed to mobilize without kyphoplasty but Sometimes it's a struggle to convince the hospitalist that it's not necessary because they feel like you could fix this, why don't you just fix this? Because even anesthesia in an 80-year-old is not trivial. So I understand that perspective, but it's not as simple as fixing a fracture. These things do heal if you can get the patient through the first week or so of acute symptoms.
Jonathan Sham	You know, I would just add, when looking at safety, I think it really is helpful to look at the kind of post-market registry data, a lot of these trials are not powered to look at rare events and so I think some of the available post-market registry data referenced actually by one of the just community commenters kind of reference the very low event rate kind of in registries. So that was also kind of helpful. I also I think Tony was with you at the moderate low confidence in the orange bar.

Jonathan Staloff I voted the same way. And I think what stuck out for me the most in presentation was the large amount of real estate dedicated to cement leakage as a potential safety concern which I guess on the surface is, outside of embolization, which on the surface I thought was important to know, but I don't think was effectively linked to, I would say, a clinically relevant safety outcome and so for that reason, I was not overwhelmed by this being an unsafe procedure. And then similarly, having worked in hospital settings, I echo the anecdotal experience about safety and perhaps urge to do something when nothing might be perfectly suitable.

Sohail Mirza I think one reason cement leakage hasn't been as catastrophic you could say, for neurological deficits it's is um most interventionalists, radiologists, and surgeons won't do it when the fracture involves the posterior cortex or if there's a gap. So they will exclude patients who have connection of the fracture planes into the spinal canal. So when you exclude those, the chances of cement causing trouble in the paraspinal tissues is pretty low.

Jonathan Staloff Thank you.

John Bramhall I thought it was interesting in the studies, the variability in the volume of methacrylate that seems to have been injected and I'm wondering I've no practical experience of doing this procedure, but it seems intuitive, it seems conceptually the case the bigger volume that's injected would probably generate a bigger pressure within the space and lead to an increased risk of embolization or protrusion. Yes. Dr. Mirza, you just commented on the, the existence of possible planes into the, the foramen into the canal. So my vote was low confidence. I thought it was safe, low confidence, but I also had that little bat squeak as an anesthesiologist. Some of these patients are going to be very frail often older women with osteoporosis who are in distress, who've got pain, that's why they're there and just giving an anesthetic to get put patients into a good position for the procedure. Yeah, I agree. There's a risk of that. But it doesn't seem to be, I mean, in the data that we've looked at, it doesn't seem to be manifest as you know complications of uh pulmonary issues. We don't see them in the studies to a large extent. So with the data that we have before us, it seemed to me that it was is demonstrably safe. I did wonder, we're on kyphoplasty and I wondered Dr. Mirza, this may just be conceptual again. The kyphoplasty procedure that the. the accolate, the, the injectate is contained within a balloon of some sort is what I understood from reading a couple of the papers on this. Whereas with vertebroplasty, it seems to be just injected into the, into the space sort of you know just goes where it goes. Is it just conceptual or is there a practical difference in embolization risk with kyphoplasty when a balloon is used versus vertebroplasty where the injectate is just pushed in?

Sohail Mirza So Dr. Bramhall, in kyphoplasty the cement is not actually contained in the membrane. You put in the balloon to create a space first, so essentially create a cavity So there's kind of a space, low resistance injection. So the cement actually is not inside that angioplasty balloon.

John Bramhall Okay, that clarifies that to me. Thank you.

Washington State Health Care Authority

Sohail Mirza	The cement and the balloons put in through the needle deflated then it's inflated with very high pressures. But fortunately, they, they don't break, they don't rupture but they're very high pressure balloons that initially were used for angioplasty and then the balloon is deflated and the catheter is withdrawn to create a space where then the injection is supposedly two goals. One was to use the balloon to correct the deformity to increase the vertebral body height. But I think most studies have shown that that's rarely achieved there's not much change before and after the procedure. It may look like it when the patient is under anesthesia and supine. But as soon as they set up, the height loss returns to the pre procedure level. But the cement, there have been techniques where they tried to create a balloon that could contain the cement, but it hasn't really panned out that well. The cement heats up quite a bit. When it cures, so it's not so easy to cures so contain it in a membrane.
John Bramhall	That's very helpful, thank you.
Janna Friedly	And can you explain then the decision making, the clinical decision making, between the two procedures and why you would choose one versus the other?
Sohail Mirza	So I don't know technically, Janna. I think one is It used to be that surgeons would do kyphoplasty and radiologists did vertebroplasty because just of training because kyphoplasty when it was first introduced In the late 90s, early 2000, it was only surgeons who were doing it, but now radiologists are trained in including physiatrists and I think some neurologists can even do it. So the market has now spread to other disciplines. I think it may have to do with coverage, I think many insurance policies cover kyphoplasty but not vertebroplasty. And I think, I hate to say this, but I don't know exactly but I think the procedure reimbursement codes are very different for kyphoplasty are much higher than for vertebroplasty. I'd have to double check that, but I think that's the case.
Laurie Mischley	Dr. Mirza? Dr. Mirza, can you talk about doing something versus doing nothing? I heard in this presentation that if you get to it quicker, we might see better outcomes. And then I just heard you say if you can get the person through the first week, this can often start to heal itself. Can you just talk, if we were to entertain coverage is there a waiting period? Is there an urgency? Is there a.

Sohail Mirza I think most studies suggest trying non-surgical treatment first and if it fails If the patient can't mobilize out of bed then consider kyphoplasty or vertebroplasty. But in reality, what I've seen happen, and I can tell you from personal experience, you know, I get called at a community hospital here and also at a tertiary care center, but mostly it's the community hospital that's dealing with low energy injuries versus the tertiary center that's dealing with trauma. In the last seven years that I've been practicing here. I've seen practice shift quite a bit. It depends on who sees the patient. And usually what happens is if the hospitalist orders the procedure in the medical record, the radiologist book it and they come and assess the patient just a few minutes before the procedure. I haven't seen them very often come and do an assessment or challenge it till the day of the procedure. And mostly they're looking at spinal canal encroachment with fracture fragments or a fracture plane getting into the spinal canal. I'm not sure, I haven't seen in my experience radiologists talk about alternatives to treatment or what the options might be. So what has changed is when I see these patients, I usually always try everything you can think of, you know, nasal calcitonin, a modest brace like an abdominal binder, mostly just as a reminder for the patients to be careful, analgesics and reassure them that they're not going to get paralyzed and the fracture is going to heal in a short time. And with that discussion, most of them get motivated and they mobilized with physical therapy and get home. Discharge often to a nursing home, whether they have the procedure or not or acute rehab, but sometimes home. But if you present it to the patient that you have a spine fracture and you need needed to be fixed, they won't say no. They'll just say, fine, you know, do the procedure.

Janna Friedly Chris?

Chris Hearne Can everybody hear me okay?

Janna Friedly Yes.

Chris Hearne Okay. It's just I wanted to make a comment about what Tony said, and it's interesting to hear your experiences with this procedure for inpatients specifically. I just want to share at our institution, I feel like this is almost never done on inpatients. So we'll get patients who are admitted for pain control and mobilization and the practice pattern that we have is we'll ask spine surgery whether we think it's appropriate kind of like Dr. Mirza was saying. And I would say 9 times out of 10 they tell us it isn't. And one way or another, those patients end up mobilizing either in a nursing home or going directly home, but it's just interesting to see that difference. So I think there is a lot of practice variation.

Janna Friedly Back to Tony.

Tony Yen: Chris, if I'm going to respond directly to you when I said I used to order this stuff or I have ordered this stuff, that's actually kind of in the past I think over the more recent years these procedures have fallen out of favor to be clear with you, but I've ordered like a ton of these before, I want to say like 10 years ago sort of stuff right seven years ago, but more recently I think these procedures, at least in our organization we talk about these procedures in the context of how should we really be practicing now. I think there's less of a push to say we will still very, very occasionally order this But it is very rare now. Whereas before hey, you have vertebral compression fracture, let's get your vertebroplasty, let's get you a kyphoplasty. Just want to let you know how helpful at least what I've observed is also practice changes within our particular organization. Dr. Mirza, I have a question for you, though. I'm really kind of enlightened by this conversation over here that it appears that it appears that intervening early with a vertebral plastic or kyphoplasty it's almost like you're intervening early that's superimposed on that natural history of disease that would the natural history of the disease, it appears to me after you know listening to this discussion is that a person is probably going to recover without intervention that's how the natural history would go so if you intervene early are you taking advantage of that natural history? I do wonder, is that maybe a property that we're seeing when we're looking at the literature over here.

Sohail Mirza: That's my sense, Dr. Yen. And all those things we worry about where patients present at the peak of their symptoms that naturally, if you wait long enough, they are going to get a little bit better so regression to the mean or just some kind of other effects where if you intervene early. So that's why if there's it's such a problem with such a single arm studies and registry data is there's no comparison, that old adage, you know, no comparison, no conclusion it's very hard to say if scores going to zero wouldn't have happened anyway if you hadn't intervened at that peak moment.

Jonathan Sham: Yeah, I mean, certainly that's the first thing that came to my mind when I saw the registry data being presented all going down to zero. I was like well you know, we have no idea whether that's related to the procedure or not. That being said, I mean, there are several RCTs, some placebo sham procedure controlled that are showing a difference, I just want to throw that out there that this isn't just all single arm studies we're looking at.

Sohail Mirza: I don't think there were any single arm studies in your analysis, Andrea, were there?

Andrea Skelly: Sorry, no, there were not any single arm studies for effectiveness. We do report harms for single arm studies in the harm section but as you pointed out, we did not include single arm case studies pre post for the reason you state that no comparison can't make a conclusion.

Janna Friedly: And I think, you know, what I struggle with a bit is, um that when you look at the studies that do have comparators, the comparators are different and so some of the comparators are usual care, which you could argue is no comparator or a variable comparator and in some of the studies where they are either another procedure or they are even a couple of the blinded studies like the, the Clark study, there was concern or that when you look at the percentage that guessed correctly about blinding, there was a big differential. So there was some concern about adequate blinding so, so to me, the studies that were the most similar in terms of the two procedures were the ones that showed the least difference between them which in my mind suggests that difference that we saw in the outcomes was not directly related to the treatment itself, which is why I was wondering earlier whether people do lidocaine injections or other things that, some other treatment for the fracture to treat the pain that might be just as effective with less risk potentially. But it doesn't sound like from what you're saying, Dr. Mirza, that, that's, that's done in clinical practice, but there may be other, other things non, non-interventional that could be used to treat these fractures from your experience.

Sohail Mirza: Were you asking a question, Janna? I'm sorry, I missed that question.

Janna Friedly: Well, so I was just comment, it was a rambling question. I apologize. So I was uh saying that the reason I asked the question earlier today about whether or not people in actual, in clinical practice ever considered treating people with lidocaine injections, like similar to the studies where they showed that there was no difference between the two treatments but there was improvement. But it sounds like from what you described earlier that people don't do that in clinical practice but it is, but it made me wonder if there are other, from your experience, are there other treatments that are effective alternatives to vertebroplasty or kyphoplasty. It sounds like from what you described.

Sohail Mirza: Procedures, you're talking invasive procedures?

Janna Friedly: Well, in procedures or non-invasive procedures, it sounds like you described some things that were non-invasive that you think are.

Sohail Mirza: Yeah, no, I think calcitonin, some bisphosphonates, mild analgesics Tylenol, tramadol and typically some kind of a brace that increases intra-abdominal pressure like a abdominal binder or a soft brace that's not too, too intrusive is so that the patients actually use it and it gives them kind of security that something's being done so that usually has been effective for the patients I've been involved with. In terms of injections, you know, occasionally you will see a patient with a vertebral compression fracture who presents with thoracic radicular pain, like nerve root compression from the fracture fragments, not cement leakage, but before any procedure. And in those patients, it's been a struggle if their pain is severe to convince an anesthesiologist to take the risk of putting an injection, a needle in that space because the risk of pneumothorax is so high, they'll do nerve blocks in the lumbar spine, but not in the thoracic spine. And Dr. Bramhall can probably speak to that a little bit because I think it's very easy to nick the pleura and cause a pneumothorax.

John Bramhall Yeah, absolutely. You're absolutely correct, Sohail. It's um many anesthesiologists do these kinds of interventions at thoracic epidural, for example, without fluoroscopic guidance. It's been the practice historically. Whereas when pain physicians I want to be sure that the local anesthetic has been put into the right space that's often done under fluoroscopic guidance with a, with some contrast. So the variable practices, but yes, you're right, when you're in the mid thoracic region working with guidance or without, the guidance of the needle is very much by feel and the feel is going to be interfered with by an adjacent compression fracture. So you're right, it's just going to make it um less likely that you want to dive in slide a fairly long Tuohy needle across a surface that's roughened or obscured or indistinct to achieve a location that would be therapeutically effective, yeah, and bottom line.

Sohail Mirza Yeah, and the other thing is these patients have severe osteoporosis, so it's very hard to even see the spine on fluoroscopy images.

John Bramhall Yeah, yeah.

Sohail Mirza You really have to struggle sometimes to even see where the vertebra are. On an AP view, it's much easier when you're aiming for the pedicle which is what's done for kyphoplasty, but otherwise, it's very hard to know where you are.

John Bramhall Yeah. Yeah. Yeah, the midline isn't very accessible in older people with osteoporotic lesions and going off uh from a uh off the midline is, there's a risk.

Sohail Mirza I hope that answers your question, Janna?

Janna Friedly Yeah, thank you.

John Bramhall But I would, so I would, Janna, I would pick up on your, your comment that was part of your question. So it seems from the data we have been presented with, it seems, I don't want to get ahead of the discussion, but it just seems to me that In the early stages of the natural history of this of this disease, this process the interventions that we've looked at, the kyphoplasty and the vertebroplasty, seem to be having an effect on pain and perhaps some on function but when you compare it with the sham that seems to disappear, it becomes much less distinct. And so your point is exactly yeah, it's the point I had in the back of my mind the whole time is if the, if the sham intervention that we've seen the data for is lidocaine or a longer acting agent or agent or something or a steroid or something like that, is that included in the in the list of things that are usual care? And I think Dr. Mirza sort of answered that question, at least from the standpoint of his practice that, uh that, that probably a percutaneous intervention is not considered to be the usual standard, standard care in the early stages and by the time you look at the later stages, six months, weeks to months we don't see a lot of difference even between sham and no care.

Janna Friedly Yeah, I think the other thing that I'm thinking struggling with is that those studies that show the, the difference, you know, some of the differences were studies where the fracture, where the procedure was done within you know very acutely within three weeks, right, I think, within three maybe, maybe six weeks but then the some of the criteria, coverage criteria suggests that you should, this should be done after you've tried conservative treatment four or six weeks. So I'm really struggling with reconciling those as well in my mind. I'm.

John Bramhall We can include in our thoughts the comments from, so Dr. Shonnard and Dr. Beall in the, the audience presentations, I think also commented on that. One quite persuasively that early intervention was cost effective at least we can include those comments in our thoughts. Josh, is that some that's, that's the point of the comments, right?

Josh Morse I'm sorry, I missed that, Dr. Bramhall. Your comments on?

John Bramhall Well, it was a fairly dramatic evidence presented in the in the early morning session suggesting that an early intervention was that that's the way to go, the early intervention gives you a big response, whereas if you wait for six months and then do an intervention you're not going to see any benefit. It was, let's say it was persuasive in terms of the drama of the presentation. But it's not data that has been sort of refined and processed through, through the data vendor.

Janna Friedly I think that the studies in the report you know.

John Bramhall They're included, yeah.

Janna Friedly Were presented you know less than, less than three weeks, less than six weeks um you know the, the criteria um uh.

Jonathan Sham So, I would just like to make a comment in the context of all the data we reviewed. I'll just be honest, my bias coming into this was kind of not in favor of coverage just to be fully blunt. And I think that when I look at the data and put it on my clinical trials hat, I really look at this as a study design issue. If you look at the pain response versus the pain scores, this is slide 36 and 37 of the data vendors review, I think that's where the difference lies. I mean, when you use pain response as your primary outcome, there's a moderate to large likelihood with low to moderate strength of evidence across studies at multiple time points, except for the one to two weeks, but then that goes away when you just use the average pain scores. And again, I think that's just being cognizant or smarter, I don't know how else you want to say about your study design, if you're trying to show a difference. So I think there's probably a small difference and the studies that were designed in a way to allow that difference to be shown, showed it. Now, whether that difference in efficacy reaches the level of coverage, I'm not quite sure. But again, I don't view it as, oh, it doesn't work. I view it as, oh, some trials were designed to be a little bit more sensitive to that difference, what's likely a very small difference.

Evan Oakes	I have a question, if you don't mind about process a bit. How permanent are the decisions of this committee? Like, has anything ever been decided and then removed later or uncovered at a later date.
Janna Friedly	Mm-hmm. So Josh can speak to this, but we do rereview topics after we have made coverage decisions. And there are examples of coverage decisions that have changed based on rereview. Josh, I don't know if you want to add anything to that.
Josh Morse	Yeah, no, this is one of the, I mean, this decision goes back more than 10 years and it has not changed. There was another one very similar to this, another pain treatment that the committee considered last year, and it did change. It was also a non-covered for many years. So yeah, yes, it does happen, that's why we're here is for you to consider this the addition of the evidence here basically.
Evan Oakes	Josh, if I heard you right, that's thank you. I mean, I appreciate that. I was asking, that's an example of where we decided not to cover something and we're rereviewing it.
Josh Morse	Uh-huh.
Evan Oakes	I'm asking about when we've covered, we've made a decision to cover something and rereview and remove it, like how often does that happen?
Josh Morse	Yeah. Yeah, that's happened too. That's happened for a couple topics. One was at least uh the partial knee replacement I think that's or the, what was it? It was registry data revealed that an implant was failing in the thousands of people or tens of thousands of cases had been entered in the registry and so that policy for a very specific hip, metal and metal hip replacements.
Evan Oakes	Thanks.
Josh Morse	Was reversed. I think hyaluronic acid is another one that was very close to, it was rereviewed a couple of times and I believe now it's non-covering. I don't remember actually, but it's um Yeah, anyway, so it does happen.

Janna Friedly	Thanks. I apologize. I misheard your question. Misunderstood your question. Any other comments, there are some folks on the committee we haven't heard much from any other comments or thoughts? We've sort of talked about safety and efficacy for both vertebroplasty and kyphoplasty. If there's no more discussion, we can maybe move to just cost and just so that we can make sure that we've talked about that. I think as we find frequently, there's much less data for cost. I think that came through in the straw poll that the majority of people found that there was no evidence, no relevant studies or low confidence in, in, but some dissent in terms of whether it was cost effective or not cost effective clearly no confidence in that data or little confidence. So I'm not sure that there's much to discuss on the cost side of things. And then sacroplasty, I think, is a much more straightforward discussion probably, at least on the cost side, we have nothing to discuss. And then going to safety and efficacy, there was a lot less I think less dissension, but I think much less evidence at all. I think that the majority of people felt that there was less evidence and, and less efficacy. Either no studies or less efficacy for the majority of people. There's one person that rated equivalent and one more, I don't know if that person feels comfortable sharing their thoughts about why they why they felt that there's why they felt that more data, evidence to suggest that there is efficacy for sacroplasty that we might want to discuss as a committee.
Jonathan Staloff	I was the person that said more. I really struggled with, I'd say which button to press in this situation. I was far less impressed with the data that was available for sacroplasty than for the other procedures, but the data that was presented, I think, showed positive outcomes and so I wasn't quite sure. So no relevant studies felt pretty absolute where I felt like there was a dearth of relevant studies and so if no relevant studies read not very many or insufficient, I would have chosen that, but since no felt absolute, I chose more with low confidence because there was nothing that said extreme low confidence.
Janna Friedly	Okay. Noted. Okay. Thank you. Okay. Any other discussion from the group or do we feel ready to move to a vote?
Tony Yen	Janna, I just have one question. For Dr. Mirza, that's okay?
Janna Friedly	Absolutely.
Tony Yen	Is it common to use these types of procedures on neoplastic lesions because I've actually never heard about this before this evidence review.
Sohail Mirza	Yes, it is, but again the caveats are often with neoplasia or metastatic disease you have soft tissue extension beyond the confines of the vertebral body. So if there's any spinal canal encroachment from tumor mass, the procedure is not done because it could make the spinal canal encroachment worse, but if there's no spinal canal encroachment, it is considered and done for that.
Tony Yen	Okay, thank you.

Janna Friedly — Okay. So thank you, Tony, for bringing up that, I guess that, I guess that could be considered a special population to consider in this. And are there any other special factors or populations that we should consider.

Jonathan Sham — Maybe Janna, I guess I kind of have a question for the group based on one of the other one of the other public commenters and I, I mainly ask, I don't really know what to do with it. I found it quite striking, but again, my gut says like, I'm not supposed to take it into consideration but yet my you know, my brain says maybe I should. So it was the medical director for Regence, I think came on. I'm sorry, I don't remember his name and essentially was like, yeah, we cover this for everybody except for HCA people and he just kind of laid it out there and just like Just so you guys know, and then left. How are we supposed to take that into consideration um or, or are we? And if not, that's fine, it just was kind of laid out there like a like an egg and I'm just trying to figure out what to do with it.

Josh Morse — I'll take that if you want me to. Dr. Jones is still in attendance here. His name is Ty Jones. HCA implements HTCC decisions, your decisions, through the Uniform Medical Plan and then Regence is charged under contract with following those HTCC decisions per that contract. When Regence has its own policy and its own book of business and those don't align with your decision, right? You can have differences of interpretations of the evidence. That obviously creates a challenge for people to implement those, right? That is you have a policy coming from the clinical committee in a policy that the entity already is working with. And I don't know exactly, I can't speak for Dr. Jones or why he wanted you to have that information today, but that is a fact, right? So their interpretation of the evidence and the application of policy under you know their structure may be different from yours. So I don't know how to, I'm not directing you on how to interpret that in any way, I think any information presented to you today is for consideration if that helps or doesn't help, it probably doesn't help but. Thanks for the question.

Jonathan Sham — And so I guess just to take a step back, we're charged with evaluating efficacy, safety, and costs, but not necessarily implementation and health equity side of things. I want to be clear about our charge as a committee and what we're.

Josh Morse — I think all factors are on the table for your consideration, right? I mean, I think definitely equity is for consideration now if. But I think equity can be has many different meanings potentially right so it's that you're thinking equity and access to coverage for something, but I think you still have to think about the evidence. The HTA.

Jonathan Sham — Just.

Josh Morse — The decisions from this program are not always aligned with what other payers do, right, and I think there could be multiple reasons for that but the legislature designed a pretty rigorous process for this, for you. By designing this committee.

Jonathan Sham — That's helpful. Thanks.

Josh Morse Mm-hmm.

Janna Friedly And also just for point of clarification, once we come up with our decision, one of the, one of the tasks for us is to compare our decision to existing national coverage decisions and existing guidelines that are in our evidence report. So we do, we do look at that and compare how our decision aligns or does not align with that.

Josh Morse Right. And if I could just add on to that the national coverage decision from Medicare is the comparator that was designed into the process, not the local coverage determinations that may differ from region to region and are developed by the regional contractors. So it's the national coverage determinations which at the time the program established, you know, and I can't speak for the process right now and so I'm not going to, but is a very rigorous evidence-based open and public process for NCDs, National Coverage Determinations, right so they wanted you to compare your decision to those and either be aligned with those or explain why your decision may differ from NCDs. And the committee has frequently done that and typically the result, if there's a difference is because you have a more fresh evidence base that you're looking at compared to maybe an aged NCD. And then the other is to consider professional guidelines, which you do guidelines which you do at the end of the meeting, we ask you these two questions after your decision and that's why we include assessment or assessment and of the guidelines in the evidence report and again, it's the same question, does your decision align? If it does, great. If it doesn't, you know there's the law asks for some explanation as to why. It's usually because you're reviewing it you know evidence-based at a different time but frequently the professional societies themselves don't agree. So, you know, it's it's, it's not homogenous, right? There's variation in those professional societies as well. So difference is you're just another different decision. But we don't look at the private payers, commercial, you're not asked to do that. Compare yours to Aetna, Cigna, Regence, etcetera.

Janna Friedly Great. Thank you. That was very helpful. Okay. Any other questions before we move to a vote? Okay.

Melanie Golob And so happy to talk this one through, but this is just kind of showing based on the sufficiency of the evidence according to what's in the language of the WAC. If coverage is not allowed, allowed under certain conditions or allowed without any conditions allowed so If there is sufficient evidence for all indicated conditions, it's coverage allowed without any special conditions, if it's only for certain conditions coverage allowed with conditions, and then if there's not sufficient evidence and coverage is not allowed so just putting that up there as a reminder before the voting.

Josh Morse	Yeah, and Janna, you asked me to remind you of any procedural steps. Yeah, at this point, I think what Dr. Rege had been doing is essentially a straw poll on what direction people were going in terms of coverage because If you get a sense of, of one or another direction, then the committee, if their committee is going to develop criteria you may want to develop the criteria and then you can vote once you have criteria on a final decision. You know, because if you if you had an option to vote no cover or an option to vote cover and you know what those conditions are, you know then then you have a comparison or a cover without conditions, right? So typically we would do, I think do a straw poll here rather than a final vote, the outcome, if that makes sense?
Janna Friedly	Okay. So for a straw poll, should we use the polling?
Val Hamann	Yes, yes, please. Yeah, please go.
Janna Friedly	System for the straw poll. Okay, so this is not a final vote, this is a first vote?
Josh Morse	Right, because you don't know what, I mean, it could clearly lead you to a final vote because there's two outcomes here that don't require more work.
Janna Friedly	Yes. Okay.
Josh Morse	And one that may, right?
Janna Friedly	That sounds good.
Val Hamann	And it does look like I have 10 connections. Sometimes time does pass and it does kick you out. So you have to log back in, so please let me know if that has happened so we can make sure that we are waiting for you.
Josh Morse	Well, and I guess I have another thing is are you going to vote on all three at once or vote on each?
Val Hamann	No, they will be separate. Yes, because we voted on them.
Josh Morse	Okay. Thank you.
Val Hamann	Separately. So we'll start with vertebroplasty. So that poll is currently live. And waiting on one more response.
Janna Friedly	Okay.
Val Hamann	And moving on to kyphoplasty. And on to sacroplasty.

Janna Friedly	Okay. So we have a decision, it looks like for sacroplasty. It looks like we will need to have a little bit more discussion about vertebroplasty and kypho, and it looks like leaning one way on kyphoplasty but evenly split on vertebroplasty. Should we have a little bit more discussion about this? Because we have an even number of people on the on the committee.
Josh Morse	Yeah, or.
Janna Friedly	Josh, just for procedures sake, if we do have a tie with no, no, uh, no, no tiebreaker. What is the procedure in case of a tie with no movement on one side or the other?
Josh Morse	That's a great question, and I don't have an answer for that. Hopefully we get beyond a tie.
Janna Friedly	Okay.
Josh Morse	Yeah, I think that's what we would, we would hope to. Otherwise, I really, I don't know.
Janna Friedly	I just wanted to know if there was a procedure for that.
Josh Morse	And I would. Yeah.
Judy Zerzan-Thul	Yeah, this is Judy. I would say discuss some more to see if you can figure it out.
Janna Friedly	Yeah, I think. Yeah, I hope we can. I just wanted to make sure I knew what the procedure was.
Judy Zerzan-Thul	Good luck.
Josh Morse	Right. And often if you're at this point. Yeah, go ahead.
Janna Friedly	Okay. So, no, you go.
Josh Morse	Well, I think, you know, you don't know what the conditions are. So that may shift. I think, yeah.
Janna Friedly	Yeah. Yeah. And I think at this point, what I think might be helpful is to go around and just have each person talk and give their give their, you know, sort of rationale and thinking so that we can hear from each member of the committee and, and have a discussion about it.

John Bramhall Well, I'll volunteer my thinking, Janna. It's a It's nuanced, not my thinking. The position is nuanced. I'm pretty convinced from the data that we've had the vertebroplasty has some benefit over usual care. The evidence isn't strong, but it seems to be a significant improvement over usual care up to about six months out from the disease. On the other hand, it's no better than sham. And so for me, I've often thought that a sham was a very good control arm for any kind of randomized study and that if you can't demonstrate that what you're doing is better than doing the sham, than what you're doing is of no benefit. But the problem I have, of course, and it's probably a problem for others as well, is that the sham has an effect right so it's like it's a torment here. You know, could the condition 'm thinking contemporaneously now. I'm not taught this through, could the condition, could this be covered with the condition that you try the sham arm intervention, the injection of local anesthetic to the periosteal region, don't know, don't have any evidence on that, really. So I'm a bit of a quandary. And the thing that also feeds in is that if you cover with a condition and the condition is some intervention other than the vertebroplasty, it's probably going to take some time to find out whether that other thing is beneficial and effective and by that time, you're getting, as Dr. Mirza pointed out, you're getting into a phase of the progression of the disease where you, you know the problem has sort of disappeared for a lot of the patients. So that's my thinking. It's a little clumsy. but I have a big problem with saying that something should be covered when it's clearly not demonstrated to be better than a sham. That's philosophical as much as anything else.

Janna Friedly Thank you. I appreciate that. And I have to say that that is almost exactly, what I would have said as well. Clint.

Clint Daniels Cheers. I really struggle with the not being sham and potential influence of natural history and placebo and I voted not covered. Also, I still feel like there's unknown about the long-term effects of the cement leakage which seems to occur in about half to more than half of the people that have this and this is a very common condition so I think they're I think there's a lot of unknown about long-term safety as well.

Janna Friedly Chris.

Chris Hearne I voted to cover with conditions although I don't have a lot of confidence in that. It's a difficult topic. I think the discussion about, can we really approve a procedure or a technology that is not demonstrated to be better than sham, that is a big concern and I share that concern. The reason why I came down on covered with conditions is that it, it seems to me the aggregate of all the evidence suggests that maybe there are certain people that would benefit. I think the question, you know, there was some talk alluded to about are there responders or people who would respond, I think the challenge with that is I don't think the data really tells us how to pick and choose those people, which makes it very difficult to carve out conditions, but it seems to me that maybe there is a population that is going to benefit.

Janna Friedly So Chris, picking up on that, how would you, what would you, if you were to come up with conditions, what, how would you do that?

Chris Hearne That's a great question and I think that's would be one of the problems with if we were to go with a cover with conditions. I think we'd have to go back to what the large RCTs are doing and use their inclusion criteria as the skeleton of our criteria, I think.

Clint Daniels This is Clint. Recalling Andrea's report. I think there were some included studies that tried to stratify too and if I recall correctly, they couldn't figure out any differences or any good predictors. I don't know if she's still on to comment on that.

Andrea Skelly Yeah, I mean, we looked at what we could but in terms of using a rigorous methodology to determine whether any of those patient factors or technical factors would differentially affect the treatment, none of them appeared to do that. Again with the caveat that the estimates are very imprecise and we're dealing with very sparse data to make those evaluations.

Jonathan Staloff This is John. I also voted cover with conditions. I had very similar logic as Chris and cannot really state my thought process better than that. The other thing that came to mind was not uh, was not like Is this the best treatment or is this the definitive treatment, but a question I was asking myself is, does, or can this treatment have a reasonable evidence supported role as one of an array of treatment options and based off of the aggregate evidence, my feeling was, yes, it can have a role as part of the array of treatment options for this condition. The concern that I had, which I think that was well stated by Dr. Mirza, and I apologize if I'm misstating your point, is that oftentimes if something is covered, it'll tend to be utilized and particularly a highly reimbursable service. If it is covered, it'll tend to be utilized. And so the reason why I voted with conditions, and this is being new to the committee, one of the questions I had is the way I interpreted conditions is not specific medical conditions, but rather certain conditions are met and in my mind, I appreciated Dr. Mirza's anecdotal sharing about basically having a very fruitful shared decision-making conversation about the array of treatment options, including the merits of non-intervention with patients. And when I was thinking about with conditions, I was thinking about sort of a documented consent that included discussing the merits of non-operative treatment.

Laurie Mischley This is Laurie. And the only thing I'll add, I also voted cover with conditions. The only thing that I will add is the forest plots for me are compelling. I mean, it seems to be consistently a little bit better for at least a little while, right? Ethically, I have a really hard time talking about a sham comparator, because I guess at least in my mind, we start getting into a question about what is the mechanism, mechanism of action by which this procedure might be doing benefit, you know, is it is if a sham is not an option for the patients we're representing, that's not a fair comparator. I mean, I think the only logical comparator that we can have here is usual care. I just, for me, just It's hard for me to value sham when that's not an option on the table in a pragmatic real-world setting.

Janna Friedly Laurie, I think your, your audio cut out, at least for me.

Laurie Mischley — Oh, I just said it's hard for me to for me, my the comparator that holds the most weight for me is usual care. It is hard for me if sham is not an option on the table as a therapeutic intervention for the people we're representing. It's hard to say this procedure is equivalent to this other one that doesn't exist. But it's better than the one you do have access to, but we're still going to vote no, even though you don't have access to that thing, it's equivalent to. I mean, I just, for me, I have to keep a tether on the usual care because that's the patient's alternative.

Tony Yen — This is Tony. I voted not cover. And I suppose, Laurie, I have a slightly different perspective from you is that the sham procedure allows me to better understand the efficacy of the procedure itself. And I think it's very rare that this committee actually is able to see literature that compares procedures against sham procedures which I think more clearly shows us what that procedure, the efficacy of that procedure in of itself. I think that's a little bit of a luxury that we have this time as compared to other procedural, you know, other procedures that we've evaluated before the past where we do like you said, compare our procedures against non-interventional care or tablets or medications or therapies, those sort of matters. How I interpret the literature right now is, is that the comparison of the, the arm that shows the actual procedure, I guess a sham procedure, my interpretation is that the actual procedure doesn't make much of a difference and when we look at the placebo effect of either the real procedure versus the sham procedure, there's not a whole lot of difference. Particularly if we kind of like frame this in terms of like how the Clark study I think skews all the data in terms of the sham procedure studies.

Jonathan Sham — Yeah, I'm happy to jump in next. I struggled with this actually even more so than some of our previous contentious topics so I'll just throw that out there. I voted for cover with conditions, thinking about, I guess I wanted a discussion about potential narrow conditions where this might still be indicated. First, I'll just say like, I know we keep saying that there's no benefit to sham but I mean, and maybe I just missed something but the Clark study did have a sham component, right? And I realize we all have our concerns about some of the particulars of study, but I don't think it's fair to say there was no benefit over sham in any study. So I'll just throw that out there. My question for Dr. Mirza is, I noticed the AOS guidelines kind of carve out neurologic impingement as like, okay, it's not indicated unless you have this. So what I don't want to do is kind of cut this off from some subset of populations where this might be a useful tool in the toolbox for a physician facing a really serious situation. I know we didn't look at a lot of data for that population, but I was wondering if you give us some context about that group of folks and is this ever indicated that in the setting of neurologic impingement acutely.

Sohail Mirza — I can say definitively, it's never indicated for neurological deficit. So I'm not sure about that document. I'll have to look at it, but I don't think anybody would do kyphoplasty or vertebroplasty. If somebody has cord compression from the fracture.

Jonathan Sham — That's very helpful. It was in the AMDG's recommendations. Again, it's slide 23 for anyone who's looking at it. The AOS.

Sohail Mirza	I'd have to read those carefully again. They don't make sense to me, but I'm not sure what exactly we're talking about, but it doesn't make sense ever do it when there's cord compression.
Jonathan Sham	Got it. That's helpful.
Evan Oakes	All right. Jonathan, I think I'm seeing what you're seeing. It's under the, and it doesn't say cord compression, it says neural without neurological impairment. Those are not the same, right?
Jonathan Sham	Correct
Evan Oakes	So that's what it says, it doesn't say cord compression.
Jonathan Sham	Yeah, I imagine like a radiculopathy or something, I'm assuming, but I'm not an expert in this. Again, just for the record, again, just so it can be read AOS says virtual capacity is not recommended for osteoporotic spinal compression fractures without neurologic impairment, strength of recommendations strong. So I was just trying to figure out what kind of neurologic impairment might be might warrant.
Sohail Mirza	I'll have to read those I there may be some kind of a is that the original document or somebody kind of summarizing them? It doesn't make sense to me.
Jonathan Sham	Got it. Thank you. Thank you for that. So again, that was just my perspective is given that, as I mentioned before, I think Janna, you really summarized nicely kind of the difference between pain response and overall pain scores I think for me as a clinical trial kind of designer helps me understand like, oh, this is why for these studies where they use this one factors showed a difference and these that don't, meaning the difference is probably there, but really, really tiny so I'm not really that compelled to cover it. But that being said, it may play a role for some subset of patients. Again, it seems like shorter time course, less than six weeks, which is the inclusion criteria for many of the studies that showed benefit and again, I was just thrown off by this carve out for neurological impairment. That's why I voted the way I did.
Sohail Mirza	Sham or. Sham, I'm sorry, were you asking a question?
Jonathan Sham	No, no, just summarizing my thoughts. Thank you so much.
Janna Friedly	Evan, did you have a question?

Evan Oakes

Nope, but I haven't gone yet, so I was going to. So I voted cover with conditions. I sort of took the conditions to mean that it was not going to be universally covered for anything that anybody ever wanted to do with this procedure and so there were some restrictions and I've sort of was thinking of the same thing Jonathan was just highlighting a little bit. I'm, there's a couple of concerns. I do get concerned about these surgical studies that are always maybe a year, maybe 18 months, you know, not very far in the future, so I worry about the long-term effects or things like that.
I'm not sure what to do with that because it seems like looking at the FAI one too, it seems like there's kind of a common sort of research that we have at our fingertips. The other thing is the coverage and overuse. If we cover it kind of thing, but those two things aside feel like this was demonstrated, I mean I was vacillating every time people would say things. I mean, I think this is not a very straightforward thing. There's a ton of evidence that seemed to be presented but in the end, it seemed like generally these were safe procedures and I'm hearing a couple of my colleagues on the call that you have used it pretty regularly. And so it seems a little strange when I look at the, and so let me just and then so with that vacillation and that uncertainty on one hand and that confusion here and there, depending on where you're having the conversation, it's hard not to look at what is or isn't covered or recommended by other organizations. And so that led me to how could the HTCC decide that this isn't covered at all. And so I do feel like it's safe enough and it has some benefit for some people and I tend to want to then respect my professional colleagues out there and allow them to have this tool in their toolkit and I voted to have it covered and with conditions, meaning not just, you know, it can't be for non-neurologic or non-symptomatic compression fractures, it seems, that kind of thing is what I was. I mean, that level of conditions. Is what I was thinking. Thank you.

Janna Friedly

Great. Thank you. Amy, I think you might be the last person who hasn't weighed in, give your thoughts.

Amy Occhino

Yeah. Hi. Yeah, I had a hard time with this. Oh, yes, it's Amy Occhino. I had a hard time as well, but I voted for do not cover for basically all of the same reasons, I don't really have another good thing to say other than just all of the reasons that were already stated.

Janna Friedly — Okay. And I think I apologize. My dogs are barking in the background so if you hear them. I don't have anything different to add other than what's been, been said, but I, uh, also voted for not covered for the same reasons. I think what I also struggle with is this, the issue of the conditions um and this this concern for me about coming up with conditions that make reasonable sense based on the literature. That if you come up with conditions that match the patients that improved in the clinical trials, which is really less than three weeks, that doesn't match sort of clinically, those are the patients that are most likely to get better on their own anyway. So it just doesn't seem to make sense to me that you would make conditions that they have to try something else and that you would do that for six weeks, but that doesn't match the literature. So I couldn't come up with conditions that made sense to me to limit the use of the procedure and so we would end up with a procedure that is broadly used inappropriately. So I just couldn't reconcile those things in my mind.

Jonathan Sham — Janna, I'll just add a little more context, it may be helpful to our proceedings, but I just looked up the kind of primary text for the AOS recommendations. And it's pretty clear that the neurologically intact is just like an inclusion criteria blanket statement. It's not like a Oh, but there's some neurologically unintact people that we should use this for. If that makes sense. So that's why I wanted to just clarify that with our expert and the primary literature. Again, that was the one kind of carve out I was worried about during the straw poll. But given I have a bit more clarity on that, I will probably change to not covered given that new data.

Janna Friedly — Should we, I think at this point, should we repeat the vote now that we've had a chance to discuss? And again, this would be a second straw poll, not a final vote.

Val Hamann — And would you want all three of them to be redone?

Janna Friedly — I don't think we need to do the sacroplasty, sacroplasty.

Val Hamann — Okay.

Janna Friedly — I think we just need to do the, I think we should do vertebroplasty and kyphoplasty.

Val Hamann — Great. And you will all have to log in again. I apologize. I was getting up there in connections, so we would have run into issues. So I needed to save the session. And we have nine connections. Let me relaunch that. And waiting on one more connection. Okay, and we'll move on to kyphoplasty.

Janna Friedly — Okay, great. So, um, with that. I think then, Josh, we can move to final votes?

Josh Morse — I think you can. Yeah, but do you want to take a, a brief break before doing that?

Janna Friedly — Yeah, why don't we take a five minute break before we move to final votes? And come back at 2:25.

Josh Morse Thank you.

Janna Friedly Okay. If you could make sure to put your video back on when you're here. Looks like we have most people, but I think we're missing a couple. Okay, I think we have our committee here. Do we have Val, Melanie. Josh?

Val Hamann I'm here.

Janna Friedly Okay, great. So why don't we move to our final, final votes. Do we need to reload the poll now or no?

Val Hamann Yes, I will. Send that through. So if anybody got kicked out hopefully not um it should have been fine, but we'll just redo these slides again and redo the votes. And that poll is live for vertebroplasty.

Josh Morse Yeah, so this is the final draft vote for this today, right?

Janna Friedly Yes.

Val Hamann Yeah.

Josh Morse Great.

Val Hamann And we'll go to kyphoplasty. That is live. And then final vote on sacroplasty.

Janna Friedly Okay.

Josh Morse I think there's a couple more questions for today.

Janna Friedly Yeah, so as we talked about earlier, we review whether it's consistent with Medicare decisions and expert guidelines. There is not a Medicare NCD for these, and there are a number of clinical practice guidelines that are somewhat variable, as we talked about and many that do recommend coverage of, of, um kyphoplasty and vertebroplasty in some situations, but some that do not. As we've, we've discussed earlier today, so I'm not sure that we need to discuss that in much more detail. I think we've discussed pretty thoroughly. Our decision making around the evidence and why we came to the decision that we that we came to as a group.

John Bramhall Janna, can I ask a question perhaps for Josh? When there's no central Medicare guidance how, how, how is the treatment adjudicated at the local level? Noridian may have local coverage but in the case where there's nothing, no statement from Medicare, how is coverage practically adjudicated, do you know?

Josh Morse Well, we for Apple Health, for Medicaid that, that Medicaid is the payer of last resort. I'm not sure I understand the question.

John Bramhall Well, so let's say someone is insured by just straight Medicare and the clinician, the physician recommends kyphoplasty. Would Medicare, how does Medicare decide whether it's covered when there's no coverage determination. How is that done?

Josh Morse I do not know. I can't.

John Bramhall It's out of left field, I know, but it seems like that would be a, it could be a problem that would crop out regularly and then I just, I'm ignorance as to how he's dealt with.

Josh Morse Yeah, I don't know Medicare coverage well enough. Not yet. Give me time. I'll get there.

John Bramhall Okay.

Josh Morse Yeah, I don't know how Medicare. For Medicaid if we don't have a policy, we, and there's a request for coverage, it's based on our state's definition of medical necessity and whether, well, first of all, whether or not it's a Medicaid benefit within our Medicaid coverage for Washington state and then it would, the question would become, is it medically necessary and it would get a, an individual review potentially if there's not a policy, that's how Medicaid works.

Val Hamann And Dr. Frank, Dr. Franklin does have his hand raised.

Garry Franklin I think as was stated earlier, the only thing that matters for this law authorizing this program is a national coverage decision. Local coverage decisions are just done by contractors, which were sort of normal insurance companies. So it'd be kind of this very similar to how the other and how the other insurers came to decided to cover it. In my opinion.

Josh Morse Did you get your question answered, Dr. Bramhall?

John Bramhall Yeah, I think so. Yes. I mean, the issue in my mind is that a Medicare uh, a national coverage determination, if there is none, that's not synonymous with we disapprove of this treatment being covered by Medicare, correct? I mean, there's two separate, separate issues.

Josh Morse Yeah, I know. This is a check that that the legislature put on your decision making.

John Bramhall Yeah.

Josh Morse In the event that Medicare had a very high.

John Bramhall Right. Yeah.

Josh Morse Very rigorous policy on something nationally that emanated from CMS directly.

Josh Bramhall	Okay. Yeah. Yeah. My question was, was oblique. It wasn't related to work here, to be honest.
Josh Morse	Then they wanted you to just. Okay.
John Bramhall	Thank you though.
Josh Morse	Yeah, no problem.
John Bramhall	Thank you, Gary.
Janna Friedly	Great.
Josh Morse	I think you have… concluded then, do we have more decision slides after this, Val?
Val Hamann	No, these were just, yeah, if there was something written so.
Janna Friedly	Okay, great. Well, thank you everyone for your participation today and for keeping us on track and getting through a lot of material today. So really appreciate your engagement and, and everyone's work on this topic today. So I hope you all have a great weekend. Clint, you have your hand up before we adjourn.
Clint Daniels	Sorry, I just wanted to ask for the next meeting is the plan currently for that to still be virtual?
Josh Morse	Yes, great question. Yes, for the moment, you may be aware the state's going through some budget exercises right now and we are, you know, we'll be virtual for until we get further direction from our leadership. Yeah, we're going to stick to virtual and for the time being, despite what we talked about a few weeks ago, and our hope to get back to in-person meetings. And I really want to say thank you all for your attendance today. It's really helpful to have but right now it's a 10 member body to have you all present. And thank you, Dr. Mirza, for your time today. I really appreciate it.
Sohail Mirza	I just wanted to express my gratitude. I learned a lot reviewing the report and the discussion today. It's so good to see Janna and Dr. Bramhall, Dr. Franklin. I still miss Harborview, even though it's been a long time since I worked there. And Josh, you and Val and Melanie and everybody have been very good. And Andrea particularly. Sorry It was very, and your report is outstanding. Thank you.
Janna Friedly	Thank you very much. I really appreciate it.
Andrea Skelly	Thank you.
Laurie Mischley	Thanks, Janna.
Janna Friedly	Okay, have a good rest of your afternoon, everyone.

Washington State Health Care Authority

Judy Zerzan-Thul	Yes, thanks all. Bye.
Josh Morse	Thank you.