

Health Technology Clinical Committee Public Meeting

June 18, 2021

Copies of the audio recording for this meeting are available by request to: shtap@hca.wa.gov.

- Sheila Rege: Is that okay with everybody? Any objections? Speak now. Okay. So let's start with introductions, and in the introductions please feel free to state any conflicts of interest you make have, and then we will go on to reviewing the November 20th meeting minutes following which we can dive into the matter of hand. I was going to go alphabetically with the introductions. First off, I'm going to start with the bottom of the L's, so if you don't mind introducing yourself. And when you're introducing yourself, just tell me something fun you have planned for the weekend. Just something personal so we know something about you and try to limit it to a minute or two. Thanks.
- Christoph Lee: Thanks, Sheila. My name is Christoph Lee. I'm a professor of radiology and adjunct professor of Health Services at the University of Washington and [indistinct] Cancer Research Center. My research program centers around emerging screening technologies in the imaging realm, and my subspecialty clinically is breast imaging. I'm thrilled to join this committee and bring my experience in technology assessments and comparativeness research to the table. Something fun for this weekend-- I'm based in Seattle and we are super excited that school is out so the kids have their first weekend without any school work hanging over them. So we're going to hit the pool and go play some tennis. Thanks.
- Sheila Rege: Thank you. Is Clinton Daniels? Yeah. Clinton, are you here?
- Clinton Daniels: I am. Yes. Good morning. Hi. I'm Clint Daniels. I am a chiropractor and in the Chiropractic Service Chief at VA Puget Sound where I have been since 2015. I'm also adjunct clinical faculty at University of Western States out of Portland and I'm a board member for Clinical Compass, which is an evidence-based group that develops clinical practice guidelines for the chiropractic profession. No conflicts of interests. And as far as something fun this weekend, my wife and I just bought a house so we're going to spend a lot of the weekend packing and preparing for our move in a couple weeks. I'm excited and honored to join this committee.
- Sheila Rege: Thank you, Clint. Larry welcome. If you don't mind, just giving us a minute or so introduction and also something fun you have planned for the weekend. I think you're muted.
- Larry Birger: Can you hear me now?
- Sheila Rege: Yes.

- Larry Birger: Okay. Hi. I'm Larry Birger. I'm now a full-time hospitalist in Kittitas Valley Healthcare Hospital in Ellensburg. Prior to this, I did ongoing hospitalist work but was primarily an internal medicine physician in an outpatient clinic and had a busy complex practice, and I have extra training in background in cardiology. I'm very glad to be on the committee. My interests are really deep in evidence-based medicine. I've had the opportunity to become a mentee of Gordon Guyatt, and he has come out twice to do his only rural evidence-based workshops that he has ever done and I was the director for those. And some colleagues and I just started a medical education nonprofit called EBM Truth in Medicine and we're excited about doing that, and so all this committee work meshes very well with that. I don't know if I have anything exciting for the weekend. Well, I get to watch my granddaughter tomorrow. That's exciting. But I have broader excitement. I also three years ago started a music nonprofit called Learn From the Masters Music Outreach, and we're bringing the healing power of music in a broad sense, and so yesterday I just had two discussions with two of my world class artists who are also disabilities overcomers. One of them is Mandy Harvey the deaf jazz singer that you may have seen on America's Got Talent and have become friends with her, and that's very exciting. We're sponsoring her new album. And Billy McLaughlin, a world class finger style player who developed focal dystonia and overcame that. So that's very exciting and I think I'm over a minute. So I'll shut up.
- Sheila Rege: Thank you. Thank you, Larry. I'm just going to go from the bottom of the alphabet. Tony Yen, I'm picking on you.
- Tony Yen: Hi. I'm Tony Yen. I am the chief information medical officer at Evergreen in Kirkland. I am also a hospitalist, so happy to see another hospitalist join the committee, as well. What I'm doing this weekend is I'm going to be driving my oldest son back to college so he can actually participate in his internship online, which is somehow kind of a strange sort of thing. I don't quite understand that but that's how it goes. So that's what I'll be doing. I'll be driving from Seattle to Eugene to drop him back off into his little condominium. That'll be a lot of fun, I suppose? But we'll get to bond a little bit.
- Sheila Rege: Awesome. Mika? You don't mind going next, Mika Sinanan?
- Mika Sinanan: Hi. Good morning. Mika Sinanan. I'm a GI surgeon based at the University at UW Medical Center of Montlake, and I've been a member of the committee since 2017. I was just looking back at the first minutes that I have, and it's been a real honor to participate. In the background of my picture is the lake that we live on and we'll be swimming in that lake this weekend. That's our fun thing.
- Sheila Rege: Nice. Shoot, I'm next according to this list if I go. I'm Sheila Rege. I'm the current chair of this committee, a radiation oncologist, and really enjoying the flexibility of Telehealth. I also enjoy teaching and mentoring at WSU, and the current course we are teaching we're trying to figure out is a mini-MBA for the medical students, which will be fun. My passion is health policy. And a fun thing this weekend, we have apparently wine to pick up at one of the local wineries in Walla Walla, so

we're going to drive there and pick that wine up. Laurie Mischley. I'm sorry. I hit mute in the middle of that. You don't mind going next?

Laurie Mischley: No, not at all. My name is Laurie Mischley. I run an integrative medicine clinic for people with Parkinson's in Seattle. I'm a naturopathic doc with a NPH [indistinct] PhD in nutrition science. I'm a big fan of patient-reported outcomes. I run two really large prospective outcomes natural history studies in Parkinson's and MS thru Bastyr University looking at modifiable variables in Parkinson's and MS progression, and I do some metabolomics research in the Radiology department. I'm running a study on NAD and ATP in the muscle in people with Parkinson's using spectroscopy, and I've done that with the intranasal glutathione boosting CNS glutathione levels. So nutrition-based neuroprotection stuff.

Sheila Rege: Yeah. Great. Thank you.

Laurie Mischley: And I'm going to paint my fence this weekend.

Sheila Rege: Wow. Nice. I'm going to go a little out of order because I know that Dr. Chesnut had a hard stop at 8:30. Dr. Randy Chesnut, if you don't mind giving us a short introduction including any conflicts and something fun if you care to share.

Randy Chesnut: Sure. I'm a Professor in Neurosurgery and Orthopedics and Global Medicine at the University of Washington. I've been involved in evidence-based medicine for a few decades and have a dozen or so co-authorships on evidence reports and guidelines in critical care and neurosurgery, which are the two areas in which I'm boarded. My specialties have been neurotrauma and spine and was the first neurosurgical faculty on the AO Spine teaching group, which was a nonprofit international orthopedic education for implants and stabilization, and I've had a long interest in evidence-based medical practice. I've been around for a while, interestingly with respect to the SI joint fusion. I was around during the previous screw [indistinct] over two decades ago, so I've seen this come around full circle. So my interests is in evidence-based medicine and trying to rationally guide medical care. As far as this weekend, it'll be trying to rebuild the rear end of a 70-year-old British car and playing coaching and being part of the medical staff for a number of rugby teams in the area.

Sheila Rege: Very cool. Very, very cool. Thank you. Thank you for being here and for being flexible and letting us ping you, and we'll try and collate the questions. Next, it would be Conor Kleweno, and did I say that right, Conor?

Conor Kleweno: No. That's okay. It's Conor Kleweno. I'm an orthopedic trauma surgeon at Harborview and faculty as associate professor at the University of Washington. My clinical practice is on orthopedic trauma with a focus on pelvic trauma. And my weekend fun plans-- so for father's day, I'm going to take my dad out golfing. He's a lifelong golfer and I'm a 10-month novice hacker, but we'll have some fun.

Sheila Rege: That's cool. Chris? Chris Hearne?

Chris Hearne: Good morning. My name is Chris Hearne. I'm a nurse practitioner. I work with Swedish Hospital medicine and also studied Epidemiology at the University of

Washington. I've been on the committee for a number of years now, three or four years. Fun things this weekend-- I'm going to go to work, so we'll see how fun that is.

Sheila Rege: Cool. Janna? Janna Friedly?

Janna Friedly: Hi. I'm Janna Friedly. I am a physiatrist and professor in the Department of Rehab Medicine at the University of Washington. I'm the vice chair for clinical affairs for our department. Clinically, I work at Harborview. Pre-covid my clinical practice was taking care of people with amputations and limb loss, and post-Covid I started a post-Covid rehabilitation and recovery clinic, which has taken up most of my clinical time over the last year. And research-wise, I do a variety of research related to health outcomes primarily related to low back pain and teach evidence-based medicine to our residents.

Sheila Rege: All right. Thank you. John? John Bramhall?

John Bramhall: Hi. Nice to see you again, Sheila. Yeah, John Bramhall. I'm a practicing anesthesiologist. My training, I work in the operating rooms at Harborview, part of the UDub system. It's a big trauma setting but fair amounts of elective work, as well. So that's half my time and I [indistinct] an appointment as an associate medical director at Harborview so a certain amount of administrative and the coordinating work that I do. It's very fulfilling. I've been doing that for about 25 years. And I've been on this committee, I'm not quite sure, Sheila. I think it must be getting up to eight, nine years now, I think. Family will be home for the weekend, which is great. I have a son and daughter and they'll be in town. And what I'm going to do on Father's day, and it'll give me immense vicarious pleasure, is clean out my chicken's nest and put clean straw, make it all beautiful for them, and they may not appreciate it because they'll just poop in there, but I'll appreciate it. A lot of fun to do that and I've been putting it off.

Sheila Rege: That's right.

Man: John, I would say that's perfectly within your professional competency.

John Bramhall: Thank you. Putting down straw and water for other people.

Man: Yeah, you're right.

Sheila Rege: Are you going to use anesthesia for them? Are they going to need anesthesia? [laughter] I'd like to move on to the other panelists if we have time. Does Josh and Melanie? Melanie, I think this is your first meeting with us, correct? Would love to get an introduction from the two of you to begin.

Josh Morse: Thanks, Sheila. I'll start off. Yes. I'm Josh Morse, the program director for the Health Technology Assessment Program, and Melanie Golob is our new HTA Program manager. I've been with the agency for, I think, almost four months now, three months, I think four months July 1st, maybe? So welcome, Melanie. Melanie has really picked this up quickly and is fantastic. We really appreciate her being her with the HealthCare Authority now, so, thanks. And welcome everybody, especially

our new committee members. Great to see you here and thank you so much to everyone, and Melanie, to you.

- Melanie Golob: Great. Thank you. And it's been just lovely hearing from everyone. Just everyone's backgrounds and specialties and fun things over the weekend. So thank you for sharing those. So, yes, as Josh said, I'm Melanie Golob. I have a background in evidence-based medicine for the last 10 years and then before that biochemistry and molecular biology. So that's my background. Nice to meet all of you. I'll leave some time for the rest of the panelists. So thank you.
- Sheila Rege: Thank you. And the rest of the panelists, I love it when we say who we are and like HCA or whatever, HTCC. I could go by my screen. Why don't I go by my screen. The bottom of my screen is Charissa Fotinos. If I butchered your name, I'm sorry.
- Charissa Fotinos: That's okay. That's not too bad. Good morning, everyone. My name is Charissa Fotinos. I am the deputy chief medical officer at the Health Care Authority. I am a family medicine and addiction medicine physician and really appreciate the work of this committee and always find interesting the discussions and presentations so looking forward to it.
- Sheila Rege: Thank you. I have Christopher Chen?
- Christopher Chen: Hey everyone. Hi. My name is Christopher Chen. I'm a hospitalist and I work as a medical director and focus on Medicaid here at the Health Care Authority.
- Sheila Rege: Thank you. Joe McCullough?
- Joe McCullough: Yes. Joe McCullough. I'm associate medical director at L and I.
- Sheila Rege: Jason Fodeman?
- Jason Fodeman: Hey everybody. Jason Fodeman. I'm associate medical director at L and I. I am an associate medical director of Inpatient and Outreach, and I'm an internist and really enjoy these discussions and looking forward to today's meeting. So thanks everybody.
- Sheila Rege: Thank you. I have Ian Zhao?
- Ian Zhao: Excuse me. My name is Ian Zhao. I am a research specialist at the Labor and Industries. My area of focus is the health technology that's been in the coverage policy in L and I.
- Sheila Rege: Thank you. Sophie Miller?
- Sophie Miller: Hi everyone. I'm Sophie. I'm a medical officer supporting the Medicaid program, and I'm also a hospitalist.
- Sheila Rege: Thank you. Have I missed anybody? I thought I saw Gary Franklin, but I'm not seeing him.
- Gary Franklin: Yeah, yeah. Gary's here.
- Sheila Rege: Emily, I see you now here there too. Okay. Gary?

- Gary Franklin: Hi. Gary Franklin, medical director at L and I. I'm co-chair with Judy Zerzan of the Agency of Medical Director's Group, and this committee is unbelievable. So it's unique in the country and produces such amazing work. So thank you.
- Sheila Rege: Thank you. Emily Transue?
- Emily Transue: Hi. I'm Emily Transue. I am an internist and one of the medical directors here at HCA. I'm primarily focused on the PEBB and SEBB programs and I'll be doing the agency medical director presentation today. Always happy to be here.
- Sheila Rege: Thank you. And Leila Kahwati?
- Leila Kahwati: Hi everybody. My name is Leila Kahwati. I am the associate director of the RTI-UNC Evidence-based Practice Center. We are one of the evidence funders that conducts the evidence reviews for the HCA program, and you'll be hearing me a lot more later this morning, so I'll end it there because you'll be sick of me by the end of the morning.
- Sheila Rege: Thank you. Did I miss anybody? And I'm going to hand it over now to Josh. You [indistinct] there.
- Josh Morse: Thanks, Sheila. I'm going to switch to our brief presentation, and hopefully you're seeing a PowerPoint.
- Gary Franklin: I see it, Josh.
- Josh Morse: Excellent. Thank you. Okay. Here we go. Hopefully you're seeing a full screen version of it now. So welcome this morning. If you haven't already noticed, we are recording this meeting. Just FYI there is a transcript created from these meetings.
- Woman: Josh, I think we're seeing your presenter mode instead of the full screen one on the PowerPoint.
- Josh Morse: Okay. Thank you. That fix it, Melanie?
- Melanie Golob: Yes, it did. Thanks so much.
- Josh Morse: Great. Thank you. So hopefully you have figured out the webinar controls. We have some details on this slide. If you have any questions, please send them to us through the chat if you're having any difficulty with the Zoom controls today. For folks on the phone today who may not be on a computer that are using Zoom, there are two key functions that you may need to know about. One is star 6 to mute or unmute yourself and star 9 would be to raise your hand, and those may be important if attendees wish to notify us to make a public comment later as we get to the public comment section of the meeting. So, again, I cant say it enough, the meeting is being recorded. A transcript will be created and ultimately available on our website. When you do participate in discussions, for our transcriptionist if you could please make an effort to state your name and, of course, use your microphone. It gets a little easier now that we're using the webinar technology to do that. Public comment today: Attendees who have been scheduled to provide public comment will be temporarily reassigned as a panelist later in the meeting

and provide the option to unmute and turn their camera on if desired. A pop up window will show for a second on your screen, and then you'll be rejoining us as a panelist. It takes about four or five seconds for that to occur. We'll give you some time for that before we get to the comment period. So please limit your comment to three minutes. We will have a timer and we will notify you throughout as you approach that time limit. When you're finished providing public comment, you will change back to your attendee mode and there will be again a brief pause as that switches back. If you've not signed up in advance for public comments, you can indicate your interest to us by providing a comment using the chat function to notify us that you wish to comment in the comment period. The volume of sign-ups today for those who do sign up might determine the available time for each person. We have a limited time period for public comments and depending on the volume of sign-ups following the scheduled comments, that time can be limited. We strive to get everybody a three-minute comment period if they'd like. We ask that when you do provide public comment that you please first state any potential conflicts of interest prior to making your comment Iready made clear, today's agenda item is a re-review of the sacroiliac joint fusion topic. This was originally reviewed two years ago and the committee is considering an updated evidence report for this. Brief background for those of you that are not familiar with the program, the Health Technology Assessment Program is administered under the Washington State Health Care Authority. It was created in 2006, and the program was designed to use evidence reports and this panel of clinicians to make coverage decisions for selected medical procedures and tests based on the available evidence of their safety, efficacy, or cost effectiveness. Multiple state agencies participate to identify the topics and ultimately to implement the policy decisions, and those include the Health Care Authority that run the Uniform Medical Plan and the Medicaid program for the state of Washington, the Department of Labor and Industries, and the Department of Corrections, as well, participates voluntarily using these decisions. State agency use these determinations from the program and apply them within their existing statutory frameworks. The purpose of this work is to ensure that medical treatments, devices, and services paid for with state healthcare dollars are safe and proven to work. The program provides a resource for state agencies that purchase health care, and we use scientific evidence-based reports on these medical devices, procedures, and tests. In the committee we help to facilitate the independent clinical committee's work. The committee is composed of healthcare practitioners who ultimately determine which medical device and procedures meets the requirements for coverage for safety, efficacy, and cost effectiveness. There are multiple ways to participate. We have all of our information from the program on the Health Care Authority website, and the address is shown here for the HTA program. We encourage people to sign up using our Govdelivery system, which is available from this website. You can see how to sign up for notifications from the Health Care Authority and the HTA programs specifically. There are many comment periods on each topic including when topics are purposed for review on key question development on draft reports, and at the

public meeting here today, and ultimately on the draft decision that may result from today. There will be a two-week comment period following today's meeting on any draft decision. And, again, we have the public attendance at the public meetings through the Open Public Meetings Act. People may present comments directly to the clinical committee, and anyone is welcome to review or nominate topics for review through the HTA program or for re-review as has occurred in this case. That's it. Any questions can be directed to me directly or to the program through the website. We have contact information there. Thank you very much.

Sheila Rege: Thank you. Any questions for Josh? That was really helpful. Thank you. And I went a little out of order, so we are done with committee member introductions trying to make sure we had Randy's introduction, and now we will move on to previous meeting business and approval if we could project that. This was on November 20th and it was on the website. I'm sure everyone has seen it. I will take a motion for approval, unless there's discussion. Go ahead.

Woman: So moved.

Man: Second.

Sheila Rege: You know, I had a meeting yesterday where in the chat we just typed in "approved." Do you want to do that to everyone? And that will not take as much time.

Janna Friedly: And Sheila, I might suggest when we do this-- I've seen this in other meetings-- that for each time that we vote we have a little clarification at the beginning of what we're voting for so that it's on the record. So when it says approved, we just put minutes approved or minutes or something that indicates what we're approving for maybe for the future.

Sheila Rege: That's a great idea. Great idea. Thank you. Thank you, Janna. Moving on. As Josh mentioned, this topic is a re-review. It was reviewed in 2019 and the draft key questions were actually published in January. The draft report was published on April 2nd with a comment period, and now we have the final report. And if we could have the agency representative, Emily. Were you going to present?

Emily Transue: Yes, I will.

Sheila Rege: And this is on sacroiliac joint fusion. Thank you.

Emily Transue: Let me know if you can see my screen.

Sheila Rege: Yes.

Emily Transue: Perfect. Always the first challenge is to get the technology working right. Thank you so much. It is always a real pleasure and honor to speak to this committee. I'm Emily Transue. I am one of the medical directors at the Health Care Authority and I will be presenting the agency medical directors thoughts on this issue. I'm not going to replicate the information provided by the evidence review but really try to focus on a few things that we think are particularly important for you to consider as you are evaluating this question. And I need to figure out how to [indistinct].

Sorry. So it is hard to overstate the importance of low back pain in terms of the burden of disease and disability. This impacts somewhere between 4% and 25% of [indistinct] adults and has tremendous impact. The SI joint has been implicated as a possible pain source. Some studies suggest that as much as 10% to 30% of low back pain may be related to the SI joint. There is, of course, a very strong desire by both patients and providers for effective treatment for low back pain, and it is also important [indistinct] that there is a strong history of procedural over abuse, I would call that spinal fusion as an example, with high costs [indistinct] patient, and that really highlights the need for rigor in assessing the evidence around treatment options. The theory behind sacroiliac joint fusion is that pain in the sacroiliac region may be related to instability of the sacroiliac joint and that mechanically stabilizing the joint with a screw or specialized device could be [indistinct]. [indistinct] for the procedure include patients who are naïve to back surgery but also a significant number of patients with sacroiliac pain after lumbar fusion, so fusing one part of the spine could put increased pressure on the other joints and can lead to people being a candidate for that. So a variety of devices as well as surgical screws have been used to do this, but the trial data is almost exclusively around a specific device called iFuse, which consists of two to four triangular rods that are placed across the joint via minimally invasive surgery. This seems familiar, it is because it is to many of you have already noted this was reviewed by the committee in January of 2019. The decision at that time was in adults 18 years old and older with chronic sacroiliac joint pain related to degenerative changes and/or sacroiliac joint disruption, minimally invasive and open sacroiliac joint fusion are not a covered benefit. This decision was not intended to apply to low back pain of other etiologies such as radiculopathy or neurogenic claudication or to sacroiliac joint pain related to trauma, fracture, infection, cancer, or inflammatory [indistinct]. This rationale for that non-coverage decision was that a majority of committee members found the evidence sufficient to determine that the use of these procedures for these indications was unproven for being safer, more efficient, or more cost effective than comparators. The low quality of evidence was a major factor in that determination including both low certainty of results and a high risk of bias. This was selected for re-review this year primarily on the basis of petition and public comment. There is some new evidence including additional two-year follow up on two randomized controlled trials that previously reviewed with just six months of data. There is also a new controlled cohort study comparing the iFuse device to another device called the Rialto Implant System, and there is some additional safety data. These are the designated CPT and HCPCS codes associated with this. I won't read these out, but one is for the minimally invasive procedure and another for an open procedure. Looking at current state agency policy across the board, HCA, and Labor and Industries follow the HTPC decision described earlier. I'll call out the new acronym here. You used to hear a lot about the public employee benefits board or PEBB. Now we also have the school employees on board, we refer to those collectively as the Employee and Retiree Benefits groups that we [indistinct]. Current utilization across the programs for the

last four years is described here. We are not able to report numbers under 11. You'll see that overall usage thus far is fairly low and fairly steady; 2020 year was the year that the prior determination went into effect. We have not seen utilization in the Medicaid [indistinct] program but across the others have seen fairly low and fairly constant utilization. You may note the numbers don't add up perfectly. There were a couple of patients who had procedures in multiple years. Those can be either revision surgeries or having one the side operated and then then a subsequent side operated. The cost experience across our programs is shown here. Again, individual numbers suppressed but you can look at the averages. Medicaid MCO data is somewhat imperfect. We have to rely on some indirect methodology for that, so probably would set more [indistinct] by the PEBB and different industries numbers ranging from 7000 per procedure to about 17,000 on average. The agency medical director concerns around this topic are high for safety, efficacy, and cost. Key questions I won't review in detail but, essentially, what is the effectiveness and comparative effectiveness of this procedure, what is the safety, and what is the cost and cost effectiveness? We want to call out a few things that we think are important with the limitations around the data and the devices. First off, FDA approval limitations. All of these devices were approved under the 510(k) approval process, i.e., substantial equivalence to other device or treatment on the market. None of these have had premarket approval studies. Additional things to note are the lack of a diagnostic gold standard. Inclusion criteria for the studies we'll see today vary. Typically, a combination of physical exam tests around five physical exam tests for these procedures for this diagnosis, and often there are requirements that three out of the five be positive. Also a reduction with pain with SI anesthetic injection. The amount of reduction varies from trial to trial. It's often 50%, sometimes 75% or 80%. There's sometimes a requirement that that injection be imaging guided, but that's a variable requirement. There's overall poor reliability of the physical exam for this condition. Kappa values for pooled parameters of inter-rater reliability are less than 0.2, and we have that citation here. So generally poor reliability there. Additionally, an analysis that looked at combined data from two trials found no relationship between level of response to SI joint block in the 6 to 12 month pain and disability scores among patients who have fusion. So essentially the closest thing we have to a gold diagnostic standard really doesn't correlate to help people [indistinct]. So other limitations that concern us in the data include limitations around the comparators. So conservative management in general is defined at the providers discretion. It is not the kind of evidence based on multidisciplinary management program that we would consider to be the true gold standard comparator. There's a lack of blinding. No sham studies have been reported yet. There is one in progress. Providers, patients, and evaluators of outcomes are all unblinded to the study arm in all of these studies. There is also a lack of an independent evaluator, so these evaluations are typically being done by the surgical team. Most of the data comes from uncontrolled studies, and there are two randomized controlled trials that we'll discuss. And finally, funding. All of the trials reviewed were funded

by the device manufacturer. There were often significant payments to the researchers. Those are available at the site cited here. And I'll also note that neither the lack of an independent evaluator nor the question of funding is considered in the Rubrik that the evidence reviewers use to assess for risk of bias. So when we see their risk of bias numbers, note that those don't include either of these issues. Looking at effectiveness, I think really the key studies are the two randomized controlled trials. Both of these are unblinded for both the patient and evaluator with no independent outcome assessment. They are both manufacturer funded. They allowed crossovers after six months with high rates of crossover that really [indistinct] long-term comparison. Conservative management not fully standardized and some highly evidence-based treatment such as cognitive behavioral therapy were not consistently approved or included.

We also have some concerns around the lack of equipoise around the description of severe adverse events. So for example, severe adverse events are described as occurring from physical therapy and are often classed in the same classification with things like having to do over [indistinct] operation. Briefly to those two trials, the insight trial is the primary US trial. Crossovers here were allowed six months. They had an 88.6% crossover at two years, meaning that in total 142 out of 148 eligible patients eventually had surgery. So very difficult to assess the long term outcomes in the conservative group from these numbers. Conservative management, again with variable per site, they specifically excluded CBT based treatments which they considered to be impractical and unrepresentative of modern healthcare. Looking at the iMIA trial, which was the large European multicenter trial -- I probably shouldn't say large. It had nine centers, 103 patients. Here, again, conservative treatment was a variable. And CBT was allowed here but not required. Crossover was, again allowed at six months. They had a somewhat lower crossover rate but still quite high at 43% at one year. These are the primary evidence presentation, of course, the evidence reviewer, but really wanted to call out here what we have that is new since the last review. So only the highlighted data here is information that we didn't have at the time that this was last reviewed. Evaluations were done on a variety of outcomes, including pain and disability, which could be looked at directly or in terms of the number of patients who had at least a 15 point improvement. Quality of life was also looked at according to a couple of different measures. We have some results on opioid use. Essentially, what we see here for the incites trial was fairly stable findings across the additional follow up from what we've seen before. Some of these are really difficult to assess to get those small numbers. So that drop in the disability impact involves a very small number of patients and a wide confidence interval. But otherwise, the impact seen previously seemed to be generally preserved. We also have some two year information in the European trial around reduction of opioid use, which wasn't available previously. And I really want to call out here, there's no question that the magnitude of these effects is significant if it's real. I think the concern is that we know that surgical procedures in particular are associated with a substantial placebo effect, which can impact both evaluators as well as patients in

terms of expectation biases. And we just don't have objective data to assess these results independently of those concerns. There's also not a huge amount more data now than there was when this was looked at two years ago. In terms of safety, most of the evidence available is around the iFuse device. There are no common protocols for data assessment nor are there standardized definitions of complication. There's a broad range of incidence of adverse effects in different trials. Frequency of severe or serious adverse events ranges anywhere from 0% to 46% in different reports. The most common complications are neurologic, including neuritis, radiculitis, sciatica, and neuralgia. Looking at revisions, post market surveillance data suggests that there's approximately a 2.8% revision rate over a median of four years. Similarly, in uncontrolled cohort studies a range from 0 to 8% was seen and about 63% for most if not all we're seeing within here. We do have a new study looking at data from 2015 to 2018, showing us 3.1% total revision rates and rule revisions around 1% for the iFuse 3d device, which is a somewhat newer version and 1.5% around the original iFuse tonight. I will also call out that the evidence reviewers confidence on the safety data actually decreased over the period since the last review. One new study that we wanted to call out compares iFuse versus Rialto. This is the only study comparing different minimally invasive implant systems. Rialto is a cylindrical threaded device implanted through a [indistinct] approach as opposed to the iFuse, which is triangular and inserted in a lateral transiliac approach. This study was found to have a higher risk of bias but it did not find any significant differences in the outcome studies including pain function, disability, and quality of life. Revision surgery was substantially more common with Rialto than iFuse in absolute numbers. But this was not statistically significant due to the small number of [indistinct]. We wanted to note some findings from the FDA mod adverse event database. This is not included in the evidence review but we think these findings are important. These are possibly reported events, typically from the manufacturer, a part of a reporting requirement. So we can't derive rates from this data. The event description almost always states that the event is not related to actual defects in the implants themselves. Over the last year, there were 130 reports of serious adverse events specific to iFuse. These include things like malpositioning with impingement on the foramen and nerve involvement, also infection, unusual sacral fractures were also seen, though it's unclear whether or not those were related to the implant. And these reports do not include events related to the non iFuse devices, of which there are dozens that have been approved by the FDA. To call out just a couple of these, I won't read these in detail. For example, a patient who had a fusion subsequently had radicular pain. It was determined that the superior positioned implant was impinging on the neural foramen and causing radicular pain symptoms. This was revised by removing the superior positioned implant using chisels. Other events are similar. Another patient who initially did well but subsequently had radicular pain that was found to be due to malpositioning and impingement. And again, the device needed to be removed. And what we want to emphasize here is really that this is not a question of just unscrewing a screw

[indistinct]. They really do need to be chiseled out of the bone. So these don't come out easily. I think we want to be very clear about whether it's indicated. Cost effectiveness and the cost. Here we have a very low quality of evidence. Ackerman study showing that patients who received iFuse had about a 14,000 increase in costs over the first three years that dropped to 6000 over five years due to higher costs in the conservative Management Group. Same author studying Medicare patients found that iFuse costs about \$3,000 less over the course of a lifetime. Cost effectiveness. One study again, low quality of evidence, suggested between a 2\$,000 and \$13,000 cost per quality adjusted life year. Again, these would be very reasonable numbers if we had confidence in the efficacy data. I do want to call out some evidence that is pending. There are multiple ongoing studies which are detailed in the evidence report. We are particularly interested as agency medical directors in the study now recruiting that we'll look at iFuse versus sham study. Completion of that is expected in April of 2023. Speaking to coverage comparisons, for Medicare there is no national or local coverage determination at this point. Looking at a variety of other payers in the state, this is a busy slide but just to call up, there's quite a bit of variation ranging from Kaiser which doesn't cover these devices or approaches at all. Some cover only the iFuse. Cigna covers any FDA approved implant. Some variability in the diagnosis considered. Some of these look at ADL interference as a criterion, others do not. Some require only adults aged 18 and older. Generally chronicity of six months is required before considering the procedure. And generally requirement of a pain score of at least five on a one to ten scale. Some of these standards are very specific about what needs to be done in terms of conservative treatment. Others are somewhat more general. Physical findings, again, some are very precise about what's required and others are more general and some don't have a requirement at all. [indistinct] for radiologic findings. Most if not all require a particular response to an injection. Looking at some of these similarities and differences, all of the competitors here require a 75% response [indistinct] two injections down to only one. And some require imaging guidance for that and others don't. They are also certain exclusions present for things like the prevalence of a generalized pain disorder or complicating mental health concerns. The Cigna policy also considers smoking. Moving on to national and international guidelines. National Institute for Health and Care Excellence. Those consider evidence to be adequate to support the use of this procedure and that should only be done by experienced surgeons. That is their guideline around minimally invasive SI joint generally. They also have a more recent one specifically for iFuse that also finds it is supported by the evidence leading to improved pain relief, better quality of life, and less disability. The International Society for the Advancement of Spine Surgery finds that procedures through a lateral transiliac approach - so that's the iFuse approach - may be medically necessary with failure of six months of conservative management, and a variety of requirements around impact on quality of life, physical exam findings, and pain relief with walk. They find the posterior fusion approach to be unproven. That guideline is from last year. The AIM specialty health guidelines also find that

iFuse may be medically necessary when a variety of criteria are met, similar to the ones described above.

They require at least a 75% pain reduction after block on two occasions. EviCore guideline is similar to AIM, although it also requires that the patient not be smoking and have some requirements around the absence of behavioral health issues and surgeon requirements [indistinct]. So how do we put all of this together? The recommendation of the agency medical director is that the community maintain the standards that were set in the review two years ago, which is to say that in adults 18 years and older with chronic sacroiliac joint pain related to degenerative sacroiliitis and/or sacroiliac joint disruption. Minimally invasive and open sacroiliac joint fusion procedures are not a covered benefit, and that this decision not apply to low back pain as other etiologies or to sacroiliac joint pain related to trauma, fracture, infection, cancer, or inflammatory disease. Our rationale for making this recommendation is that the evidence of efficacy in these conditions is based on unblinded manufacturer-funded trials with a high risk of bias and a real absence of objective data. Serious adverse events are a concern and may be underreported in trials. Furthermore, we're concerned that additional evidence since the prior review is very limited and really does not address the concerns that led to the prior determination. I am happy to answer any questions.

Mika Sinanan: Hi. Emily, Mika Sinanan. Could you go back to your slide number three?

Emily Transue: Sorry to do this manually. I'm sure there's a better way.

Mika Sinanan: No, that's fine. And so I think this is a question that I have for both Conor and for Randy that we could put on our blackboard. But the theory and the treatment appear to be unlinked to me. So the theory is that the pain is related to instability, yet conservative therapy doesn't increase the stability of the joint, and injections don't increase the stability. And a number of other potential causes, inflammation, nerve impingement, infection, what have you, temporarily would be improved by an injection or steroid injection, an anesthetic injection. So the temporary treatment doesn't address what the underlying theory of the cause of this is, which may explain some of your observations that this evidence that we have is still out there still to be proven. So I wanted to ask Conor, given your specialty area, and Emily, from your more detailed review, if you could comment about the theory underlying all of this.

Conor Kleweno: Yeah. Thanks, Mika, and a couple of intro comments. I was the expert advisor that last time this was reviewed, so I had the roll that Randy Chestnut has and, obviously, that's available for record review. And then for the committee, since that time, I had a lot of specialty in this area and so I feel like my comments could be helpful to the group today. I am proposing to the committee that I will recuse from voting today because I have acted recently as an unpaid consultant for a research study design for one of these companies. I predict that my vote would be similar to many people on this committee, but to protect against any optics or concerns, I propose to the committee that I will participate in the discussion,

answer questions from other committee members like Mika has proposed, but I would propose that I recuse from voting, and I just wanted to make sure that was okay with everybody today. Great. So speak up if that's different. But in terms of your question, so a great question, Mika. And so we know from a traumatic perspective the observation that an unstable pelvic girdle is almost invariably a symptomatic condition. Now, the theory that is proposed is there is some sort of mechanical microinstability, whether it's degenerative or adjacent segment microinstability from a lumbar fusion, at least in this particular bullet point, and that stabilizing this should alleviate some of those symptoms. The problem is correctly as you identified, there are competing potential diagnoses that cause pain in this area. The injection, if there is true pain that is localized to the SI joint, if you put a local anesthetic that is truly image-guided into that area, I have observed that 90 minutes to two hours of pain relief that then wears off and the pain returns. I would just comment to the committee as well as the interested parties that an injection should be image-guided, and my recommendation is at least CT scan-guided, because that joint in that area is difficult to access with accuracy and precision just with simple ultrasound or even with non-imaging techniques. And I think you had a secondary question there, Mika, that I have since forgotten because I kind of was verbose there.

- Mika Sinanan: Yeah. So thank you, Conor. So that the microinstability is thought to be degenerative. But where does that come from? Are there actual variability in the position of the bones one to the other or-- I mean what's the evidence to say that it's microinstability versus inflammation from another cause?
- Conor Kleweno: Again, that's a great point, and if Randy is on the call, too, I'll offer to have him comment, as well. But I have done a handful of SI joint fusions. I have declined or recommended nonoperative treatment many more times than I have recommended treatment. The handful of patients that I've done a fusion for include the autoimmune arthritis degeneration of the joint, a postinfectious complete degeneration of the joint, and an acute traumatic disruption of the joint that had a sort of obliteration on radiographic follow-up imaging of that joint. Those are all kind of an etiology that's separate from, I think, what was the previous HCA recommendations for this chronic micromotion across the joint is the theory. So it's, for example, in the setting of lumbar spine fusion, that there's increased stress and strain seen on the adjacent joint-- in this case would be the sacroiliac joint-- and so that stiffness that's adjacent to it is creating a [indistinct] environment with more micromotion that is leading to symptoms and then potentially to a theoretically arthritic condition. And Randy, you got your hand up, so I'll pass it over to you.
- Randy Chesnut: Yeah. I think that's spot on, and I quite agree with what Conor said. One of the issues is that we lack physical evidence of instability there. I mean, in Conor's patients, when it's broken it's pretty straight forward and we probably don't need it. But in the case of degenerative disease, it's theory. I mean, that first word is absolutely spot on. It theorizes because we think this should hurt, especially with

adjacent level, multiple level fusion where the stress riser is high at the SI joint. But it has not been proven that there is actually instability in the vast majority of these patients. Plus it has not been proven that either these devices actually result in fusion of that joint or that the outcome correlates with the success of that fusion. In other words, sort of a control for a placebo effect. Finally, the injections lack controls. And there is a very prominent literature on the use of control injections. For instance, in Nik Bogduk's work in a whiplash injury, they used placebo injections plus lidocaine and bupivacaine, and the only positive was not only did they not respond to the placebo but that they responded differentially in length of effect to lidocaine and bupivacaine. So we have theoretical instability and our best test, our most objective test would be the, I think-- I'll agree, including the funders-- the response to injection has not included the controls that can address things like placebo effect and the multifactorial nature of chronic pain.

Mika Sinanan: Thank you. Mika Sinanan, again. So just one follow up question, or actually two. One, is these studies ended in 2013 or 2014 and 2015, but they're only two years of follow up? Is there more follow up data that's coming, or is there a reason that we only have two years' follow up? And two, many of these devices evolve over time. And is this device that would be put in now, like for the iFuse, the same thing that was put in in 2013, or is it a substantially different device that might have a different performance?

Conor Kleweno: Mika, I'll comment on your second question and, again, I apologize to other committee members. This is something that multiple times a week I'm operating on the SI joint, and so I do have some opinions. This CPT code, this condition that we are considering and with potential surgical options, I think is still in its implant-dependent phase. There are different companies with different implants that are quite different, and it is an evolving field. So as opposed to what I would say in analogy like a total hip replacement where there has been a coalescence of the technology where most hip replacements are relatively similar types of implants. That's why the outcomes are more consistent. In this particular situation, I think that the implants are continuing to evolve. For example, the decortication of the actual articulation between the sacrum and the ileum is still evolving, as well as the compression across that articulation is evolving. The potential perceived conflict that I wanted to highlight to the committee was a different device that has been published. And so I think to answer your question, you are absolutely spot on. This science is still evolving, and it is highly implant dependent.

Emily Transue: Randy, did you have any comments? Otherwise, Larry. Thank you.

Larry Birger: Okay. I was wondering if we can have you comment on the role of neuroplasticity, abnormal central nervous system, brain processing, and so forth in this condition. My study in chronic pain and dealt with a lot of chronic pain patients in my clinic practice really led me in the direction of that phenomenon as being quintessential to the treatment of chronic pain, really in chronic conditions in general. And I've spent a lot of time educating patients in that and, as you know, you guys with your expertise, I'd like to have you weigh in on that on this situation.

Randy Chesnut: Well, I think I agree that this is a very vulnerable population. It's chronic pain, not acute pain. There are so many different variables involved in that: the original pain source, evolution of the pain source, the body's response to the pain source, the incredible impact on the patient's life, employability, view of self, quality of life, financial, relationships, etc. So it's definitely n-dimensional vector space. And, indeed, in the lumbar spine pain surgery studies, the randomized trials, it appeared that the more cognitive the therapy offered as part of the non-operative management the less likely you were to see any effective operative management. So if your control, as in almost all of these studies, was simply doing the things that haven't worked up until randomization, that generally shows in effect placebo or [indistinct]. But in the back pain studies, if they addressed the life issues with cognitive therapy, it was much less likely, and in some studies, didn't happen that there was any beneficial influence of surgery. So I'm not sure we can pick out one particular vector, but clearly this is multiple, multiple vectors in a very vulnerable population that's desperate to any treatment.

Emily Transue: Sorry, [indistinct]. It's okay. Go ahead, Conor.

Conor Kleweno: Yeah. Did you have any thoughts on that? I know one of the biggest influences on me in terms of chronic pain was my former neurology attending, and he dealt with the failed neurosurgeries and all this really difficult stuff. And he said that he spent a great deal of his time treating chronic pain in helping people to adjust their belief systems as part of the therapy. And to me, that fits very well with the idea of changing the concept of neuroplasticity.

Larry Birger: Yeah. I definitely would not be purposed to be an expert in neuroplasticity, but I do see many patients with chronic pain. I think it is an unanswered question, but it is clear an ill-advised or a poor surgical candidate who is provided surgery for chronic pain, I think we have pretty well demonstrated, at least all of us surgeons, that that can be quite problematic. And so providing surgery for a patient with chronic pain that is not an appropriate surgical candidate and their pain is unlikely to be solved by that, I think we've shown that that is an ill-advised path. And I agree with Randy that this can be a population who is desperate for pain relief.

Sheila Rege: Josh, I'm going to turn it over to you. I know we are on time with schedule and open public comments. Thank you.

Josh Morse: Thank you, Sheila. Yes, we are a couple minutes into the public comment period, and we have had some attendees joined. We do have one hand up from an attendee and I'd just like to check in. I'm going to try to unmute you and see. This is number-- it starts 936—Oops, I just lost my screen. The attendee with the hand up, can you identify yourself? We're not able to hear you. Okay. Dr. Polly, I see that you have your hand up, as well. Do you have a comment here?

David Polly: Yes. Thank you very much for allowing me to comment.

Josh Morse: Okay. No, I just wanted to check your audio. Thank you, Dr. Polly. I'm glad your audio is working. We have a list of commenters, Dr. Rege, and Dr. Polly, you are on

this list, but we're going to go in order from the list here. So, Melanie, can you confirm that we have the commenters ready to--

Melanie Golob: Yeah. We might have to check in on some of these phone numbers. The first one on the list, Peter Ameglio, I do not see him on the attendee list. So if Peter Ameglio is one of the phone numbers, perhaps he can raise his hand.

Josh Morse: I think that might be the 936 number.

Melanie Golob: Oh, and maybe having audio issues?

Josh Morse: Are they a panelist now?

Melanie Golob: I can do that. Okay. So if the phone number starting in 936 is Peter Ameglio, go ahead and unmute yourself and provide your public comment.

Sheila Rege: Can we have clarification of how long the public comment would be and if we could have a statement of any conflicts of interest, if any, if you're being paid for your time or if you represent an institution or any entity. Thank you.

Josh Morse: It doesn't appear that we can hear the person on the phone from the 936 number. You do appear to be unmuted, but we are not hearing you. Oh, I see you. You are speaking, but we are not hearing you. You're still muted. Yep.

Melanie Golob: Josh, we can give him some time to potentially check his audio settings and just keep going down the list.

Josh Morse: Sounds good. Thank you, Melanie. So then the second signed up speaker is David Baker. Dr. Baker, are you on the call?

Melanie Golob: Okay. If you're one of the call-in participants, please raise your hand using the star 9 function on your phone.

Josh Morse: Okay. We don't see Dr. Baker. The third signed up commentor is Thomas Flory.

Melanie Golob: Okay, and I did see that. So I will promote Thomas Flory to panelist, and if you'd like to share video and provide public comment and, as Dr. Rege said, providing conflicts of interest. You will have three minutes.

Josh Morse: And Thomas Flory, you are--

Thomas Flory: Can you--

Melanie Golob: Yeah. We can hear you.

Thomas Flory: Great. Thank you. So first, I should say I work for Dr. Baker, and he's currently unavailable. He's still up at the hospital doing a case. And as far as a conflict, I put this in when I signed up, but just so everybody knows, I went two or three years ago down to the SI Bone headquarters and spent a day as a paid consultant to help them understand ambulatory surgeries that are reimbursement. Okay, I'll assume from the lack of response that I can continue. So my thoughts as the administrator for the Fourth Corner Neurosurgery Group is that we've worked with Regis and Premera to help them set up their criteria and would suggest that it would be better to have a more restrictive set than to have no availability at all. Largely

because what we can foresee is having, say, an L and I patient end up going through a long and cumbersome process and in front of an administrative law judge who would eventually potentially allow them to have the surgery. And as much as I'd like to comment on the science, I don't know that I really qualify for that. Although, I have to say that I had the pleasure of meeting Dr. Bogtuk a number of years ago and potentially setting up a more structured injection criteria would work.

Melanie Golob: Okay. Thank you. Is that the conclusion of your public comment?

Thomas Flory: That's it.

Melanie Golob: Okay. Thanks so much.

Josh Morse: Thank you. Mr. Flory.

Melanie Golob: Alright, next on the list we have Anton Jorgenson. If you are an attendee on the phone or with another name, please raise your hand. Okay. And, again, that is star 9 if you're on the phone. I do not see any hands raised. If you are on and need to figure it out, then we can circle back. Roland Kent will be the next one. I will promote you to a panelist.

Roland Kent: Are you able to hear me now?

Melanie Golob: Yeah, we're able to hear you well. Do you want to state any conflicts of interest you might have?

Roland Kent: Yeah. I was going to try to share a screen if possible. I mean it's not going to work as far as my camera is concerned, and I need to--

Melanie Golob: You should be able to share your video. I think you just have to click the share video option. It's over on the left side kind of by the mute and unmute button.

Roland Kent: Okay. I'm sorry. You are correct. It looks like I'm there now.

Melanie Golob: Yeah, perfect.

Roland Kent: My name is Dr. Roland Kent. I'm an orthopedic spine surgeon at Northwest Specialty Hospital in Post Falls, Idaho. It's actually great to see Dr. Chesnut here today. I trained under him a long time ago at Harborview and I enjoyed that time. I mean no disrespect by saying a long time ago, Dr. Chesnut, so I hope you don't take offense to that. I learned a lot from him and am glad to return to this population. I returned to this area about six years ago and have been doing spine surgery and SI joint surgery ever since that time. I have received reimbursement for education from both SI-BONE and SImmetry, which is another device that is used for SI joint arthrodesis, and I'm currently doing research with SI-BONE for bedrock in the realm of complex deformity. I have dealt with a lot of these patients and Washington L and I, and I've had the opportunity to meet with a lot of you and discuss opinions with a lot of you in this regard. I appreciate the time today to be able to share my opinion on this. I agree with some of Dr. Chesnut's comments from the get go. This is kind of a second go around of this. We talked about this 20-

30 years in Medicine, and I think what's caused the rekindling in our interest in SI joint surgery is the idea that we're able to do this much more productively with less potential morbidity to the patient than we could when we did open SI joint surgery. And I wanted to comment on some of the things that have been said so far. Looking at SI joint pain as a form of instability, I think this may be a misrepresentation of the pathology which besets the SI joint, and the current radiographic criteria accepted for SI joint stabilization by Washington Labor and Industries reflect that. That's essentially the same radiographic criteria that were used for unstable pelvis. And so even this idea of instability or microinstability, I think is potentially the wrong way to look at this particular disease entity, and I would prefer to look at it as arthritis and traumatic arthritis in the case of our Workman's Compensation clientele. And to that end, throughout the surgical world we all need to have three answers for arthritis, and one of those is joint replacement. Obviously, that's not an option for sacroiliac joints. The other is joint resection or resection arthroplasty. We used to do that in the hip world all the time with good results. We still do it with the distal clavicle with good results but, obviously, we can't resect the SI joints. That leaves us with a third surgical option, which is the only option that's been found to be effective with the SI joint, which is arthrodesis or fusion of that SI joint. So that gets to the idea that was brought out that a lot of the conservative treatment recommendations don't seem to go along with the idea of instability, which I would have to agree. They're really designed to help is the idea of arthritis. And motion is good and that's where physical therapy and chiropractic there come in as far as conservative treatment algorithms for this. Stabilization of that joint often helps, as well. We see people with bad knee arthritis wearing knee braces all the time. They tell us all the time that helps. That goes along with an SI belt, etc. And in this case, thankfully, we have literature to review if it's been reviewed by large spine societies, and this been brought up already [indistinct] that provided coverage recommendations for us to usher us out of the concept that this is experimental medicine and into the idea that this is actually accepted by the individuals that perform these procedures and that these procedures can be done well with very few side effects. But, again, I also urge that this should be done in the appropriate population. And that's been part of the discussion and, obviously, that comes to patient selection.

Melanie Golob: Dr. Kent, you're just over three minutes, so did you have any concluding comment?

Roland Kent: I just wanted to say that I think we should rely on the professional organizations, and those who meet inclusion criteria or covered recommendations that we should consider them to be a good population for this procedure. Thank you for the time.

Melanie Golob: Thank you. Thank you for your public comment. We appreciate it. So I think we can circle back to Peter Ameglio. Before we do that, if there is Morgan Lorio in the attendees, maybe you could try to raise your hand if you're an attendee. But in the meantime, let's circle back to Peter Ameglio for public comment. If you are able to unmute yourself. There we go. We can see you. Oh, still can't hear you though. All

right. We can try again later. Okay. It looks like Morgan Lorio. I'll promote you to a panelist so you can give your public comment.

Morgan Lorio: Okay. I'm unmuted now, if you're ready.

Melanie Golob: Okay, yeah. Do you have any conflicts of interest to state?

Morgan Lorio: No. I don't. I'm Dr. Morgan Lorio. I'm a board and chair for [indistinct] reimbursement for [indistinct]. I have no conflicts and I, sorry, I'm just getting in on this conversation. But I would like to ask number one, if you're not familiar with the [indistinct] policy to please familiarize yourself with it. Clearly, some of the comments that were made by Washington HCA relative to the diagnosis, they allude to the fact that they think things are fuzzy. And clearly the diagnosis is very specific with a significant positive predictive value, and we list the references in our [indistinct] policy 48 through 51 [indistinct] and Szadek which speak to the positive predictive value which exceeds that of lumbar radiculopathy. So this is a real diagnosis, a real thing that can be diagnosed clinically and subsequently treated. Additionally, the residency program that I trained in in Buffalo is instructing their residents on how to manage sacroiliac pathology that occurs a more of an arthritic and/or a microinstability pattern that presents that separate and apart from the traumatic Legacy procedures that are accepted currently. The worker's compensation population improves. There's an opioid issue within the US. Narcotic use has diminished having the SI fused and, unfortunately, the imaging to date doesn't readily confirm it. It is a diagnosis by exam, but it has significant positive predictive value. Our society has been following the SI treatments since 2012. We have been actively working to provide care, which is currently rationed. And, lastly, I would ask you why should Washington HCA be a non-sanctuary insurer for those unlucky enough to suffer from chronic sacroiliitis? And why doesn't Washington HCA accept the current data and walk in tow with other insurers moving forward?

Melanie Golob: Okay. Thank you. Is that the conclusion of your public comment?

Morgan Lorio: Yes.

Melanie Golob: Great. Well, thank you so much. We appreciate you providing public comment.

Morgan Lorio: Thank you.

Melanie Golob: So next on the list we have David Polly, and I saw him as an attendee, or I did.

David Polly: My hand is raised. I don't know if you can--

Melanie Golob: Oh, great! Oh, you've already been promoted. Okay. Yeah, go ahead.

David Polly: So I do have significant disclosures. I am a consultant for SI-BONE and for Globus. I receive royalties from Springer Verlag and from SI-BONE. I have research support from Medtronic, Mizuho, and AOSpine. I'm on the executive committee of the American Spine Registry of the American Academy of Orthopedic Surgeons. Those are my disclosures. In terms of comments, as an information update there is published five-year result data called The Lowest Study, which was a combination of patients from the planned two-year randomized control trial and from a

prospect of cohort study called the [indistinct] study, and that data suggests that patients who have benefited at two years maintain their benefit through five years. So that's the first information update that I hope the organization finds useful. In the area of diagnosis, my experience has been in participating in the RCT and in subsequent care of these patients that its reliable as the Peterson study says, that it's a clinical prediction rule that it is more reliable than a diagnosis of lumbar radiculopathy by physical exam. It does require three of five physical exam maneuvers being positive, and with the physical exam being positive there is an 85% positive predictive value of response to image-guided local anesthetic. I do agree with Conor Kleweno about the utility of CT-guided injections. I have many patients who were referred to me for SI joint pain based on a possibly image-guided or possibly nonimage-guided injection and having a positive injection response, but they are physical exam negative. When they're physical exam negative, I do not offer them the surgery. The criteria that are used in Minnesota, the state where I practice at the University of Minnesota, for most insurers is that of the randomized controlled trial inclusion criteria. With that utilization criteria, we have not seen overuse or overabundant application of this technology. These patients are significantly debilitated. In a study we published looking at the impact of the burden of disease, they are equivalently disabled to people needing total hip [indistinct], BondEase, and other problems with an HRQOL or a quality rating of about 0.5. And most of the patients in the clinical trials were, in fact, long term pain patients. No argument about that. But the majority of them benefited from the intervention. In the past, there was a comment about difficulty of revision. My partner, Mark Swienckowski, a former Harborview director, and I have performed more than 60 revisions. We've fortunately or unfortunately gotten a reputation as a place that they can be revised, and we have a manuscript in preparation demonstrating that revisions can reliably be done. My experience has been that the revision rate in my primary since about in the 1% to 3% range, and so that's consistent with the published data. And I am a fan of cognitive behavioral therapy, but I'm unaware of high-quality data for CPT specifically for the SI joint, so not quite sure how to apply that other than a generic chronic pain program. In terms of the pain generated, the best work is by [indistinct] that looks at the nerve patterns of innervation within the SI joint. And they're in the anterior capsule and within the subchondral region of the cartilage, and these nociceptor fibers are well represented and well characterized as pain fibers. And so I think the concept of it as an arthritic overload is probably more accurate than a dynamic instability. Although, I have seen Ehlers-Danlos and Marfan patients who have had frank instability. With those comments made, in general, my experience has been that patients who have had prolonged pain have been able to achieve a minimal clinically important difference as determined by their own patient reported outcomes, such as the ODI and the VAS, which in our practice is administered by our medical assistants and not by the physicians and [indistinct].

Melanie Golob: Dr. Polly, your time is up if you have any [indistinct].

- David Polly: That's it. Thank you very much.
- Melanie Golob: Okay. Great. Thank you so much. I appreciate you providing public comment. And next on the list we have Cheri Somers, who I believe I saw. So I'll promote you temporarily to a panelist. And if you would like to unmute yourself and provide any conflict of interest you make have, and you are public comment.
- Josh Morse: Cheri's muted.
- Cheri Somers: Can you hear me okay now?
- Josh Morse: Yes.
- Melanie Golob: Yeah.
- Cheri Somers: Great. Thank you all for the opportunity to present today. My disclosure is that I'm a paid consultant for SI-BONE, and in that roll I educate other healthcare providers about diagnosis and treatment of the SI joint. Today, I want to talk to you a little bit more from more of a real world versus an academic standpoint. I work as a nurse practitioner in Spokane for MultiCare. I have worked in partnership with my physician colleague, Tony Tohmeh, for the last 10 years treating SI joint pain. We believe in this as a diagnosis, and we believe that there is viable treatment in the surgical intervention for patients. We've had excellent patient outcomes with MIS fusion surgeries. We participated in the SImmetry outcome study, and in that study alone we treated more than 25 patients with excellent long-term outcomes. The revision rate for SI joint fusion surgery from our perspective is very low. We personally have never had to revise any of our primary fusions. The issue that's raised with the diagnostic criteria being fuzzy is really a misnomer. It's been well established by both NASS and by ISIS, that have published criteria for following for diagnostics in these patients. The same criteria has been adopted by those local [indistinct] who have decided to cover these surgeries. Thus, we are creating a standard for the diagnosis of SI joint fusion. There has been some discussion about chronic pain, which is very real, and it is certainly a consideration in treating patients with surgery. But it's not just a consideration in SI joint patients, it's a consideration in any patient who is having surgery. Patient selection is key, and addressing all of the issues in the entire body of the patient including the mental health issues is paramount. There has been a statement made that doctors and surgeons think SI joint pain is uncommon. I would offer that the diagnosis is actually being missed or confused with another pathology. An example for you is yesterday in my clinic I saw a patient in follow up. I met him last July. He's 50 years old. He's had back pain since the age of 28. He does have spondylolisthesis, which is widely accepted as a spinal diagnosis and generally treated with lumbar fusion surgery. This patient's history and presentation was consistent with SI joint pain, and on my physical exam he had four positive findings. The criteria outlined by NASS and ISIS is that three of those be positive. I referred him for a therapeutic SI joint injection, which he had on July 30th last year. Yesterday, he returned to my clinic because he's starting to feel that the injection is wearing off. Up to that point, he had had 90% improvement in his symptoms. And, again, this is a man who has

had pain for more than 15-20 years. He was very thankful that someone had finally figured out where the source of his symptoms was. Another example for you is a 28-year-old active duty Army service member who had been having pain for more than two years following an injury while serving our country. We diagnosed him with SI joint pain. He was treated with surgical intervention. Within six months he was returned to full duty and he was just recently deployed overseas. We've made big differences in these patient's lives, and they are able to get back to their jobs, their families, and their functions. We've had several Labor and Industries patients. We have one patient, Washington L and I, who was able to overturn the denial, and we did treat with surgical intervention. The patient successfully returned to the job of injury. We also have several self-insured patients who have done the same.

Melanie Golob: Okay. Thank you so much. Do you have any concluding comments? You're over your time.

Cheri Somers: We owe it to the patients to properly diagnosis them and treat them, and I would really urge the consideration for coverage. Thank you.

Melanie Golob: Okay. Thank you so much for providing public comment. Next on the list, last of our scheduled, but we'll circle back to those who may have been missed previously. Jose Valerio, if you are an attendee please raise your hand now. Okay, I don't see any hands raised in the attendees. So let's circle back to Peter Ameglio, if you got your audio working, go ahead and raise your hand. Okay. And you can try unmuting yourself. Unfortunately, I'm not hearing anything. Okay. Let's continue on to David Baker. David Baker, if you're an attendee please raise your hand, and Anton Jorgensen and Jose Valerio. Please raise your hand if you are available for public comment. Okay, then I think we can open up the floor. Josh, did you want to share the slide or we can just ask any other attendees who want to provide public comment. Please raise your hand either using star 9 if you're a call-in provider or raising your hand using the browser.

Josh Morse: Dr. Rege has pointed out if Dr. Ameglio would like to email comments to us now, you can do that. You can email those to me josh.morse@hca.wa.gov and I will share those with the committee if you're having some technical challenges.

Melanie Golob: Okay. I don't know if you want to give one more chance for public comment, but I think that's everyone.

Josh Morse: Great. Thank you, Melanie.

Melanie Golob: Thank you.

Josh Morse: So Shelia, I think we have completed the public comments.

Sheila Rege: All right, and miraculously that is right on time at 9:45. I am truly sorry. I did see at least one person having trouble and we apologize, and if you use the email that Josh mentioned, we can even try at some point read those comments if it's short. Thank you. We are due for a break, but I would like to see if anybody has more questions for Emily, and I don't think Randy is on at this time. Yeah, Randy's on.

Any questions while we have Randy? Because I know his clinic schedule is busy. If not, then we will go for a break until 10 minutes.

Conor Kleweno: [indistinct] I have--

Sheila Rege: Go ahead.

Conor Kleweno: I have one question, but I think it'll be more relevant at the end when we discuss, but it was on your last slide. The term disruption was in the first categorization of non-coverage, and I think that may just a term we should clarify if we revise the coverage recommendation from our end. Just the term disruption was a little bit vague to me, and I just think we should consider that in our discussions at the end.

Sheila Rege: Thank you. So break until 9:55. Please leave the zoom call on so we stay as panelists, and we'll see you in a few minutes. Bye.

[break]

Sheila Rege: Welcome back. Josh, do we need confirmation that we have a quorum, or can we go ahead with the presentation?

Josh Morse: No. We have a quorum. Oh, as far as having returned from the-- good question.

Sheila Rege: Why don't we all type in HERE or I'm back from break.

Josh Morse: We're good to go, I think.

Sheila Rege: Okay. Leila, thank you very much. We look forward to hearing your presentation.

Leila Kahwati: Okay. Can you all see the full slides? Yeah?

Woman: Yeah.

Man: Yes.

Leila Kahwati: Okay. Well, I just want to start out that a lot of what I'm going to cover has already been touched upon, so I'm going to maybe skip over some slides or touch on them briefly to avoid some redundancy. But I'm happy to be here today to present on behalf of the RTI-UNC Evidence-Based Practice Team, which you see listed on the slide. On this slide is a brief overview of the evidence presentation and, as Emily mentioned, this is an update to the 2018 Health Technology Assessment that we also conducted for this topic that informed the January 2019 coverage decision. Before I start, as you've probably already heard from the discussion that has occurred, this particular topic has many stakeholders with very strong opinions. For example, whether chronic SI joint pain dysfunction is a real thing, whether industry-sponsored studies pose so much inherent risk of bias that they should be used, whether existing frameworks for conducting evidence syntheses, specifically risk of bias assessments and grades are inherently flawed, and/or disagreements with how they were applied. What I want to convey to you all is that as the state's independent contractor for conducting these evidence reviews, it's our team's job

to synthesize that evidence through an independent lens using existing standards for evidence synthesis and to convey what that evidence demonstrates and what its limitations are to help you for consideration in making your evidence informed coverage decision. So Emily's already kind of described a bit of the background, so I'm going to go through these first slides pretty quickly. As you've already heard, chronic SI joint pain is believed to originate from either one or both surfaces of the SI joint, but the entire SI joint complex including the capsule, the ligaments, subchondral bone contain pain receptors, and the pain is often thought to be caused degenerative sacroiliitis from that repeated axial loading and rotation. The clinical presentation of pain varies, but a typical pattern is pain over the SI joint proper and down into the buttock that extends into the posterolateral thigh. As Emily also mentioned, prevalence estimates are limited by the lack of a rigorous case definition, but it's thought to be the primary source of pain in between 10% and 38% of patients who present with mechanical low back pain. Chronic SI joint pain or dysfunction is a clinical diagnosis and has already been discussed at length. It is challenging. There is no single pathognomonic imaging finding that definitively points to the SI joint pain as the source of pain, and how the diagnosis is made in clinical practice varies. So a number of people have already alluded to the guidelines and expert recommendations for diagnosis, which includes a combination of appropriate history confirmed by several physical provocative physical exam findings, imaging to rule out alternative diagnoses, and with an appropriate history and physical exam and alternative diagnoses ruled out, then proceeding on to a diagnostic SI joint injection with anesthetic to see if the pain is relieved after injection. And this appears to be universally used for enrolling participants in prospective research studies, and I'll say a little bit more about the injection on this next slide. So it's the current reference standard for diagnosis. And you'll notice I'm not calling it a gold standard because, as you've already heard, it's an imperfect standard. The injection itself, it should be under imaging guidance to ensure intraarticular placement of a sufficient volume of anesthetic either with or without steroid, and to monitor for extravasation from the joint. However, studies that have used diagnostic joint injection to estimate the prevalence of SI joint pain have actually varied in the volume of injectate that is used, which could influence, again, those prevalence estimates. Also, as mentioned, we didn't identify any studies that provide data from placebo-controlled injections to quantify the magnitude of any possible placebo effect of the injection itself. The amount of pain reduction required for a "positive" diagnostic injection test, you've also heard a little bit about that, and in the studies that we've evaluated, that threshold varied anywhere from requiring 50% pain relief to requiring 80% pain relief. And some people find that this lack of single therapeutic threshold in the literature problematic, suggesting fuzziness in the diagnosis. However, there are several ways to look at that. Several studies using lower thresholds for pain relief actually only report slightly higher prevalence rates than studies that use higher, more stringent thresholds, suggesting that differences in threshold probably above some certain level, whether that's 40% or 50%, probably have only small clinical significance.

And then the other aspect to that which, again, Emily also mentioned, was that in a pooled analysis of more than 320 subjects from the two trials of SI joint fusion with iFuse where people were diagnosed by a combination of history, physical exam, and confirmatory blocks. Both those studies used a 50% pain reduction threshold. The improvements in SI joint pain and disability scores after fusion were independent of the degree of improvement in pain relief beyond that 50% threshold, meaning that using a very high threshold for pain relief to define the condition actually might misclassify some patients who would benefit from the intervention. So it may be that, yes, achieving a certain threshold of relief matters for ensuring appropriate diagnosis, but it's not clear that a direct linear relationship between degree of pain relief and degree of improvement post-surgery can really be expected or anticipated. And then lastly, as some of you saw in some of the payor coverage policies requiring a repeat confirmatory block can reduce the prevalence of the diagnosis and reduce the false positive rate of a single injection. So this slide kind of summarizes the bottom line from our perspective of the evidence review in terms of the diagnosis, making the diagnoses complicated. Current approaches to diagnoses do have limitations and may not be an ideal standard. However, we didn't identify any studies or commentaries to suggest that the current guidance related to diagnosis is absolutely fatally flawed. Okay, moving on briefly so that you can understand about the comparator treatments for SI joint pain. Nonsurgical options include things like medications, analgesics, anti-inflammatories, physical therapy, and some of the other things listed here on the slide. For example, pelvic belts were mentioned earlier. Surgical fusion for SI joint pain is an intervention of last resort. It can be done via an open procedure, but that's rarely used anymore for chronic SI joint pain, and it's reserved for those cases of acute fracture, trauma, infections, tumor. More commonly now are the minimally invasive procedures performed under imaging guidance. Numerous proprietary surgical systems and devices for SI joint fusion exist. Most are designed for minimally invasive procedures. These systems typically consist of two to three either specialized implants or specialized screws that are deployed under imaging to span the joint for immediate fixation, and they often have specialized designs or coatings to promote bone growth onto and into the implant to achieve fusion. An example of this type is shown up here at the top. This is the iFuse that you've already heard a bit about. It uses triangular shapes, titanium implants, which you can kind of make out here on the figure on the right here. And as you'll see further on the preponderance of evidence that we have in this evidence review is for this device. In terms of surgical approaches used by these devices, it varies by the device. Often, it's either the lateral transiliac approach or a posterior dorsal approach. Outcomes by approach may vary as I think it was alluded to that this is still sort of an early phase of development in these devices, and so the approach used may be very specific to the device used.

Man: I'm sorry to interrupt, but two slides ago you mentioned something about the diagnosis not being fatally flawed.

- Leila Kahwati: Yes.
- Man: And did you look into the current diagnostic criteria? Was that valid? Do you do any type of evaluation in terms of the current criteria for a diagnosis with, I think, about three physical findings and some quantitative pain relief or, I should say, subjective pain relief from joint injections from an SI joint to alleviate pain.
- Leila Kahwati: Yes.
- Man: Have you, in terms of your report, is that a good diagnostic criteria? Is that valid?
- Leila Kahwati: So, yeah. What I can tell you is those were the criteria used in the trials.
- Man: Okay. Okay.
- Leila Kahwati: So the trials that we're going to talk about used those criteria and so, in fact, probably the coverage criteria that were developed probably evolved from their use in the trials more so than the other way around, if you see what I'm saying. So the coverage criteria that CPGs, the clinical practice guidelines, and they payors have articulated are largely based on what was used in the trials.
- Man: Okay. Good. And the reason why I'm bringing this up is because I'm struck by Dr. Transue's initial presentation about the inter-observer variability, and how does that even fit into all of this?
- Leila Kahwati: I think, if I'm not mistaken, I think those were referring to the physical exam findings. Emily, maybe you-- is that right, Emily? I don't know if you're still on.
- Man: That's fine. I just wanted to-- I'm just trying to process all of this right.
- Leila Kahwati: Yeah. Yeah.
- Man 2: Does the physical exam findings have very, very low [indistinct] rate of reliability?
- Leila Kahwati: Yeah, and that's why I think this is a clinical diagnosis, right, where you're accumulating the history, the physical exam, the diagnostic joint injection, ruling out other alternative pathologies with imaging, and to come to a clinical diagnosis. Yep. Okay. The last I just wanted to say about the--
- Sheila Rege: We do have Conor who has a question. Sorry.
- Leila Kahwati: Yep.
- Conor Kleweno: One physical exam comment/question. These are physical exam maneuvers, but the "answer" is the patient saying they have pain. Not like they're auscultating, we as clinicians are auscultating and finding something different to our ears, or we're not palpating and feeling a lump, or manipulating and feeling a difference in range of motion or distraction across something. All of these physical exam findings are we do something to the limb or the body, and the patient says, "yes, I have pain" or "no, I don't have pain." So just to clarify they are physical exams, but they're not based on any sort of clinician/user interpretation. It's the patient saying, "yes, I have pain," and that may be some of the reliability concerns, maybe.

Man 2: Thank you. That sounds like the typical provocative maneuvers we do during examination.

Leila Kahwati: Yes. Yep, exactly. Yeah, they're often referred to in the literature as provocative physical exam maneuvers. Okay. The last thing I wanted to say about these SI joint devices is that some of them use decortication of the bones with placement of a bone graft, followed by or concurrent with to immediate fixation where the screws are implants to achieve what someone would refer to as a true fusion and that's, for example, the SImmetry system shown here on the bottom is an example of combining that immediate fixation with decortication and bone graft. So we, for this update, identified 34 products currently marketed in the US specifically for SI joint fusion. So 17 of those have FDA 510(k) clearance. The full list of all those devices is in the full report. As Emily mentioned, 510(k) clearance is based on evidence that the device is substantially equivalent to something that's already on the market or approved by the FDA or that was marketed before 1976. Eight products are structural bone allografts or implants and their biologic tissues, so they fall under requirements to be approved via Title 21 CFR. And there are nine devices that actually have both 510(k) clearance and Title 21 CFR approval because they are designed to be used again with demineralized bone matrix allograft, so they need both types of approvals. So none of the devices or implants on the market were required to be approved through the FDAs premarket approval process, which is the more rigorous pathway for demonstrating safety and effectiveness of medical devices. Also related to this is that these products have been commercially available, which makes it somewhat challenging to study them in the most rigorous way or it disincentivizes their study in a really rigorous controlled way, because recruiting surgeons, recruiting patients to participate in a study where they potentially might be randomized to sham or placebo can be challenging. So I just want to put that out there for information. A very quick tour through the methods. We use typical systematic review methods for this review. This is the analytic framework which covered three main key questions related to effectiveness, safety, and cost. We also had a couple subkey questions specifically for comparative effectiveness sort of between two alternative procedures, and so all the details are related to the framework or in the full report. For this update, we did pull forward all of the studies that were previously included in that 2018 review, and we updated our search to cover through January 31, 2021 and with surveillance for new primary studies through the end of May. To address, I think, Mika's comment earlier about if these studies were done in 2013, why don't we have longer outcomes than two years? Part of that is just the publication lag between when study's finish, when they get written up, when they get submitted and accepted. And the five-year study that Lois mentioned by Dr. Polly, that is only eligible for this review for the safety outcomes, because it's not a controlled comparison. So the lowest study that he mentioned is in the evidence review for safety outcomes, but it doesn't contribute to comparative controlled efficacy outcomes. The table here at the bottom of the slide just summarizes our study selection criteria, which I'm not going to describe in detail again. Just to remind

you the way this review was scoped was, again, we only allowed controlled studies for the research question on efficacy so that we could have the highest confidence in those findings, where as we allowed uncontrolled studies for the research question on safety, which is typically when we want to cast to a broader net to make sure we're not missing any important safety signals. A few words about risk of bias assessments. We conducted those on all included studies. We used different risk assessment tools depending on the study design, as shown here, and all studies were assessed as having either a high risk of bias, some concerns for bias, or a low risk of bias. The domains that we assess during risk of bias are included in the blue box, and I do want to clarify something Emily mentioned, that we do assess whether the outcome assessments were blinded to the group allocations, so that is part of our standard risk of bias assessment. Two things that I will point out that is not here, one is sample size. Sample size we consider as part of a precision estimate and grade and then study funding, and I'll say a little more about that in a minute. So risk of bias assessments apply at the study level, unless we determine that different outcomes within the same study require different ratings. For example, studies reporting shorter term outcomes versus longer term outcomes where you have crossovers, and you'll see that. The longer term outcomes may be assessed as having a different risk of bias than the shorter term outcomes. Secondly, I want to note that risk of bias is on a continuum. It's not really a binary concept where it's either high or nothing. Current method emphasizes evaluating not just whether any factors contributing to risk of bias are present but rather whether that risk of bias could substantively influence how you might interpret that outcome. And lastly, there is no currently internationally recognized risk of bias assessment instrument that considers study sponsorship or source of funding as a consideration for evaluating the method of logic risk of bias. So as you all know, drug and medical device studies are frequently sponsored by industry or they involve industry employees in the design, execution, and reporting, and people do often raise concerns about the risk of bias from some studies. We suggest using terms to describe those kinds of concerns as potential conflicts of interest rather than risk of bias, which we tend to reserve for describing methodologic issues related to the study design or the study execution which, frankly, can be fatally flawed in a study, whether it's industry sponsored or not. There is some evidence that across health research that industry-sponsored studies do report more favorable outcomes compared to studies that don't have competing financial interests, and these findings do appear to be independent of the methodologic risk of bias or study design. So it is important, absolutely, to note where potential conflicts of interest may be and, as we do with all the reviews, we've included all of the information that is reported in the studies about study sponsorship in the full report, and we've also included them on the slides for the presentation so that there is full transparency around the issue of study sponsorship. Lastly, I know some of the members are new, but it sounds like all of you have very deep evidence-based methodology backgrounds. So, hopefully, this is not a new concept for you, but we do generate certainty of evidence ratings

using the grade approach. And as a reminder, grade is applied to a body of evidence, meaning one or more studies relevant to a specific comparison and a specific outcome and we assess the five domains that you see here listed in the top left. Risk of bias, you'll note, is what we were just discussing. It's only one of the domains that contribute to the overall assessment of certainty. We also assess the consistency of findings across studies, the directness of the measure used, the precision of the estimates which, again, relates to the sample size and adequate statistical power, and then publication bias. Our assessment of those domains leads to a rating of very low, low, moderate, or high certainty, as shown at the bottom left of the slide. And I've included a slide at the back of the deck that provides some guidance for interpreting these certainty ratings. So a study could be rated as very low for risk of bias, but it also might be rated as very low for inconsistency or imprecise. So the certainty ratings do not directly correlate to risk of bias. That's important to keep in mind. And then just as a reminder, for bodies of evidence comprised of RCT studies, we start with a default of a high-grade rating, high certainty rating, and then we downgrade that rating to moderate, low, or very low based on the five domain considerations here at the left. And then bodies of evidence that are observational start with a low rating based on their study design and then can get downgraded further and, in some cases they might also get upgraded. That rarely happens. So before we move onto the results, I want to pause here to see if there are any questions or people need clarifications about the background or the methods before we dig into the actual results.

Mika Sinanan: Mika Sinanan. A quick question about one of your earlier comments. Do we, from the studies that you've looked at, know what proportion of patients who present with low back pain that is attributed to this actually respond to the nonoperative treatments? What proportion actually come through and eventually get the injections and the physical tests in preparation for possible surgery?

Leila Kahwati: I don't know that we have that information from the studies that were included. What we do have is either the comparison groups in the two trials, the Insight and iMEA trial, we sort of know what happens to them after six months of follow up, because we are comparing their pain outcomes and their disability outcomes to the group that got surgery. So we can see what happens after that six months of follow up, but I think one of the challenges is that people come to study enrollment with a different pre-enrollment history. So I think the average duration of pain in the two trials was somewhere around three to seven years, but what we don't really know or have detailed data about is how many of those people exhausted every single nonsurgical option that was out there versus how many have maybe only been dealing with this for maybe six months and haven't had years and years of nonsurgical therapy. That we don't have from these studies. Does that answer your question?

Mika Sinanan: Thanks.

Leila Kahwati: Anything else before we move on? Okay. Hearing none. So quickly, this is a summary of just how we got to the included studies. We screened 233 titles and

abstracts, 50 full text articles. There were 43 studies from 50 publications included in the previous review. We identified 14 new studies represented by 17 articles in the update search, so for a total of 57 studies represented by 67 articles in the current version of the report you're seeing now. The breakdown of included studies by key question is also shown on this slide. So for the effectiveness key question, we have two RCTs, which you've already heard about, Insight and iMEA, and then there are seven controlled cohort studies. For the safety question, the same two RCTs and controlled cohort studies plus there are 43 uncontrolled studies that contribute to the safety question, and then there are five studies contributing to the costs question. So to orient you a little bit to the result section, let me describe the three comparisons that I'm going to be presenting so that you can more easily map to your decision tool that you'll be using to guide your coverage, your deliberations, and your coverage decisions. So first I'm going to be presenting slides that evaluate SI joint fusion. We'll start with minimally invasive compared to conservative management. These slides are all going to be color-coded blue, and I'll present the effectiveness outcomes like pain, physical functioning, and then safety, things that adverse events and revision surgeries and then cost, and then I'm going to briefly touch on the open fusion surgery compared to no surgery. Since that's a really less relevant comparison for your decision making, I'm not going to spend a lot of time on that, but all the details are in the full report. Then next, I'll briefly describe the comparison between minimally invasive joint fusion and open fusion, and there is only effectiveness and safety outcomes for that. There's no cost for that. And, again, I will focus on high-level findings since that's less relevant. And then lastly, in the yellow color-coded slides, I'll be presenting the two studies that compared two alternative procedures for minimal invasive surgery and, again, these slides will be gold-yellowish color. So let's start out with the minimally invasive surgery compared to conservative management. So there are three studies for this comparison.

Larry Birger: I have a question.

Leila Kahwati: Yes, go ahead.

Larry Birger: Apparently you didn't see my hand evidently.

Leila Kahwati: Oh, no. Sorry. I've got two screens going, so it's hard. So just verbally interrupt me, because I can't watch the chat and watch the hands at the same time.

Larry Birger: Sure. No, that's fine. Do they address-- the idea of conservative management, at least when it comes to cognitive and behavioral type things or manual therapy is a different kind, that is by no means a monolithic or uniform modality, and it may fall under a broad Rubrik, but I think any of us who have any amount of clinical experience would see that one physical therapist can accomplish something that three other haven't. One chiropractor works magic and five others haven't. One physician gets through to somebody with something when others haven't. I've had that experience a lot in my own practice, and so I always step back when I see conservative management and that kind of term listed as a comparator, because

that is really heterogeneous on multiple levels. And I'm just wondering if in this case that has been recognized.

Leila Kahwati: Yeah. When I describe this slide, I'll talk a little bit about what the conservative management group got, and then perhaps if there are further questions, you can ask at that point. Would that be okay?

Larry Birger: Sorry. I muted it. Sure.

Leila Kahwati: Okay. So there are three studies that compare SI joint fusion to conservative management. Two of them are the trials in the first two rows here, the Insight trial and the iMEA trial. Insight was the US trial. iMEA is the European trial. They were conducted over roughly the same time frames, 2013 to 2014 to 2015. The numbers in each study are located in this last column. The surgical intervention was the same in both trials, but the comparator groups did differ somewhat. So these were not trials that just compared surgery to usual care, meaning people got whatever their doctor felt like giving them. There was a standardized protocol for the conservative management groups in both studies. Insight use a step-wise approach that was outlined by the study protocol, but that was directed by the site investigator, which included physical therapy, which nearly all the participants underwent, therapeutic joint injections, which about three-quarters of the participants received, and radiofrequency nerve ablation, which about 45% of the participants received. In the iMEA trial, conservative management consisted of optimization of medical therapy, individualized physical therapy focusing on mobilization and stability at least twice per week for up to eight weeks, and patient education. Individual cognitive behavioral therapy was also allowed, but it was not available to participants at all sites. So the way I would characterize conservative management for these two trials is not completely standardized, manualized, with fidelity checks and adherence checks and lots of extensive training to the people delivering the conservative management intervention, but it's also not like no standardization, people just got whatever their site investigators felt like doing. There was a menu of options that was available to the participants in those groups. So I would characterize it somewhere in between usual care and a really robust, well-standardized intervention. I think that was Larry who asked that question. Does that address your earlier question?

Larry Birger: At least to some degree, yeah.

Leilah Kahwati: Okay.

Larry Birger: Leilah, I have another. This is kind of similar but on the other end of this, but does your evaluation tools take into effect the limited sort of surgeon input. Let me explain that better. So you have 19 centers and 102 patients. And then at each center, if we there's only one surgeon, that means that max on average five procedures per surgeon. Obviously the range is going to be greater. So you have a trial with input of surgeons that maybe only have done one or two and then [indistinct] numbers are low any event rate is going to be substantial. So I just didn't know if that was in your notes.

- Leila Kahwati: Yeah. We did not pull out any numbers reported by site. And to be honest, I don't recall-- they certainly didn't report by individual site. What I can't recall is if there were some reporting by surgeon experience or clusters of sites, but in our report we did not tease things apart down to the site level.
- Larry Birger: And does that come into the quality measurement or evaluation of this?
- Leila Kahwati: It does not. Yeah. It's not part of the-- yeah.
- Larry Birger: Okay, thanks.
- Leila Kahwati: Yep. Okay, so the next thing I want to mention, because it is critical to understanding this evidence, is that both of the trials allowed crossovers for the people who are originally allocated to conservative management. They were allowed to crossover to surgery after six months of follow ups. So the first six months of the trial, people stayed in their groups, and this requirement to allow crossovers was reported by the study authors as a requirement of them getting their IRB approvals. And also I think in some of the public comments we received about the report, it was also mentioned that because these devices are commercially available, there were concerns over being able to recruit surgeons and patients to do this study if the device is already commercially available. So they made a decision to allow crossovers to not stifle their ability to recruit. So how this factors in is that we assess these studies as having some concerns for bias for outcomes up to the six-month mark, primarily because of the lack of treatment blinding and the lack of outcome assessment blinding. So from Insight, 89% of the participants crossed over, and for IMEA, 43% of the participants crossed over. Because of this high rate of crossovers, we considered all the outcomes after six months is high risk of bias. The studies did attempt to account for the crossover issue by using last observation carried forward method of [indistinct] or by reporting results as treated instead of as intention to treat. However, neither of those approaches is particularly robust for handling the issues of crossovers, and so that's why we rated those longer-term outcomes as high risk of bias.
- John Bramhall: Wait, sorry. Not to interrupt you too much. Are there any studies where the intervention, the minimally invasive intervention is carried out because the patient is in that study arm but they continue to receive what you might call conservative therapy at the same time? I'm sort of asking, once you get your screw placed are you done? Or are there other opportunities for people to get cognitive therapy and what have you?
- Leila Kahwati: Yeah, I believe I don't think there's any study driven provision of those kinds of services to patients, but certainly patients could have received those things through the normal course of postsurgical clinical care. And so I don't have it right in front of me, but it's certainly something I can look back to see if the studies describe doing. But I think there was a standard postop course of care, but whether people received continued long-term physical therapy or long-term CBT in the surgical group, I'm just not sure about it. I'd have to look back at that. All right. Real quick, because I don't think it merits quite that much attention, but there is a

third study here. It's a study by [indistinct] in this last row. It's a retrospective controlled cohort study conducted at a single center in Spain. It compared iFuse with two comparator groups. The first group was a conservative management group, which included smoking cessation, weight control, physical therapy for at least three months, nonsteroidal drugs, and therapeutic steroid joint injections. The other comparative group was radiofrequency nerve ablation. We assessed this study as high risk of bias, mainly because there was a high degree of participant [indistinct] and missing data but also concerns around confounding and selection bias related to the retrospective observational design. All right. So here's a little bit about the diagnostic criteria and the participants who were enrolled. So this is for really all three studies, but mostly I'm focusing here on the RCTs. The criteria in the cohort study was very similar. And I think to the earlier question, these criteria are pretty much the same as what's in all the guidelines and what experts recommend in current clinical practice. So they all required chronic symptoms, positive Fortin finger test, at least three provocative physical exam findings, 50% or greater reduction in pain after an SI joint block. In addition, the two trials required a baseline visual analog pain scores or the VAS score of more than 50 mm which, again, goes on a scale from 0 to 100 mm. So that's a score of at least 50 or higher, and has a Oswestry Disability Index (ODI) of greater than 30 points, and that scale goes from 0 to 100 with higher scores indicating greater impairment. The mean duration of pain in the enrolled samples were between three and seven years, and about a third of the participants in both trials and the cohort study did have a history of a prior lumbar fusion. And Emily mentioned this before, as well. I think there are several ways to think about this last characteristic about the number who have a lumbar fusion, from the studies we don't know the reason for the prior lumbar fusion or whether patients presenting for these trial entry had new onset low back pain since their lumbar fusion surgery or whether they had persistent pain despite their lumbar fusion surgery. So its hard to know what to exactly make of this data point. Some experts have suggested that a prior lumbar fusion alters the biomechanics of the SI joint pain, resulting in a faster degenerative process that then leads to pain. Others have suggested that subjects with low back pain that received lumbar fusion as a prior treatment may, in fact, have had SI joint pain all along and were misdiagnosed. Their SI joint was always the initial source of their pain and lumbar fusion doesn't fix that, and so they continued to have pain. So its kind of hard to really know what to make of this data point, but maybe there's a little bit of both things going on. And lastly, so the entry criteria, as I mentioned, was a baseline VAS of 50 or more. The actual mean VAS score in both groups on a scale of zero to 100 was actually 82. So these are people with a fairly high level of pain at study entry. Okay. This is a very busy slide, but it's basically a topline summary of the changes from the previous report to what is in the updated report, and these are the grade certainty ratings, and on the left is the prior report, and on the right is the updated report. So let me just walk you through the top line findings. So just to orient you a bit to the figures, the outcome domains are located along the left-sided vertical axes. Each shape that's on the grid indicates the body

of evidence for the outcome that we've depicted. The evidence from our CTs are located separately from the bodies of evidence from observational studies. A rectangle shape indicates outcomes at six months. A diamond indicates outcomes at one to two years. And then the oval indicates outcomes anywhere from six months to three and a half years. We had to have that because that controlled cohort study only reported outcomes over that very wide time span. And so when you see the oval, you can think of it as that's the controlled cohort study. Everything else is from the trials. The color of the shape represents the certainty of the evidence according to grades. The red is very low. Green is high. You don't see any green on these maps. And finally the location of the shape in these groups indicated down here along the x-axis indicate whether the outcome favors conservative management, whether it favors minimally invasive surgery, or whether there's no difference between the groups. However, the specific location within this larger group being along the x-axis doesn't indicate magnitude. So outcomes depicted further to the right are not any larger than outcomes depicted closer. It's just that we don't have a great way to depict magnitude because these are all different measures using different outcomes. So the last thing I'll say is that the updated evidence map does not reflect any new studies, but we do have new articles with new data. So what the evident updated map represents is this new additional data from new articles, but there are no new unique studies. So for effectiveness outcomes at six months, these are the shapes that you see up here in the original report. It's the yellow and the red ovals. For pain, function, and quality of life, we had before and we still have moderate certainty from the trials evidence that minimally invasive fusion is more effective that conservative management. We did adjust our evaluation of the opioid use outcome because the rationale for that was before we had it as low certainty for no difference between treatment groups, as you can see here that the orange rectangle over here, but the new additional data going out to two years and also additional data from a second study rather than just one study, one isolated time point six months, we were able to see a little bit more of the trajectory, and so our rating changed to very low for favoring surgery for opioid use. There was no new data from the controlled cohort studies, so all of those stayed the same. So what is new for effectiveness outcomes is now we have data out to one or two years, and that's the orange diamonds on the right hand graph. The results reported for these outcomes suggest a persistent benefit of surgery compared to conservative management. Although, as you can see, our certainty is reduced to low at these time points because of those study limitations I talked about earlier with issues with crossovers and how to interpret the longer-term outcomes. The safety part of the map, which is depicted on the lower part of the evidence map, we have added a new row at the bottom to reflect revision surgery. We didn't include it last time because it's an outcome that can only happen for people who initially had surgery. You can't have revision surgery if you didn't have surgery in the first place. But what we decided to do is show it here on the map as favoring conservative management because the incidences of revision surgery will always be zero for the conservative management group, and so it can

only be higher for people who initially received surgery. So we're electing to show that on the map in that way this time around. And then lastly, the only other change for adverse events we adjusted our strength of evidence rating to very low for favoring conservative management. So we used to have it over here in the no difference, and we've moved it over to favoring conservative management. And this was based on a couple things: updated data for the time points that we were provided in new study publications and a closer look at how these events were reported across the various publications. I don't know if I have mentioned this, but each of these trials actually have results reported in between three to four different publications and the data were not always consistent across those publications. So Emily alluded to the fact that we lost a little bit of confidence in the safety data, and it's because we had trouble making sense of inconsistencies in the numbers reported across the various publications. And then lastly to adverse events, the data at time points beyond six months that was presented by study authors was largely uninterpretable because study authors were not clear about whether those events were occurring in just the crossover patients or those who did not crossover or whether they were combining them. And so we had a lot of trouble making anything out of adverse event data beyond six months. Okay, that was I know a lot, so I'm going to-- maybe this would be a good time. I have slides that take a deeper dive into each of these outcome domains that follow this. And so Josh and I had talked about a choose your own adventure style presentation in terms of are there specific outcomes you would me to take a deeper dive into, or would you like me to just go through them all? I'm happy to do whatever would work best for the group.

Sheila Rege: We've looked at this. I would ask Conor or Randy. You've looked through these slides. What do you think would be best helpful for this committee?

Conor Kleweno: That's tough. I don't feel really strongly one way or the other. I feel like clinically that the pain and function ones are what are often highlighted in the visit, but I don't feel strongly on this which one we should be focusing on or not.

Sheila Rege: Janna?

Janna Friedly: Yeah. I was going to suggest the same. Pain and function clearly are to me most important, but also I do have some questions about the opioid use data and how that was measured and collected. Just knowing that its very different to collect this data and to analyze this data, and I had trouble assessing this out from the primary manuscripts, myself. So I would appreciate that.

Leila Kahwati: Sure.

Janna Friedly: And then, sorry, I'll just make one more comment that I struggled myself reconciling some of the data between the different publications. It wasn't huge differences but slight differences in all of the outcomes and even in their supplemental table that in the Insight study, in particular, in the 12-month paper. There was a supplemental table that provided data that conflicted with the table that was presented in the main study and particularly related to crossovers. And so

because we are looking, the 12-month data is really what has driven this change and I think is most important for us to think about the change between our last report and this one. I think it would be helpful for me if you have any insight into this.

Leila Kahwati: Yeah. I can say a bit more about that, yep.

Randy Chesnut: Hello? Can you hear me? Sorry, I was having trouble with my mic. Hello?

Leila Kahwati: Yes.

Randy Chesnut: Yes. Okay, good. The outcomes in which I am rather suspicious about VAS and ODI. ODI is really a lumbar outcome study index with questionable validity outside the lumbar spine. I mean it has been looked at not convincingly [indistinct] standardized against non-lumbar spine pain. And the VAS is entirely subjective. Hopefully, it would be backed up by decreased opioid use. So I would much prefer some discussion of the more objective measures such as opioid use, return to work, or which doesn't exist, I'm afraid, evidence of fusion.

Leila Kahwati: All right. Well, sorry. Is there one more comment?

Larry Birger: Yeah, if I could just piggyback on that. You know the report of pain, as I think Conor pointed out earlier, really takes it out of the objective. The experience of pain versus noxious stimuli that would normally cause pain are so disparate, and so I just want to echo the idea that if we're looking at outcomes in something like this, it seems to me it should be focusing on something that-- I'm not saying that reported pain is irrelevant. I think it's in one sense maybe more relevant, but I think it also highlights the complexity of it. But to me, when you cross a threshold where you're good enough to go back out and function-- and this added to the other thing-- especially work. I find that considerably more reliable, I think, in trying to wade through these sort of outcomes measures, so.

Leila Kahwati: All right. Well, what I'm hearing is we should spend some time going through the pain and function and opioid use outcome. So that's where I sort of prioritized the next part of the presentation. And then the rest of the presentation, I think will go more quickly because it's either stuff you've already been presented with or it's the less relevant comparison. So with that, let me just orient you to how all of the results slides are organized. Again, the comparison here is iFuse to conservative management. That's at the top. Each outcome that we graded is presented in a box. The specific outcome is listed right above the box. So in this cases it's change and pain at six months as measured by the visual analog scale. The scale goes from zero to 100, and the minimally important difference is about 7 to 11 mm. On the left side of the box is the number and type of studies comprising the body of evidence that we graded, for which for this outcome is the two RCTs. Below this is our assessment of the certainty of evidence using grade, which in this case is moderate, and the direction of effect in this case favoring fusion. This means that participants who were allocated to fusion had greater improvements in pain at six months compared to participants allocated to conservative management. And then

the right side of the box provides you a sense of the degree of difference. So in one study, I believe we have Insight listed first here and iMEA as the second one. The difference between the groups is about 40 mm in one study, about 38 mm in the other study, and these are both statistically significant differences. And if you recall, remember I told you the baseline visual analog score at baseline was 82 in Insight. It was 75 in iMEA. So these are fairly large differences in reductions between the two groups. Again, this is at six months. Yes.

Chris Hearne: Just want to clarify that the one thing that's missing from this graphic is that this finding has a high risk of bias, right? Or serious risk of bias?

Leila Kahwati: So this finding has some concerns for bias. The long-term outcomes is what we label this high risk of bias. So the certainty ratings for grade take into account risk of bias, so it's at a moderate. It would, otherwise, be at a high, except that we had concerns for risk of bias. So that is what downgraded it from high certainty to moderate certainty.

Chris Hearne: Okay. Thank you.

Leila Kahwati: Yep. In addition to the absolute change in pain on the VAS, the study authors also reported what we call threshold improvement. So this is the proportion of subjects who reported at least a 20 mm improvement in pain, which is about double the minimally important difference. So 82% versus 27% in the Insight trial. The first number is the surgery group. The second number is the conservative management group and then 79% of people getting surgery. And iMEA had a threshold improvement of at least 20 mm versus 22% in the conservative management. So to somebody's earlier question about what happens to the people who don't get surgery, some of them improve. Nearly a quarter of them will improve just from conservative management, but more of them improve with the surgery intervention. Okay. Now, here we go into the longer-term outcomes. And so this is change in pain at one year. Again, with the visual analog scale, you can see the difference between groups is a little bit less than what you saw at six months, 32.6 mm in the Insight trial, and this is compared to the conservative management participants who did not cross over. When you look at people who got surgery versus the people who crossover surgery, there's no significant difference in their change in pain. But when you compare surgery people to people who did not cross over, you see that that difference that was observed at six months persists. And then in the other trial, which handled crossovers by imputing the last observation that was measured prior to the person crossing over, the last observation carried forward method, you see, again, a persistent significant difference between groups favoring surgery. We considered the outcomes at one year to be high risk of bias, so that is reflective in the low certainty level. So for six month outcomes we had moderate certainty. We've downgraded our certainty in these findings to low, primarily because we've rated these outcomes as high risk of bias, and so our certainty decreases as a result of that. Both studies reported threshold improvement. Now, this is at two years. So, again, this is at least a 20 mm improvement. And you can see in the first study, which is Insight, 83% of subjects

at two years had a 20 mm improvement versus 10% in the conservative management group. For this particular study, they treated the crossovers as failures, so they basically were considered a very conservative estimate. They considered anyone who crossed over as not having improved. And then in the iMEA study where they used less observation carried forward, the difference was 79% versus 24%. So these are these longer-term outcomes definitely have higher risk of bias, lower our certainty, but they do show evidence that the changes that were observed at six months do persist over the one to two year time frame for pain. Thirty seconds on the controlled cohort study essentially similar finding to the trials though larger in magnitude, so the difference between conservative management and surgery was 60 mm. So that's much larger than what was observed in trials. And same difference when comparing to the control group that got radiofrequency denervation. As you have heard, this is very low certainty evidence because of the design because of high risk of bias. So the way I would think about the controlled cohort studies, is it confirming or does it mirror what you're seeing in the trials? If so, I wouldn't pay too much attention to it. The only time, I think, to pay attention to it is when it's telling a different story than what you're seeing in the trials. So if you have limited bandwidth to try to keep track of all these things, I would not worry too much about trying to track on the controlled cohort study. Okay. Moving into physical function now. The same two trials, Insight and iMEA reported on changes in physical function using the Oswestry Disability Index, which goes from zero to 100. I think some comments were already made about the appropriateness of it for this particular condition. A minimally important difference on this scale is somewhere between 8 and 11. As you can see, this is again at six months. People who got surgery had a significantly larger improvement compared to conservative management. So 25.4 points on this scale in the Insight study compared to 19.8 in the iMEA study. Both of these were statistically significant. We rated this evidence as, again, moderate certainty. This is not new. This is from the last report, so nothing really changed with respect to these outcomes. But now here we get into the outcomes at one and two years. So in one study, the improvements were sustained at one year, so the difference between groups is 20.1 points. However, in the second study, there was no significant difference between groups both when comparing participants who crossed over to those who got surgery and for the participants who didn't cross over. So in addition to downgrading the certainty of evidence because of risk of bias concerns, we also downgraded it for any inconsistency. Because one study is showing persistence of a benefit and the other is not, and so that's how we get to very low certainty around this particular outcome, because the findings are a little bit mixed. However, when we go and look at threshold improvement at two years, again, measured based on at least a 15-point improvement on the ODI, we end up back at low certainty for favoring fusion. In both trials, a significantly larger proportion of participants who received surgery achieved the threshold improvement. So it's 64% versus 24% in one study and 68% versus 8% in the other study. So given that physical function was more improved at six months and was

more improved with surgery at two years in both studies, it's really hard to know what to make of the findings at one year. It may just be a fluke, but the trajectory seems, if you look across the accumulated evidence, that there is a benefit and that it does persist out to two years for function. Thirty seconds on the controlled cohort study. It basically tracks with the trial evidence. There's an improvement of about 24 points when compared to one comparator group and about 17 points when compared to the other. Again, the certainty of this is very low for all the reasons I have said before. Okay, I'm going to quality of life. I'll say in two words, it basically tracks with pain and physical function, so it's very consistent. It's improved with surgery compared to conservative management, but their details are there if you'd like them. Let's move on to opioid use. So I'm glad to hear-- I don't know, I think it was Janna, who mentioned trouble figuring this out with looking at the primary source articles, and we had the same issues trying to sort out what was reported, how to interpret it. And so that's part of our consideration for how we ended up at very low certainty is just the challenges with how the data was collected and reported and then making it difficult to interpret. So in terms of opioid use, only Insight reported this data at six months. The percentage of participants using opioids decreased by 9%. The absolute incidents decreased by 9% among the patients who got surgery, and it increased by 8% among the conservative management patients. But this difference was not quite statistically significant, so it's not precise enough to say, yes, there's a difference, which is how we ended up at very low certainty that it probably does favor surgery. The data for longer-term follow up is even messier because of both crossover issues. Both trials did report this at either one or two years. In Insight, the proportion of participants using opioids continued to decrease. So by one year, it was 1.6 points lower than the baseline and 20.3 points lower by two years. In the conservative management group, use initially decreased by 8% at one year, but it's unclear which participants were included in that analysis with respect to crossover status, so we don't know if those are people who got surgery or the people who didn't get surgery or if it was being reported for both. In the iMEA trial, which is the second bullet here, which used less observation carried forward approach for outcomes after six months to account for crossovers. Use decreased by 23.1% from baseline in the surgical group but only decreased by 1.4% in the conservative management group. And so we ended up calculating a relative risk for this assessment, which is 0.75, again, suggesting decreased use in the surgery group. But you can also see this was also not statistically significant. So the bottom line is the studies weren't really powered for measuring opioid use. The estimates are imprecise, but the direction and magnitude seems to suggest a benefit, but we can't really call it anything other than very low certainty because of the limitations in the data. And then the controlled cohort study reported in a completely different way. They reported mean daily morphine equivalent doses per day compared at just a single point in follow up at the point of last follow up, and it was 3.1 mg per day in the fusion group versus much higher doses in the conservative management group in the denervation group. There was a significant difference between the three groups

and they didn't do any [indistinct] postop comparisons, but it's pretty obvious from the absent values that the differences between fusion and the other groups, so it tracks generally with the evidence from the trials. So let me pause there and see if there are any questions people have about the pain function or opioid use outcomes as it relates to how you might fill out your decision tool or if there's other random questions about this evidence.

Janna Friedly: I know we're running a little bit behind, so I don't want to take too much time but, again, I'm struggling with a couple of things. Again, going back to, and I've said this before, but there was a supplemental table that looked in the Insight trial that was only published online that broke the data up by crossed over and not crossed over at one, three, six, and 12-month outcomes that contradicts some of the findings here and, so I'm just having a hard time reconciling that in my mind. And then the opioid data here, to me it's so hard to decipher how they collected this data and how accurate it is, and there's no statistical significance between the two groups but, yet we sort of characterized it as favoring. So in my mind I'm struggling with those two issues, and we may be able to discuss it more later.

Leila Kahwati: Yeah. So I was going to mention this when we get to the safety section, but we did reach out to the authors of both iMEA and Insight and asked for clarification. We asked for quite detailed clarification of the discrepancies in the data. They did acknowledge our request but did not actually send us any updated data or clarified data. So we did attempt to try to shore up some of the inconsistencies but are basically left with just what's in the published reports to use. And then to your point about statistical significance, so when we say something is favoring or no difference, that is the global judgement based on grade. So whether something is statistically significant or not is one of the considerations, because that plays into precision, which is one of the domains we assess and grade. So the decision about whether something favors a direction or not is beyond just statistical significance. It's all of the domains together, and we assign very low certainty because if you interpret that, it means could future studies come along and change our conclusion? And, yes, it could, and that's what very low certainty means. It's like we don't have a lot of confidence in this interpretation. Future studies that study it may come to a different conclusion. So if that helps you think about how to interpret very low certainty, it's not that we are so sure that despite lack of physical significance, it's that based on the info we have and the limitations and what's there, this is what we think, but we don't have a super lot of confidence in that based on everything together. Okay, in the interest of time, I'm going to move ahead to make sure we get through adverse events. So this slide is adverse events reported at six months for both Insight and iMEA trials. I've laid out the data in a table to make it easier to compare and contrast across the two trials. As I mentioned earlier, each trial has between three and four publications associated with it, and the number of events reported across the publications is not consistent. I also want to clarify that the standard meaning of adverse event in sort of the modern era of clinical trials is something that untoward that happens to a

study of participants during the time they were enrolled or participating in the study, regardless of whether it might be considered related to the drug, procedure, device, or intervention. For example, someone comes down with the flu, ends up hospitalized during the time they're enrolled in this study. That should be captured as an adverse event, even though it's clearly not related to fusion surgery or physical therapy in the case of a conservative management group. In a randomized trial, those kinds of adverse events would be expected to occur at similar frequency in both study groups. So all cause adverse event reporting is really the least biased way of reporting adverse events, because it takes away the judgement about whether something might be related or not related, which often can be subject to investigative biases. So that what you're left with is any differences in all cause adverse events between study groups can be attributed to the study intervention. So I want to make sure that everyone understands that, because when you look at the total number of events reported, there's 129 events for 102 subjects in Insight. And you might think, "Gosh, that's really high," but keep in mind that's all cause adverse events. That's people falling and breaking their arm. That's people getting the flu. It's everything. It's not just the stuff that's particularly related to the surgery. So total events reported in the different groups is in the first column. The number of events related to the device or procedure is in the second column. The mean number of events per person is in the third column. The number of severe events is in the fourth column. And then number of severe events specifically related to the device is in the last column. And you can't do an apple to apple comparison because Insight had 102 people in its surgical group and 46 people in its conservative management group, and they report events, not people, so we can't actually calculate incidents. But a couple things to point out here is, one, the actual number of events that investigators judge to be related to the device or procedure is lower than the total number of events, and the number that are severe is also even lower than the number just related. So that's one thing to point out. And you can also see that the mean number of events is actually slightly lower in the surgery arm compared to the control arm. Again, it wasn't statistically significant, and this is in the IMEA trial, where as the reverse is true in the Insight trial, slightly higher in the surgical group but, again, no statistical differences. And then lastly, the absolute frequency of total events appear to be higher in the Insight trial compared to iMEA. This likely just reflects differences in how the trials ascertained adverse events, though there might be some differences in the control group because Insight, if you recall, included therapeutic injections and nerve ablation in their control group while the IMEA trial did not. But that doesn't really account for the differences observed in the adverse events between the surgical arms aside from the different number of participants. So the bottom line around adverse events is there's some uncertainty related to the robustness and rigor with which these trials collected this data, reported this data, inconsistencies in this data, and for all those reasons this is one of the shifts from the prior report is we've shifted to saying that this favors conservative management and that our certainty is very low, again, are largely related to the

discrepancies and the data across multiple publications. In terms of at two years, they both also reported outcomes at two years. However, Insight only reported severe events, and 55 events among 102 participants and only 5 were considered related to the device or procedure; 23 of those severe events were among the 46 conservative management participants who ended up crossing over. So we don't really know severe events in the people who did not cross over. In iMEA, there were 54 all cause events among 52 subjects; four were related to the device or procedure, 39 were considered severe, and then 47 events among the 51 conservative management participants. Again, that includes crossovers. Three were related to the device or procedures and 27 were considered severe. So because of the way that the authors present the data and we can't really separate out the crossovers from those who didn't crossover, we really could not determine a directionality for this because just the limitations and how the data was reported. The controlled cohort study did not report any serious events in either group, so there's not much we can say about that. Revision surgery is not an applicable outcome for conservative management participants. If you didn't have surgery in the first place you can't have revision surgery. So in our certainty of evidence rating, we classify the directionality of this outcome as always favoring conservative management because the incidents will always be zero in that group. So really what you're looking at here is the incidents of revision surgery in the surgical group. So in one study the incidences reported as 3.4% among the people initially allocated surgery and then among the people who ended up crossing over, some of them also ended up getting revision surgery and the incidents in that group was 2.6%, and then in the other study, the incidents was about 3.8% among the people originally allocated to surgery, and then it was about 4.8% among the people who crossed over. And these are data reported at two years out, so we don't have data from these trials, at least in these published trials beyond the two-year point. Now, some of that data might show up in the lowest study that Dr. Polly mentioned earlier in terms of comparative data, this we only have it out to two years, and there were no revision surgeries reported in the controlled cohort study. Okay. So circling back--

Mika Sinanan: So could I just ask you?

Leila Kahwati: Yes.

Mika Sinanan: Hi. Mika Sinanan. Could I quickly ask a question about the revision surgery question?

Leila Kahwati: Yes.

Mika Sinanan: Indications for revision surgery, and it may have been in the detailed papers which I didn't see, but of course a proportion of patients will have little or no reduction in their pain or will have a reduction of pain and then it will come back. So the indications for revision surgery are what?

Leila Kahwati: So what we saw in the papers listed sort of fall into two types, and maybe the surgeons on the call can also weigh in here. Early revision, those were generally revisions required because of implant malpositioning or radiculitis or irritation

soon noticed or complained about soon after surgery. And then late revisions, which we saw most often described as implant loosening or persistent pain combined with radiographic evidence of no fusion having happened. That is my recollection of some of the indications for revision surgery, and I'd be interested to know if Conor or Randy if that tracks with their clinical experience.

Conor Kleweno: Yeah, so some agreement there. So first one will be a malposition, so that's people who are placing these implants into the neuroforamen, and that needs to be revised. Second would be people who don't-- and I can't remember the granularity of this trial, I'd have to look back-- clinically, it's people who do not get better or have a transient improvement and then go back to pain and then switch over to a new company's implant. And then, obviously, third would be loosening, although I don't know how common that would be. The other one you mentioned-- what was the third thing you mentioned?

Leila Kahwati: Well, implant loosening.

Conor Kleweno: Lack of fusion.

Leila Kahwati: Yeah. Implant loosening, continued pain, and the lack of--

Conor Kleweno: The radiographic fusion thing, I think is a little bit questionable, because that's one of the criticisms. Can you truly demonstrate fusion radiographically without CT scan, follow ups, and weighing on some of these, and whether that's the true source of pain or not, so.

Leila Kahwati: Yep. Okay. So this is recapping the evidence maps. Since we already spent a lot of time on this, I'm not going to rehash it, but it's just here to remind you where we landed on effectiveness and safety, if it's helpful for when you go to fill out your decision tool. Very quickly on cost. There are five studies that report cost or cost effectiveness outcomes. All were sponsored by the manufacturer. Two studies were conducted by the same author group to Ackerman studies. These are comparative cost modeling studies of iFuse to nonoperative care. The one in the first row focused on a commercially-insured population. The mean age there is 45, and they model costs over three to five years. The second focus is on a Medicare population starting at age 70, modeling lifetime costs. And so that's why you'll see differences in the outcome. It's a different population model over a different time span. The study in the third row is new to this report. It was a cost effectiveness analysis comparing surgery to a stepped care intervention consisting of physical therapy, steroid joint injections, radiofrequency ablation, or they had a couple different comparison groups. All were variations of conservative therapy, and it looked at cost and effectiveness over a follow up time of five years. And then the last two studies, the first one is also new to this update. It was a retrospective analysis comparing actual SI joint fusion costs one year after surgery to low back pain costs before and after surgery among a commercially-insured population, and most patients were between age 45 and 64. And then lastly, the last study was a cost effectiveness analysis. It was included in the prior report comparing iFuse to nonoperative care. It used a follow up time of five years. So the bottom line on cost

is that we've evaluated the evidence of very low quality for cost over both three to five years in a commercially-insured population and lifetime costs over a lifetime for Medicare population. So in the commercially-insured population, surgery with iFuse costs roughly \$15,000 more over three years. That cost does decrease down to about 6,000 more compared to conservative management over five years. We don't have any data past five years, at least from this analysis. In contrast, lifetime costs, which was modeled over about 14 years based on life expectancy, actually shows that costs from iFuse were \$3,300 less than costs compared to nonoperative care. So it seems like costs, at least, the longer time frame that you look out the more favorable the balance maybe tips toward surgery over nonoperative care. But it's important to know not to just look at cost. We need to look at cost effectiveness. So we did use the two cost effectiveness studies. They were rated as very low certainty, and these studies authors estimated that the costs for quality adjust to life gain from minimally invasive surgery ranged from about \$2,700 to a little over \$13,000 over a five-year time horizon. So that is a somewhat wide range, but both of those estimates are within a range that would be considered cost effective by today's standards. So we did not end up grading the findings from the FIST study, because it only reported some before/after comparisons and actual costs related to low back pain, but all that data is in the full report if you would like it. So that's all of the cost data that's in this entire presentation. Everything else that I'm going to whiz by is really just effectiveness and safety. I'm only going to say about 30 seconds worth of information about open fusion compared to no surgery. It's the same as last time. It's no difference between open surgery compared to conservative management and, obviously, for revision surgery, conservative management would be favored. So I'm not going to spend anymore time on that, unless people have questions. Again, moving on to the comparison of minimally invasive surgery compared to open fusion. I'm not going to spend more than 30 seconds on this one, either, because this comparison is, again, less relevant. It's also the same as last time, so there is some evidence that pain and length of hospital stay are improved for minimally invasive surgery compared to open surgery. The evidence was sort of mixed and inconclusive about function and disability. Adverse events appeared to be no different, and the risk of revision surgery was also a mixed picture between the three studies that contributed to this evidence space. Again, this is a less relevant comparison, so we're not going to spend a lot of time on it. Lastly, the last comparison is comparing alternative minimally invasive procedures. This is the evidence map summarizing minimally invasive fusion with iFuse compared to the Rialto system. It's new compared to the 2018 report. As you can see, we evaluated all outcomes as very low certainty since they are based basically on one controlled cohort study. That study reported no differences in the four efficacy outcomes of pain, function, quality of life, length of hospital stay, and no differences in revision surgery. We didn't show this on this evidence map, but there is one old study that we did report last time comparing minimally invasive fusion with iFuse to percutaneous screw fixation. That study only reported a revision surgery outcome and showed the iFuse resulted in fewer

revision surgeries. The details are in the full report, and I think there's a slide on them if people have questions about that. On this slide, the two studies comparing. The first one is the one that compares iFuse to percutaneous fixation with screws, and then the second one is the new study comparing Rialto to iFuse. Both were single studies conducted at single US centers. Here are the findings for pain and function for comparing Rialto to iFuse. You can see there's really minimal differences between groups. Nothing was specifically significant, so we concluded with very low certainty no difference between the two. In terms of pain at six months to one year, again, really no significant differences between the groups and up to one year. And then same quality of life also tracks with pain and function. Length of stay, again, no significant difference; 1.7 days versus 1.8 days, and then revision surgery. So this is high, as Emily, I think mentioned, a higher absolute rate of revision surgery with Rialto 6.1% versus 2.4%, but those differences are not statistically significant, and the study is not powered based on revision surgery, so we end up here concluding no difference. And then revision surgery at two to four years for the study comparing iFuse to percutaneous screw fixation, much fewer revisions with iFuse compared to screws, 4.6% compared to 65.5%. This is not a new study. This was in the previous report. Okay. Next, I'm going to briefly summarize outcomes from the 43 uncontrolled studies. Most of these were conducted retrospectively using data from the medical record. A few were conducted prospectively. We don't grade evidence from these studies because they're not comparative by nature, but I will just point out a couple things. This slide summarizes the 43 studies. The first row summarizes the 11 open fusion studies. The next row summarizes there's 20 studies for iFuse, so the largest number of uncontrolled studies for minimally invasive surgery is with the iFuse device. Most of the other devices are only evaluated in anywhere from one to three studies. This last study, I just want to mention, is based on claims data, so participants were identified through the CPT code indicating minimally invasive surgery. It's not really entirely clear which device they received, because that's not part of the claims that is reported in the study. Huge caveats around the use of the safety data from uncontrolled studies. It's very heterogeneous in terms of how studies ascertain these outcomes they're reporting. Most of these studies had a high risk of bias. It's particularly a problem with the studies that were conducted retrospectively. They often only enroll patients into the study if a full complete year follow up date was available, so it's huge selection bias. And these studies are typically not being conducted according to a protocol, so it's not really clear the method for the safety outcomes reported. A lot of times they are probably relying on just whatever clinician's documented in the medical record. And so I'll give you one example of maybe a better quality study within this slot, and that's a study based on insurance claims. This is from 2007 to 2014 claims from 469 beneficiaries who had minimally invasive surgery. The incidents of any claims for complications attributed to the device or procedure was about 13.2% at 90 days and 16.4% at six months. The most common complication that there was a claim submitted for was neuritis or radiculitis. And estimates are, as you can see, higher than what was

observed in the two RCTs, so this probably reflects actual use in practice, although, the dates here are sort of old now. Whether those numbers would still be the same if you were to repeat this study in the last two to three years, it's not really clear. This 2007 to 2014 is a very early phase of this intervention, so it might be different if you were to repeat it. A couple notes about the 20 studies that evaluated iFuse. The incidents of adverse events ranged from zero to 92%, and that is the great example of differences in how studies ascertain and report it. A range that wide makes no sense, right? So it is really limited. The data is very limited about what we can say is what the true estimate of adverse events are. Incidents of serious adverse events were zero to 46%, and the incidents of device or procedure-related events range from zero to 30%. There were a couple studies based on post-market surveillance databases that are maintained by the manufacturer, and in those they reported the incidents of revision surgery to range from zero to 8%. The most recent of that data is I think what Emily quoted, and that was a study with about 14,000 participants who got surgery between 2015 and 2018. The incidents overall was about 3.1%, and the year annual yearly cumulative incidences is about 1% to 1.5%. And so that's probably the most current estimate of revision surgery, and that tracks pretty well to what we saw in the trials. All right. I'm going to pause here. Most of the rest of the slides I think have already been presented by Emily in terms of payor coverage, clinical practice guidelines, in terms of some of the limitations. I think Emily's already mentioned that there is a sham-controlled study in the works, and it does not appear to have any manufacturer sponsorship. So it appears to actually be a true independent study, but that won't be available until 2023. I think Emily has covered guidelines, payor coverage I think Emily has also covered. I do want to just make a point of reminding you that some of the payors have device-specific coverage, right?. They only cover iFuse, whereas others cover the procedure and are agnostic to device, and that is something maybe for you to consider or grapple with as you deliberate. Limitations, I think I've covered most of these as we've gone along. We've got issues with blinding. We've got issues with crossovers. We've got issues with observational studies. We've got issues with how adverse events are reported. I'm happy to dive into any more detail on any of those limitations if people have questions. In terms of the limitations of our review, itself, we only considered studies in English. We did not use unpublished data or data that was only presented in conference abstracts. We did not use efficacy outcomes from uncontrolled studies, and we did not use data from MOD for several of the reasons that have been mentioned. It's a passive surveillance system, and it does not allow for the calculation of rates. And I think that's it. Let me just put up the conclusion for-- so we've really got two comparisons that are most relevant for you. The minimally invasive fusion compared to conservative management and then the alternative minimally invasive procedures. So the final two concluding slides are just a summary of those certainty grades. So let me just pause and see what other final-- I know I whizzed through that last backend pretty quickly, but, hopefully

you've had a chance. And if there are any questions that I can go back to and address, I'm happy to do that at this point.

Sheila Rege: We are going to come back and ask more questions and, Leila, you will be available--

Leila Kahwati: Yes.

Sheila Rege: -- during our discussion.

Leila Kahwati: Yep.

Sheila Rege: So one option is to take a break, and then when we return go around the table and kind of commenting on availability and is the evidence sufficient, and especially is it new or different from 2019 in terms of would we have to consider safety, efficacy, or cost, and so we could be thinking about that during the break, and then we'll continue on with the discussion. That was a thought that Janna and I thought may help steer us. But any questions before we break? So we are 30 minutes behind. If it's okay to take a five-minute break instead of a 10-minute break and return, I'm looking for thumbs up. Otherwise, you may go over. Okay. Five-minute break. We will return at 11:35. Thank you. Bye.

Sheila Rege: Leila, thank you for an amazing really thorough presentation. Can people hear me?

Leila Kahwati: You're welcome.

Sheila Rege: If we could do kind of going around the table and just talking about our impression so far on the evidence and what we see as new or different than 2019. And I just randomly went from the top of the alphabet, which meant, John, you are up. You can take a pass if you're not ready and we can keep going.

John Bramhall: Well, I, no, I'll make a comment. I'm sorry, I don't really. Okay, this time around I'm a little bit more impressed with the efficacy. I'm impressed a little bit more by the reduction in pain, and I'm impressed a little bit more by the increase in functionality. And I'm also, and I can't remember whether this is older evidence or it's just new, I'm impressed in the Medicare population of the overall cost of treatment which was reduced, apparently, with low evidence but reduced by the intervention minimally invasive intervention over conservative therapy. So those are the four things that I sort of made a note in front of me that strike me as positives. And I'm sorry, Sheila, I can't remember now really whether I was similarly impressed in 2017, whenever, and then my hopes were destroyed by the quality of evidence. So that's my comments at the moment, is that the functionality data, the cost data in the Medicare population, the improvements in function are all things that strike me as positives for the minimally invasive techniques. I do have some technical questions which we could get into later on maybe for Randy and in particular for Conor, technical questions about the different implants and the logic behind them, but I'll leave that for later.

Sheila Rege: Thank you. [indistinct] good points. Janna, any comments?

Janna Friedly: Yeah. So I'll just start to say I really struggled with this, and I think I struggled the first time that I reviewed this data. This time around, it's the same data. It's just more papers about the same studies that were done, so it's not that there are a wealth of new studies that we have to evaluate. My concerns the first time I read through these was that the two randomized trials that the evidence basis is really built on are not only funded by the company, but they're also conducted by the company. So there is no separation between the data analysis and the conduct of the study and the funding, which is often the case in some of these industries sponsored studies. So I struggled then with that and I struggle with that now. Now that there are multiple papers that have come out with different time points, I'm really having a hard time reconciling some of the data, and there's inconsistencies in the reporting and even some of them not-- the ones that we didn't really specifically look at today, but in the one of the one year papers for the one that was in the pain physician, the iMEA, they reported depression outcomes where the depression outcomes were exactly the same but the statistical significance was completely 0.0003. I had a really hard time reconciling some of their results, so I have concerns about the conflict of interest and how that plays into the interpretation of these results. We know that in straight industry sponsored studies tend to have better outcomes than others, so if I keep that in mind in thinking about these results in combination with my concerns, I'm must less enthusiastic about the results. I'm really interested to see the results of the trial that's coming out in 2023, because I think that that's probably going to give us a lot different information. In terms of the methodology of the studies, though, the thing that I keep going back to, as well, is that you take a group of people that didn't do well with conservative treatment and then you give them conservative treatment and then you compare them to surgery. And so you're sort of setting it up in a way that is stacked in favor of the surgical treatment and specifically not including cognitive behavioral therapy and some of the other's treatments that really take into consideration of biopsychosocial model of chronic pain that we know is effective to me, it isn't the right comparison, and so I also struggle with that. So just overall, I'm not convinced that there's new or significantly different information than we were provided the first time around.

Sheila Rege: Thank you. That's a good point. Chris, would you want to go next?

Chris Hearne: Sure. Yeah, I tend to agree that it's good to see that some of the beneficial effects of the interventions seem to persist over longer time periods. I mean I think that's an argumentative favor. But as it's already been said, I'm not sure fundamentally the problems with the original review were really addressed for me, at least at first glance. I still have issues with some of those original issues.

Sheila Rege: Conor? Any comments?

Conor Kleweno: Yeah, just because I've spoken so much I'm going to pass until the end to let other people talk. I did have a quick question, though, for Leila. I saw that you mentioned Dr. Woody Cross as the external consultant. I respect him very much as a clinician,

as a scientist. He's at the Mayo Clinic. I've known him for years now. What roll did he play in your review?

Leila Kahwati: He was a peer reviewer. He was an external peer reviewer of the report, and his comments along with the comments from the other peer reviewer are publicly available. I don't know, Melanie, if the committee has that document, but it's at the HCA Program website the comments that both peer reviewers provided on the report and then our response to their comments. I'm just trying to think if I can quickly summarize. His comments were, he thought the evidence was accurately represented. His comments were, I believe, more along the lines of concerns over not wanting to stifle innovation by landing on device-specific coverage, that this is sort of early still in the development of the field, but I don't think he had any specific comments related to the studies that were included or not included or the interpretation of the evidence. But all those comments are at the state's website. Thanks, Melanie. She just put the link in the chat.

Sheila Rege: Laurie? Would you care to share your comments, or you want to take a pass for now?

Laurie Mischley: Yeah. I mean I'll say that most of my opinions echo what has already been said. I'm happy to see that the benefits persist. As a self-proclaimed advocate for patient-reported outcomes, the lack of objective improvements make me very uncomfortable. I mean I'm a little stuck on the lack of objective improvements, the fuzzy diagnosis, this idea that the improvement after injection don't correlate to the improvements after surgery. It's the lack of anything objective and the lack of placebo-controlled trials, the lack of objective evaluations, no blinded evaluations, all of those things kind of stagger on top of each other to make me lean very heavily toward where the committee landed last time. And I just want to say, I really appreciate the vendor taking the extra step to reach out to the authors. I know they didn't get the feedback that they wanted, but that is really above and beyond what I would have expected, and I really appreciate that extra step.

Sheila Rege: I would agree. That and the fact that they didn't respond and it was inconsistency kind of makes me also, I mean, maybe this is a bias within us as physicians, that industry-supported trials, the negative trials have a harder time getting published than the positive trial. So I'm struggling with this, too. Although, John's comment that "maybe slightly more impressed," it may just be because there's more papers rather than truly new evidence. Mika?

Mika Sinanan: Thanks. Well, many of the comments that I would make have already been made. I continue to struggle as I think about this with the fact that pain is such a difficult problem. It's a difficult problem for patients. They are obviously very desperate in many cases to find any treatment. I can remember discussions from my own clinical practice when people come in with pain for other reasons when we're trying to find an objective reason to offer treatment and they're convinced that they have an idea of where it is and what it is and try to get to anything objective is very difficult for them. I also appreciate the difficulty of a patient who is in a

surgeon's office discussing a study where they may be randomized to a conservative versus a surgical approach and how to get them for something that's commercially available already elsewhere to get them to agree to participate in it. Often, the only way is to promise them the capability of crossing over, which is what accounts for the very high rate of crossover in the first study, I think. And then, of course, the greatest interest in Fidelity to follow up as early on in this study, it drops off over time for in all studies. It gets harder to maintain that relationship. So the quality of ongoing data collection I think is always suspect. I was initially impressed by the comparison of the evidence map from the 2018 report to the updated report that showed, as John alluded to, a persistence of benefit and the Medicare data, but I also agree with Laurie about the lack of any objective measures. I continue to struggle with whether this is just a very expensive placebo for a desperate group of people versus actually an intervention that makes a difference for understandable reasons. And I've raised those before about the question, is this actually microinstability versus arthritis and, if so, why does stabilization make a difference? And do we actually know that it makes a difference? All of these are soft measures. So I'm very torn by it, but I also recognize that there is a constituency that's very deeply invested in having this as a capability. Thanks.

Sheila Rege: Tony?

Tony Yen: I think that the evidence is really not that new. I think Janna summarized that really quite well in that the two RCTs that have more follow up, that that type of data is, I think to me, brought into question given the lack of consistency within that follow up data as a bottom line though there is more data. What does that really mean with that lack of data consistencies I think a problem for me personally. Also, the other piece of information that is probably new is the case control study, and our vendor here, Leila, really helped us understand that, at least for me personally, a lot better that it doesn't really add that much to the evidence that we have at hand. So the conclusions right now are that this doesn't really differ that much from what we did before with our part evaluation. I really like Mika's comments about the plausibility behind the mechanisms underpinning what we're dealing with over here and also the folks who are really seeking a solution to a lot of very severe symptoms.

Sheila Rege: Agree. Difficult conversation. Larry? Would you like to comment?

Larry Birger: Yes. Thank you. Of course, I wasn't here last time when this took place, but what struck me about this process was what seemed to me to be a pretty jarring insufficiency of the evidence. It's one thing to state conclusions, but as different people offered their input, they're all kinds of problems that I saw. There's a problem with trying to get the diagnosis defined in the first place. I felt like the comments from our public. What do you call those? Public comments, or whatever, that kind of focused in on, "well, no, actually you can diagnose it." Well, even if that were true, it doesn't address the other problems, which are you have a limited number of surgeons doing a limited number of procedures. So now there's

issues with-- first you have issues with the P in PICO population. The questions about the surgeons raise issues about the intervention itself. My emphasis, and echoed by others, the comparator, the what I would call, the heterogeneity of so-called conservative management, which makes it sound like it's just some sort of standardized thing, which is not at all the case. So if there are problems with each one of those three points in the PIC and then we get to the O, the outcomes, even if the outcomes are listed as favorable, and that's to say nothing of the comments that have just been made here about sufficiency of follow up and inconsistencies and all that, I just step away and say I can't say they have proved much of anything except that I would still keep an open mind. Gordon [indistinct] had a saying something to the effect of lack of proof of efficacy is not the same as proof of inefficacy. And I don't know, maybe that's some famous adage and he just said it. I don't know. But I liked it and I thought it's helpful for me to keep an open mind about stuff like that. But I definitely did not feel like there was a good proof of efficacy in this trial, and it just smelled of bias and fuzziness. Not trial, I mean the compilation of trials.

Sheila Rege: Right. Thank you, Larry. Clinton?

Clinton Daniels: Yes. Thank you. As a VA chiropractor, I've lived in the world of mechanical and chronic spine pain and posterior pelvic pain, and my clinic actually performs all the physical maneuvers that were described as a standard part of our back exams. And my opinion over my career is that chronic SI joint pain is real, but I also think it's very rare. I think a lot of patients have pain in the SI joint area, but I think it's mostly back pain, hip pain, or overlying structures. Again, we're talking chronic, not acute traumatic. And as I think back, I can only think of a few cases I've ever had where I thought it was the primary generator, and each of those was either a pregnant patient or someone coming directly off of trauma. So I find the diagnosis to be very fuzzy. It also seems like there's very limited new research from a couple years ago. And then I also have some concerns, and maybe this is a better question for Conor or Randy, about the potential for development of adjacent segment disease of the lower lumbar spine after the fusion and whether two years in the RCTs or three and a half in that cohort is a long enough time to see if that develops as a result of the procedure. So maybe there may be some more adverse events that would be reported later. And then [indistinct] it would be really interesting to see that 2023 study [indistinct] once that comes out with the sham comparison. Thank you.

Sheila Rege: Good points. Thank you.

Christoph Lee: So I also came in new and was not part of the first review, but as I read through the final report this time around and compared it to prior, I was struck by the fact that not much is new. We have some follow up data from RCTs and a cohort study, but when I compare the two, I was struck by the lack of new studies and new evidence. What was also striking to me was that the risk of bias for every single outcome reported in the evidence report was either serious or very serious. And I was also struck by the certainty of the direction of every effect, the vast majority being very

low and low. So there is a real paucity of evidence here to support these interventions. Every study basically is confounded by the placebo effect. And as much as I am struck emotionally by the public testimony, and I'm empathetic to the chronic pain patients that are looking for hope and solutions, the evidence to me clearly points to not supporting this intervention coverage.

Sheila Rege: Fine. Randy, would you be kind enough to give us any thoughts?

Randy Chesnut: Sure. If I'm redundant, sorry, I've been just been in and out a little bit. But, again, I was just in training and finishing training when this came around the first time, and it was a bit popular, and the diagnosis was no better because we haven't come up with anything new. But it was open and it was more invasive and it kind of died out because it didn't seem to work. It's my impression that the reason it's come back is not because someone has found a new diagnosis or a more precise definition but because industry has come up with new implants, and it's really that's my impression that nothing else is really different other than that. And then there's this [indistinct] about something new and fun and maybe it'll help, and this is an exceptionally vulnerable population, the chronic pain people. I mean their lives are wrecked by this, and they're desperate. And unless you offer them something that is really going to hurt them, they're almost always going to say, "yeah, let's try this." And to be perfectly honest, when you offer them as an alternative in a randomized trial, the continuation of the same treatments that didn't work up to that point versus something new and shiny, the thing that goes "bing" so to speak, then they're likely going to choose the latter. And the placebo effect, of course, it's huge, unquantifiable, and we don't know the duration of it. And the other thing is that when you start to look at quality of life outcome, very few people-- there are always these studies that look at that efficacy is patient reported, and like, would you have the surgery again? Would you recommend it to a colleague? Well, unless you are really hurt by it, most people don't really want to think they made a big mistake by having a procedure. And so those are extremely biased responses. So I just don't see a lot of evidence that says works, which may mean that we should err on the side of allowing it because these people need something, but I think the population is so terribly vulnerable that doing that is an error, because then we will have all these people walking around with an unproven device. And if it was a life-threatening thing, then a lot of times you'll say, "Well, let's go ahead in the interest of saving lives" or etc., but this is something that can just go completely out of control. The diagnoses aren't good. The studies have not done the hard yards to make sure that placebo-controlled injections have been done. They haven't offered broad-spectrum cognitive therapy as an alternative treatment, at least in general like some other randomized trial in low back pain did. And so I just think based on the vulnerability of the patients and the lack of evidence, the lack of strong evidence, that I just can't see supporting this, to be honest.

Sheila Rege: If we were in person, now would be the time we could ask questions or we could go on to kind of a straw poll of what we do of the unproven last equivalent.

Melanie Golob: Sheila, I think Conor hasn't spoken.

Sheila Rege: Oh, Conor! Sorry.

Conor Kleweno: No, that's okay. I wanted everyone to comment. Obviously, this is part of my practice in terms of trauma of the SI joint, the destabilization in the setting of the pelvic ring, and so I'm in the weeds a lot mentally on this, but I'll try to summarize this as sort of as [indistinct] as possible. So first in terms of etiology and diagnosis. So I know do believe that there is pain the can be generated from a source anatomically of the SI joint. We see it in true instability. Somebody has a pelvic ring fracture that's somewhat mild to moderate. Maybe it was missed. Maybe it was trialed nonoperatively and we can see their pelvic ring displaced on stress views, and then we stabilize that, and I do believe in the placebo effect, but I do see stabilizing the pelvic ring as something that is very reliable for improving function and pain. And then we get to in my mind people that have an infectious sacroiliitis and they have pain. They localize it to that area. They receive antibiotics and it gets better. Some of those once in a while will go on to a very degenerated joint. I've seen autoimmune patients that have a degenerated joint that I have done a procedure on with efficacy, and those are pretty straight forward for me mentally. The patients who have had pain for a long time and the thought is, well, maybe this is related to adjacent segment from a lumbar spine. Maybe it's just primary degeneration of the SI joint and whether or not it's micromotion or not. I think this surgeon in Idaho did have a good comment, that it may not be true motion if we can't measure on the microns. It may be just arthritis that's causing the pain. And we have observed in other joints-- the SI joint is different-- but that degeneration of cartilage can be painful. The challenge, again, I agree. Diagnosis is challenging. A CT scan-guided injection I have used as my best guess of diagnosis when we talk about coverage. How do we diagnosis this being a source of the pain? I think the physical exam is challenging, particularly if patients are looking for surgery. They have already looked on the internet. They've already told me what five signs I'm going to find on them if I do a physical exam, so that can be challenging. And then we get to what are we paying for? What are we approving? The CPT code here is an arthrodesis. Classically, an arthrodesis of a joint is a decortication procedure and then essentially boney union across that joint. Now, again, the SI joint doesn't move like the ankle or the knee or other joints that we fuse historically, but now we have devices that kind of cross that articulation somewhat, but not always. Okay? So you have devices placed that do enter the bone in the ileum and then enter the bone in the sacrum but aren't actually crossing the SI joint. And that's where we get into a little bit of the weeds of this can be a device-specific feel but still evolving. So in my practice, I do like the decortication compression with a goal of fusion, and I think as we move forward in the future that may be what is required by payors as this technology improves. I thought it interesting in a question to Leila on the methods of the Insight trial was a 24-month CT scan that, as far as I know, has not been reported. On their article, it said we will report it elsewhere. Maybe that's still coming out. It's difficult to get two-year CT scans on patients in terms of follow ups. If we're paying for fusion, we have not yet talked about in this discussion, an outcome of fusion. Obviously, we want patients to feel

better, but fusion is an outcome that should be on the table with that. And then, lastly I'll comment on safety. I agree with the concerns that Emily put forward. It is user dependent. It's not like the devices are leaching a toxic material into the bloodstream. So in the acute setting, it is a surgeon error that is the first safety issue. However, long term I don't think we know either. And I think there was a comment on an active duty military member. I haven't reviewed that case. I don't know anything about it, so I don't want my comment to be with respect to them, but if there is a proposition that we're taking young, healthy, active people and because of a transient pain in an SI joint, we are now fusing that SI joint, I would have long-term safety concerns. The last active duty member I saw for a CT scan positive SI joint injection small steroid dose, he was back to duty in a week. So I would have concerns with long-term effects if we're taking young, healthy patients with pain in the SI joint and then doing a fusion procedure. That's an all-in procedure. There's no turning back from placing large titanium or stainless steel implants that cross the articulation from the sacrum to the ileum. And then I had a couple comments I'll reserve to the end when we are discussing the policy. I just had some of my thoughts on input on that, on the wording is all.

- Sheila Rege: Any other comments? Now, we were asked to look at this to treat chronic SI joint pain related to degenerative sacroiliitis or SI joint disruption, and the studies excluded anything related to acute trauma, infection, or cancer. Just for us to keep that in the forefront. We could go to questions or we could do a straw pull first on just safety, efficacy, cost, the [indistinct] and more in some compared to conservative management. Janna, as my co-captain, what would you advise?
- Janna Friedly: I think we should go to a straw vote at this point.
- Sheila Rege: Okay. And so if we do it, it's a straw poll. So we could go safety if, I, for example feel safety it is better than conservative management, then I would say, this is mor- - I'm sorry. If it's the safety track is better-- God, this is confusing-- it would be equivalent or the safety is actually better. So we can type-- so if I say unproven slash unproven slash unproven, that's with safety efficacy and cost. Will that help and you can just put in the chat or, Josh, would you like it called out individually?
- Josh Morse: So, Sheila, I'm sharing the decision aid to just show the questions. You're referring to these questions. Is that correct? Is there sufficient evidence that the technology is safe?
- Sheila Rege: Correct, just in the straw poll.
- Josh Morse: Right. So how about I share this screen. Melanie has a spreadsheet and she's recording individual's votes, so maybe Melanie can call off each person's name and they can say what their vote is. And the choices, again, are shown here on the screen. And typically I think you say you're voting on the sufficiency of the evidence that the technology is safe compared to the alternatives.
- Sheila Rege: Yeah. And we can just type it, Josh, if it would make it faster. I have had some panelists tell me that they do have a hard stop at 12:30, so I'm trying to just do

these polls faster. If the safety, if you say left, that means that the procedure is less safe than conservative management. And now we will go to efficacy. [indistinct] conservative management is equivalent or one of those choices. And we'll have Melanie announce at the end for the call-in people, because we're just like [indistinct] in the room. Cost effectiveness-- equivalent means that the procedure is equivalent cost to conservative management. More in some means that the surgical procedure costs more. And while Melanie is recording that, if there's questions for Leila or Randy or anybody, we can maybe ask that until Melanie collates our responses.

John Bramhall: Can I just ask Randy? I think it was Clinton who made the comment about the potential for disruption of adjacent structures by stabilization of the SI joint. Do you have an opinion on that, Randy? I mean we see this with spine surgery in general, fixation of adjacent segments causing stress on the adjacent segments that had not been fused. Do you see the same kind of hazard with this, potentially?

Randy Chesnut: That's a really difficult question to answer. I mean if you go to the evidence, I don't think we have solid evidence that that happens. Theoretically, it could, but the transition from the spine to the pelvis is very complex. Plus, a lot of adjacent spine disease is actually partially iatrogenic from damaging joints at the time of initial exposure, putting screws partially through unfused joints, stripping ligaments and denervating muscles. So the transition from the spine to the pelvis is really quite complex. So I would have to say I do not know. Theoretically, it's possible. I would not suspect that it has a high impact, but to be perfectly honest, based on evidence, I don't know.

John Bramhall: Randy, I'm sorry. But can I ask you what you repair traumatically separated SI joints on occasions. You seem to use a lot of threaded equipment rather than the smooth equipment, and there was a screen shown by Leila that seemed to suggest that the revision rate for threaded components was higher than for the smooth components. I'm not quite sure how valid that observation was, but it stuck out as a pretty high percentage of revision. So is there is a comment you could make on the difference between a threaded component I know you tend to use for disrupted SI joints and these smooth components.

Conor Kleweno: So Leila pointed out there are 50-something plus devices, I think, approved right now or at least indicated for it. So there's many devices out there. The ability to compress a joint, which is one of our [indistinct] for trying to obtain stability for a boney union, typically is done through a threaded screw so that its allowed to compress across that to improve stability. And in the traumatic setting, that's what we have. Again, we'll go back to this as a field where the implants are evolving. And so whether the device is smooth or has an on-growth surface for bone to grow onto or into is evolving, but the threads that you see are designed so that we can compress across to improve stability, and that's in a trauma setting. Some of these other devices have on-growth surfaces without any ability to compress some of the devices on the market, and so I tend to not favor some of those as much, just because I don't see that they can provide compression across it.

- Mika Sinanan: I have a follow up question for Randy on the question. I was just curious, so for patient who will develop adjacent segment disease in the lumbar spine, how long does that typically take to show up radiographically? I realize it probably varies, but is it something you could see in two years or is it longer than that?
- Randy Chesnut: Oh, sure. Yeah. Again, adjacent segment disease has a 3% per year, at least in the cervical spine, reoperation rate. So, yeah, it can show up pretty early. The chronic sort of degenerative changes that show disc degeneration and joint degeneration, and either angulation or listhesis generally take a bit longer. But in terms of symptomatic disease, yeah, it can show up pretty early.
- Mika Sinanan: Thank you.
- Sheila Rege: Any other questions? I had one. When do we expect more data? Is there any thoughts from the orthopedic community about randomized trials? Non-industry?
- Leila Kahwati: So, Sheila, the only randomized trial that we identified in the pipeline is the one sham controlled trial that's coming out of Norway that is currently recruiting. They're estimating completion in April of 2023. The other three trials are uncontrolled trials. So they're single group intervention only, and they wouldn't really give you, I think, anymore data that you already don't have. But that sham control trial, I think, is the pivotal one that would give you the most new information.
- Conor Kleweno: The one I'm involved that I've have provided consulting for is, I believe, still in the process of submission to FDA. I don't have any updates on that process, Sheila. It is not started though.
- Sheila Rege: [indistinct] we could have Josh and Melanie tell us-- oh, go ahead. Sorry.
- Josh Morse: I've update the count I think on your screen. Can you see the numbers in the document? Okay, great. And Melanie has confirmed that our numbers agree, so.
- Sheila Rege: Okay. So summary we think-- and let's stay with safety. In the package, we have kind of what we consider for safety. If we can go back a page, Josh, adverse events, revision surgery. Is there anything that we have missed when we are thinking about safety as presented by the studies? How about efficacy? And then cost outcomes? And special population? Okay. What would this group like to do next? Would we like to ask more questions? Are we looking at next steps about a second vote? Are we ready for that? And the next vote is it's not covered, covered unconditionally, covered under certain conditions. Would we like to vote on that, or should we wait for more questions?
- Mika Sinanan: Sheila, Mika here. I think we should go ahead and vote as a straw poll.
- Sheila Rege: Okay. So the choices would be not covered, and you can type it in, covered unconditionally, or covered under certain conditions?
- Josh Morse: So you're doing a straw poll now? This is not the formal vote?
- Sheila Rege: Yeah.

- Josh Morse: Okay. Thank you.
- Sheila Rege: This is the straw poll. And for the new people, what we look at with a straw poll is if everybody goes one way and we've all seen the data and are coming to the same conclusions. But if there's anybody who sees it a different way, we stop to make sure that we've heard, because that person may actually have seen something that the rest of us haven't. So that's why we do a straw poll and for the discussion, because this is pretty important and we want to make sure that we've thought of everything.
- Larry Birger: One quick question. If we vote for not covered, there's always the opportunity for this to be revisited at some point if new evidence becomes available that at least a subset might benefit from it? Because that would be my only concern. Let's say that we could identify some segment of this population, whether it be because we have better diagnostic criteria or whatever, and I would hate to make a sweeping generalization and overlook benefit that might apply to a select few, because I have seen that, as well, in my career. So is my understanding accurate, that this is always subject to review in the future?
- Sheila Rege: Yeah, and there's a process, and I'll have Josh and Melanie explain that.
- Josh Morse: Dr. Birger, that's exactly how we got here. This was reviewed two years ago, I believe, roughly two and a half years ago, and we're here now because some new evidence has emerged. If new studies come out in the future that could change this, that's exactly what we would be responding to or looking for, and it would come back as a re-review.
- Larry Birger: Because, otherwise, if we wanted to make exceptions based on the discussion today, I don't know that we have any very good criteria, if any, at all to make exceptions [indistinct], so we would be just sort of giving no advice on that point?
- Mika Sinanan: Larry, Mika Sinanan. I think we would be anticipating where the data would go but not make an evidence-based recommendation. So that's why we kind of way either for the Healthcare Authority or outside folks or committee members to raise a question about a previous decision and then evaluate whether there's new data that would support a change in the decision. But it's data driven.
- Larry Birger: Okay. Because the only thing I can think of is if there were exceptions were allowed when reviewed by a committee composed of... whatever, but then we don't have the criteria. So I'm just not sure that's feasible.
- Mika Sinanan: Well, I think as you have heard, there is an appeal process through administrative judges and through the Healthcare Authority. So this is not the ultimate final "no, it never works." There is an appeal process, as well.
- Larry Birger: Okay. We're just simply saying that the strength of the evidence is not enough to justify. So okay, I'm good with that. Thank you.
- Josh Morse: Yeah, and I want to make clear that the appeal processes differ from insurance program to insurance program. They each have their own frameworks. So the

processes are clear in each one of them, but it is not necessarily true that there's an appeal process for a decision like this for a not covered decision for all programs. I don't know. Does that make sense?

Josh Morse: So for the record for your straw poll, 10 people voted for not cover, and that is 10 members who are voting today on this subject.

Sheila Rege: Okay. Any more questions before we do our real vote?

Larry Birger: I just have the question about so the not covered is a no change from the previous policy. Is that right?

Josh Morse: That would be the same, yeah, and I can share with you the language in that decision if you would like to see the final determination. It does have a few caveats in there about the scope, as already mentioned, related to inflammatory processes and things like that.

Conor Kleweno: Yeah. I don't know. Sheila, tell me if this is the appropriate time to just comment on the wording of that.

Sheila Rege: Yeah. And maybe projecting our previous, because I remember having a lot of discussion at that time about which population we were looking at. So, yeah, Conor. Thank you.

Conor Kleweno: Yeah. The first comment to question is there is a word disruption in the first paragraph, and I wonder if that's the accurate word intended or dysfunction is the intended word. When I think of disruption, that means like ligamentous disruption, which is a pelvis that has been traumatically disrupted. I was just basing it on that slide--

Sheila Rege: You mean [indistinct]?

Conor Kleweno: -- that Emily had had up there.

Sheila Rege: That one.

Conor Kleweno: Yeah, disruption. Was that intended to say dysfunction, as sort of a generic term? Chronic dysfunc-- I don't know what was intended by SI joint disruption. I wasn't clear on that.

Tony Yen: This is Tony. I agree with Conor's comments about changing the disruption to dysfunction. That makes sense.

Conor Kleweno: And then I had a question back to the medicine doctors. The inflammatory arthropathies-- does that include autoimmune and autoinflammatory? My memory was those are subtly different. Does inflammatory, is that inclusive enough of that sort of genre of abnormalities, so to speak?

Josh Morse: Do we need to differentiate autoinflammatory and autoimmune?

Tony Yen: This is Tony again. I would agree that inflammatory covers autoimmune.

Josh Morse: Okay.

- Male: I would agree.
- Conor Kleweno: Okay. Great. And then the last question is, there's been a couple patients that I have seen that have had percutaneous fusion procedures and things didn't go well, and so now I'm in a position to potentially revise it. And because of what's been done, I'm not clear that this joint has not been sort of disrupted so that it does have some instability. So what I as a provider, would that be a covered fusion if I'm revising someone else's fusion? I ask the group that.
- Sheila Rege: So you say dysfunction, which should be D-Y-S, [indistinct].
- Conor Kleweno: Thank you.
- Sheila Rege: --this is out of my field of expertise. So, Janna, help me out here, because you do rehab. I mean, at least on the Mayo Clinic side and everything else, they do use the words sacroiliac joint dysfunction, and that was what we used in the initial questions. So I just like to be consistent. If it's something that was a typo, it's a typo, but it seems like it is a real disease.
- Janna Friedly: Sheila, I'm not sure I understand your comment.
- Sheila Rege: We changed which--
- Janna Friedly: Are you saying dysfunction is not consistent with the way that we did the key searches and--?
- Sheila Rege: Yeah. The key question said disruptions. Am I right, Josh? I'm now pulling up my [indistinct] questions.
- Leila Kahwati: This is Leila. I think we, in the evidence review, referred to it as degenerative, sacroiliitis, or sacroiliac joint dysfunction. I don't think we used the term disruption. So I think dysfunction is consistent with the way the population was scoped.
- Sheila Rege: Yeah. I just want to make sure. So that then was a typo and [indistinct] consistent, and then inflammatory. Sorry. Sorry. This is for clarification. Thank you.
- Janna Friedly: Conor, would it make sense then to, in the decision does not apply to other etiologies or to sacroiliac joint pain or disruption related to recent major trauma, surgeries, or fracture? Would that--
- Conor Kleweno: I don't know if you need the disruption in the second part.
- Janna Friedly: Okay.
- Conor Kleweno: I think the second part is pretty clear. I didn't know how you would treat revisions. I mean clearly you can use a different CPT to address it.
- Janna Friedly: Yeah. I guess in my mind if it [indistinct]—
- Sheila Rege: Did you see the data?

- Janna Friedly: --that it's not something that needs to be built into this, that if there is an alternative way to bill for this. Certainly, it's not the intention of our committee to exclude those that was not [indistinct] or reviewed.
- Leila Kahwati: Yeah. Revision surgeries weren't reviewed. So everyone who was enrolled, it was like they were getting initial surgery, so people who are coming back for revision surgeries were definitely not in the scope of the evidence review.
- Conor Kleweno: It's just that the process of having a "fusion surgery" that then didn't go well, your option is you may really want to be doing a true fusion surgery. So I didn't know if that was something that should be considered under coverage or not. I know it's not part of our data set, so I thought it was a challenging question for me.
- Sheila Rege: Any input, because it wasn't part of what we were asked to study? How do we deal with that? I mean I'd be interested if the agency directors have an opinion.
- Man: [indistinct].
- Woman: Yeah. I think you should--
- Conor Kleweno: Because there's a lot of people trying to do this. This procedure has become more popular, and so as people switch insurance plans, you may find patients with this situation.
- Emily Transue: So this is Emily Transue. One thing that you could say would be to add that to the out of scope below. You could say the scope of this decision does not include revision surgeries if that was your intent, and it is very helpful to us to have that be clarified in one direction or the other.
- Mika Sinanan: Mika Sinanan. That makes sense to me.
- Sheila Rege: Anybody in favor of that, just say "approve." And so if you'll type that in as a second bullet point.
- Josh Morse: Prior-- help me finish this sentence.
- Sheila Rege: This decision does not apply to-- Emily, help me out here. You said it well.
- Emily Transue: Sorry. I would say the scope of this decision does not apply to revision surgery.
- Josh Morse: Thank you. Plural? Singular? Thank you.
- Sheila Rege: And I also heard a [indistinct] changing an S to an R.
- Josh Morse: I think I got that up here. Is that where you were-- Dr. Transue, is this which you were referring to?
- Emily Transue: Yes.
- Josh Morse: Okay. Thank you, and go ahead.
- Emily Transue: Wait. I'm not-- actually I'm not seeing what you're pointing to. For me it's still showing as not a covered benefit. That should be an R-- not a covered benefit.

- Josh Morse: Oh, perhaps I'm not-- let me share the right screen here and make sure that I'm sharing it. Did that make a difference?
- Emily Transue: Oh, yes. And then it would be you could take out the A.
- Josh Morse: Yep. And dysfunction, we are putting dysfunction in place of disruption. Is that right? I want to make sure I didn't miss that.
- Emily Transue: Correct.
- Josh Morse: Okay. Thank you.
- Sheila Rege: This is where in a regular room we would actually take a couple of minutes just to read it, so if anybody wants to stand up and stretch. I know we are a minute over time, but just read it carefully and we can have some music going or somebody can sing and then we're done with this and we would go up for approval of this language. I will take a motion to approve this language.
- Man: I move to approve.
- Woman: I second.
- Sheila Rege: All in favor, say aye.
- Man2: Aye.
- Woman2: Aye.
- Man3: Aye.
- Woman3: Aye.
- Woman4: Aye.
- Man4: Aye.
- Man5: Aye.
- Man6: Aye.
- Man7: Aye.
- Sheila Rege: Anybody objecting? And we did have one outstanding, correct? So just for the record.
- Josh Morse: So we are recording 10 not covered for this decision. Is that correct?
- Sheila Rege: Correct.
- Josh Morse: Okay. Thank you. We need to consider whether CMS has a noncoverage decision and consider the Professional Society guidelines.
- Sheila Rege: Correct. We are done with this item. So now we're going to go to our analytic tool and for the next steps.
- Josh Morse: So, yeah. The final question here is-- is the determination consistent with Medicare decisions and expert guidelines? And, if not, what is the evidence that

the committee has relied upon? And Medicare decisions are specifically defined for national coverage.

- Sheila Rege: Is not covered. Go ahead. Right. Anybody seen anything different from Medicare?
- Leila Kahwati: So there is no national coverage determination. The Medicare administrative contractors do cover it, though, but there is no national coverage determination.
- Sheila Rege: Any discussion about that given that knowledge?
- Janna Friedly: No. I think it seems in looking at these both organization guidelines and other insurers, there's a little bit of variability with a range from not covered to covered with very specific conditions. So we are, I think, not in line with some where they are covering it. But I'm personally okay with that, and I think that based on the evidence that we have been provided that our no coverage decision is the right decision.
- Sheila Rege: If there is going to be new data in whenever in 2023, can this topic somehow be flagged to come back before the committee? Is there a mechanism for that so we can look at that new data?
- Josh Morse: Yes. All the decisions are on our list for we consider them internally annually or whenever we receive petitions from the outside. On some, we will have our contractors actually do formal signal searches, and this is one that we'll continue to monitor, and in 2023 that will be two years, so we will have hit an 18-month-- we have these on at least an 18-month cycle at a minimum to be at least looking at considering. That's what's in the law for the program. So, yes.
- Sheila Rege: I'd like to go around the table to see if there is anybody who wants us to relook at things given that there is a new screening down there. Organizations are covering it, it sounds like with conditions. Any thoughts? Any discussion? Or are people comfortable?
- Larry Birger: I would want to know. If I could just interject I would want to ask these other organizations or covering entities, what evidence they were basing that upon. I haven't seen anything today that would even allow us to formulate a set of criteria for these conditions let alone give a broader coverage. I'm open to it.
- Chris Hearne: Hi. This is Chris Hearne. I tend to agree. I'm not sure on the basis of the evidence we've been provided that we could make any rational conditions to apply.
- Larry Birger: I think based on that what you've proposed, Sheila, of having a review of this when arguably the best conceived study data are available with a good comparator. I think that would be a good idea, and it would also show due diligence.
- Sheila Rege: Okay. If there is nobody else, then I do know we are over time, and I'm very cognizant that other people have other tasks and they may be having to log off. Josh, what's next?

- Josh Morse: So, thank you. This decision is complete. Thank you all for your hard work on this. If we can just go back to the agenda for just a minute. We're very close to being able to wrap up here. Way too many windows open.
- Sheila Rege: I think the staff and the organizers do a lot more work on these virtual meetings with sharing files and stuff. We really appreciate it. Thank you.
- Josh Morse: Yeah. We have so many different technology options. It's hard to switch from one to the next, to be honest. That's what I'm finding most challenging today. Okay. Maybe you're seeing the agenda. The last thing in our agenda, we had this open for other program business. We don't have other business today, so I will only provide you with one update and that is a re-review was just selected by the director of acupuncture for headaches, so we're starting work on that. We have two other topics in motion for review in November, as you've seen through emails. We'll have two meetings two weeks apart in November for the cardiac imaging topics, and we will begin work on the acupuncture re-review here shortly. So you'll see that probably, it won't be for another 9-12 months before that comes to you. And we are working on topic selection now within the agencies, so if you have any topic ideas, concerns about existing topics that you think should be re-reviewed or new ideas, I'm happy to receive your thoughts on that. So thanks everybody for your hard work today and for those still in attendance from the public, for your participation. Thank you. That's it for me, Sheila. Thanks so much.
- Sheila Rege: Josh, will you explain for the new people the July 9th the meeting that's only from 8 - 9 AM?
- Josh Morse: Yes. My apologies. So July 9th is our next meeting from 8 to 9 AM. Following today's meeting, we'll take the draft decision that we just typed up. We'll put it into our format, and we'll put that out next week for a two-week comment period. So anybody who has concerns about that can comment on that. For consideration on July 9th, will be if any evidence was missed, so if anybody submits a comment and says, "hey, we missed something here," or if the language in the document is not clear. There's really two questions we bring to you for consideration are on that revolves around the comments that might be submitted between now and then. So we'll see you on the 9th for that meeting as well as reviewing the minutes from today.
- Sheila Rege: Thank you. I will take a motion to adjourn.
- Man: I move to adjourn.
- Man2: I second.
- Sheila Rege: Bye now.
- Josh Morse: Thanks everyone.
- Conor Kleweno: Goodbye. Thank you.